

HTA Matériel de Stomie en Belgique

KCE reports vol. 21 B

Le Centre Fédéral d'Expertise des Soins de Santé

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PRÉFACE

Pour ce rapport HTA relatif au matériel de stomie, le KCE était confronté à un double défi.

Premièrement, il s'agit d'un sujet de la catégorie 'medical devices', pour laquelle la force probante des études cliniques est moins grande que pour les technologies comme les tests diagnostiques et surtout les médicaments. Cette constatation est moins liée à la nature même des produits (pour le matériel de stomie par exemple, des études contrôlées randomisées seraient faciles et peu onéreuses à mettre en place sur le plan méthodologique) qu'à un processus de R&D différent et à des exigences administratives moins contraignantes pour le remboursement.

Deuxièmement, dans d'autres pays européens (même plus grands), on constate aussi que peu d'évaluations ont été réalisées. C'est assez surprenant étant donné que les principaux fabricants sont tous des multinationales qui sont sur le marché dans la plupart des pays européens. L'Europe devrait donc saisir l'occasion de rendre sa politique sur les 'medical devices' plus cohérente.

La quasi-absence de publications 'peer-reviewed' d'études cliniques dignes de ce nom rend dès lors impossible la première étape logique du HTA (évaluation de l'efficacité clinique). En soi, ce problème n'est pas insurmontable, étant donné qu'il est évident que le matériel de stomie ne peut être utilisé à d'autres fins. Plus difficile sinon impossible, s'est avérée une comparaison de la qualité de vie et des effets secondaires liés à des produits similaires de différents fabricants qui prétendent tous vendre le meilleur produit. A fortiori, des mesures de coût-efficacité reposaient sur un terrain glissant méthodologiquement. Le KCE ne s'y est pas risqué.

Notre étude n'a cependant pas été inutile. Au contraire, la fixation des prix, le fonctionnement du marché (ou son absence) et une organisation des soins de stomie mettant l'accent sur le service aux patients ont ainsi bénéficié de l'attention qu'ils méritaient. La pose d'un matériel de stomie constitue en effet pour le patient un événement marquant et qui le rend extrêmement vulnérable, surtout en phase initiale. La plupart des patients s'adaptent rapidement et deviennent des consommateurs critiques, exigeant des informations complètes et un service de qualité. Le fait qu'un certain nombre d'associations de patients bien organisées soient actives en Belgique y est pour quelque chose.

Un patient informé de manière objective devient attentif, notamment aux prix. Le fabricant, l'importateur et le distributeur final auront donc à coeur de proposer un service rapide et accessible aux patients ayant un esprit critique. Les auteurs défendent un modèle de soins durable donnant plus de liberté aux patients et favorisant un fonctionnement plus transparent du marché.

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Résumé du rapport Matériel de Stomie

Objet

Un rapport HTA complet sur le matériel de stomie semblait, d'un point de vue méthodologique, irréalisable en raison d'un manque d'informations en provenance d'études cliniques pour évaluer, par comparaison, l'efficacité clinique et le rapport coût-efficacité des différents produits sur le marché belge. Le présent rapport vise à décrire le coût de production et l'organisation du marché belge du matériel de stomie du point de vue du patient et de l'assureur en soins de santé. Une analyse exhaustive des poches, plaques, pâtes et poudres de protection, systèmes d'irrigation, ceintures et autres produits annexes disponibles était cependant impossible compte tenu des contraintes de temps et de budget. L'objet de l'étude a été limité aux produits les plus courants des principaux fabricants pour les principales catégories de remboursement des soins de santé belges. Ces catégories (voir tableau) couvrent plus de 90% des dépenses remboursées¹ de matériel de stomie dans le secteur ambulatoire² et concernent la majorité des stomisés belges.

Concrètement, l'analyse a trait aux matériels de soins en une ou deux parties pour les colostomisés, les iléostomisés et les urostomisés. La suite de l'étude a été basée sur les produits les plus vendus dans ces catégories par les fabricants BBraun, Coloplast, ConvaTec, Eurotec, Hollister-Dansac et Welland.

CODE N	LIBELLE CODE N
640275	Matériel pour stomie Système de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en une partie Collecteur, adhésif fermé muni d'une couche protectrice péristomale, quels que soient les accessoires Dotation : 1. 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes 2. 90 pièces/3 mois, si utilisé en combinaison avec d'autres systèmes collecteurs ou de continence Liste 0275
640393	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en deux parties : Poche fermée avec système de fixation (par exemple anneau-clip), quels que soient les autres accessoires Dotation : 1. 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes collecteurs ou de continence 2. 90 pièces/3 mois, si utilisé en combinaison avec d'autres systèmes collecteurs ou de continence Liste 0393
640371	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en deux parties Disque protecteur péristomal avec système de fixation (par exemple anneau-clip), quels que soient les autres accessoires Dotation : 45 pièces/3 mois(iléostomie) 35 pièces/3 mois (colostomie) Liste 0371
640872	Matériel pour stomie Systèmes de soins pour urétérostomie et/ou cystostomie et fistules des voies urinaires Disque protecteur péristomal muni d'un système de fixation (par ex. anneau-clip), quels que soient les autres accessoires Dotation : 45 pièces/3 mois Liste 0872
640894	Matériel pour stomie Systèmes de soins pour urétérostomie et/ou cystostomie et fistules des voies urinaires Système en deux parties Collecteur d'urine à vider avec système de fixation (par ex anneau-clip) et valve anti-reflux, quels que soient les autres accessoires Dotation : 60 pièces/3 mois Liste 0894
641351	Matériel pour stomie Systèmes de soins pour situation exceptionnelle en cas de stomie et/ou fistules des voies urinaires et du système intestinal Pour stomies rentrées, où la base de la fosse de la stomie a au moins 1 cm de profondeur, mesurée en position dorsale : Système en deux parties Plaque protectrice péristomale convexe, avec une épaisseur minimale de la plaque de 3 mm au centre avec système de fixation (p ex. anneau-clip) quels que soient les autres accessoires Dotation : 45 pièces/3 mois Liste 1351
640290	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en une partie Collecteur adhésif à vider mini d'une couche protectrice péristomale, quels que soient les autres accessoires Dotation : 90 pièces/3 mois Liste 0290
640415	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Système en deux parties : Poche à vider avec système de fixation (par exemple anneau-clip) muni d'une agrafe de fermeture, quels que soient les autres accessoires Dotation : 90 pièces/3 mois Liste 0415

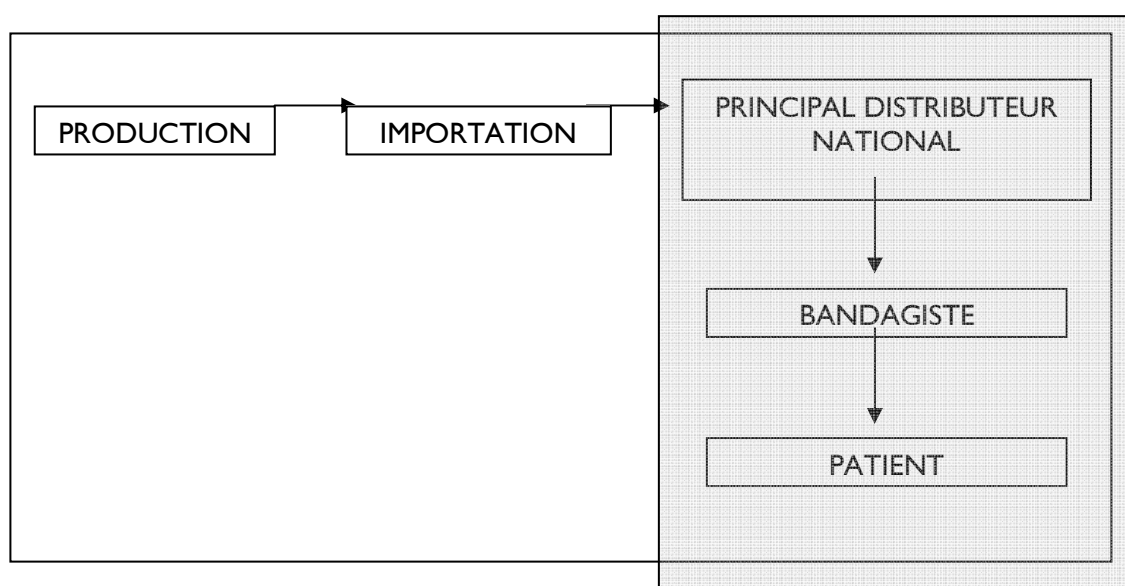
¹ Les avis sur le remboursement sont formulés dans le cadre de la commission de conventions des bandagistes.

² Pour l'utilisation du matériel de stomie à l'hôpital, un forfait journalier est prévu.

L'analyse de ces produits permet d'identifier divers aspects :

- le contexte scientifique (analyses cliniques et économiques) ;
- le coût de production et le prix final ;
- le cadre législatif ;
- le rôle des principaux acteurs.

Le schéma ci-dessous représente les principaux acteurs de manière fonctionnelle. Les connaissances (scientifiques) concernant les produits et les coûts de production influencent en théorie le prix final pour le patient et la société dans tous les pays de la même manière. Les fonctionnements institutionnel et économique concrets du circuit de distribution national (partie grise du schéma) sont par contre des facteurs importants au niveau belge et sur lequel les décideurs belges ont également plus de prise.



Questions de recherche

On distingue un certain nombre de questions de recherche tant sur les aspects cliniques et médicaux, sur la fixation des prix que sur l'organisation des soins stomathérapeutiques :

- Concernant les produits et la production :
 - Quelles conclusions peuvent être tirées du rapport coût-efficacité scientifiquement établi des produits de stomie en question ?
 - À combien s'élève le coût de production des produits de stomie en question, compte tenu des exigences de qualité médicales ?
- Concernant le marché belge :
 - Comment le prix final doit-il être évalué pour le patient et l'assureur ?
 - Quelles influences exercent les divers acteurs du marché belge à ce niveau ?

Message clé

- **Le présent rapport analyse le coût de production et le fonctionnement du marché des produits de stomie du point de vue du patient belge et de l'assureur en soins de santé.**

Méthode

Les connaissances scientifiques disponibles et publiques (rapportées) au sujet de l'efficacité médicale et des coûts liés au matériel de stomie ont été recherchées à l'aide d'une étude approfondie de la littérature en la matière. Conformément à la procédure HTA, les divers fabricants ont également été contactés pour mettre à disposition, éventuellement de manière confidentielle, toutes les études cliniques importantes. Un groupe d'experts scientifiques externes a, en outre, été composé.

Le coût de production, facteur de prix international étant donné que la production (pour l'Europe occidentale) est concentrée dans un nombre limité de sites en dehors de la Belgique, a été estimé en tenant compte des matières premières nécessaires et d'hypothèses sur le travail et le capital à mettre en oeuvre. La résultante de cette estimation constitue le coût d'achat valable pour les distributeurs nationaux d'Europe occidentale.

Une comparaison internationale des prix de différents pays européens (Belgique, Danemark, France, Pays-Bas et Royaume-Uni) a révélé la position relative qu'occupe la Belgique. Dans cet exercice, l'homogénéité des éléments comparés a été, dans la mesure du possible, respectée, tant en ce qui concerne la similarité des produits sélectionnés (nom de produit, fabricant, composants matériels,...) que les facteurs macro-économiques (pouvoir d'achat des pays en question, système de remboursement, taux d'imposition,...). Pour ces cinq pays européens plus la province canadienne de l'Ontario, les principaux facteurs institutionnels (à savoir la fixation du prix, le remboursement, les canaux de distribution et les prescripteurs mandatés) ont ensuite été comparés.

Ensuite, le contexte belge spécifique a été abordé grâce à l'analyse des informations obtenues lors de l'interrogation, orale et écrite, des acteurs concernés : il avait été demandé aux patients, aux fabricants, aux bandagistes et aux décideurs d'indiquer les points prioritaires et, en particulier, les points névralgiques du système actuel.

La synthèse des éléments susmentionnés vise à contrôler la position relative du patient belge en Europe. Quelle plus-value offre le système actuel au patient et quels sont les points d'amélioration potentiels ? Des recommandations utiles découlent de cette synthèse.

Résultats

Efficacité clinique

Il a été impossible de répondre à la question de l'efficacité clinique des produits considérés et encore moins de réaliser une comparaison entre des produits similaires de différents fabricants, sur la base de la littérature (publiée). Deux fabricants ont confié au KCE de la littérature non publiée, mais ont insisté sur la confidentialité de ces documents. L'absence quasiment complète d'études cliniques de premier plan en la matière ne permet pas de tirer une conclusion sur l'efficacité clinique dans le rapport. Une étude prospective de la satisfaction des clients sur des éléments comme la sensibilité aux fuites, l'adhérence, les nuisances olfactives, les irritations de la peau, la durée de port des produits sélectionnés (6 fabricants, matériel pour urétérostomie, colostomie, iléostomie, poches en une ou deux parties et plaques) est donc recommandée, de préférence dans le contexte européen.

Message clé

- **La littérature scientifique en la matière est extrêmement limitée et ne permet aucune évaluation de l'efficacité médicale.**

Analyse du coût de production

L'analyse des coûts qui a été réalisée visait à estimer le prix ex-usine d'une poche standard et d'une plaque (simple et double) pour les colostomisés ou les iléostomisés mises sur le marché belge par les 6 fabricants retenus. Bien entendu, il s'agit d'une estimation déterminant un prix à l'aide de modèles basés sur des hypothèses de coûts crédibles et lorsque le matériel de stomie est acheté par les détenteurs belges de licence. La valeur ainsi obtenue est ensuite comparée au prix du marché qui comprend une partie remboursée et éventuellement un supplément pour les patients. L'analyse des coûts montre que le prix du marché pour les patients et la sécurité sociale est en grande partie déterminé par le distributeur final. Sur la base d'entretiens avec les distributeurs et de l'analyse de leurs comptes annuels, un facteur 2,5 semble plausible ; cela signifie que le coût d'achat à l'importation représente 2/5 du prix de marché total. Cette donnée de marché est confirmée dans l'estimation des coûts pour les poches en une et deux parties. Selon les fabricants et l'organisme de coordination UNAMEC, ce facteur pourrait dépasser 2,5 en Belgique. Le prix final des poches de stomie pour l'assurance maladie semble relativement conforme à l'estimation. Le prix final pour les plaques est même plutôt 3 fois plus élevé que ce que l'on pourrait attendre sur base de l'estimation des coûts : le prix d'achat estimé pour l'importateur s'élève à seulement 2/15 du prix final pour l'assurance maladie et le patient.

Message clé

- **L'analyse des coûts démontre que le distributeur final joue le rôle principal dans la détermination du prix de marché.**

Comparaison internationale des prix

Pour vérifier si le prix des produits de stomie (partie remboursée et supplément pour le patient) était relativement élevé pour le patient belge, les prix d'un panier de produits couramment prescrits ont été comparés dans un certain nombre de pays européens voisins : le Royaume-Uni, la France, le Danemark et les Pays-Bas. Un coût total estimé sur base annuelle pour un patient (et son assurance maladie) a été calculé pour les autres pays. Une correction des prix en fonction du pouvoir d'achat a été effectuée et les quantités des dotations prévues en Belgique ont été prises en compte. Cette analyse révèle que :

- le coût annuel belge est systématiquement plus élevé que le coût français ;
- la Belgique et le Danemark présentent un coût annuel comparable ;
- la Belgique est respectivement moins cher et plus cher pour le matériel en une ou deux parties que le Royaume-Uni.
- La Belgique est systématiquement moins cher que les Pays-Bas.

Si on fait une comparaison au niveau des produits, il s'avère, en outre, que le prix du marché pour les plaques varie considérablement dans les pays considérés. Cette observation rend l'écart estimé pour la Belgique entre le prix final estimé et réel (cf. ci-dessus) d'autant plus frappant.

Message clé

- **Une comparaison internationale des prix montre que le coût annuel total des produits de stomie pour un patient belge se situe dans la moyenne des pays considérés.**

Réglementation internationale

La comparaison internationale des caractéristiques institutionnelles pour la fixation du prix, le remboursement, les canaux de distribution et les prescripteurs mandatés révèle que la Belgique peut être considérée comme un phénomène à part sur un certain nombre de plans :

- contrairement à ses voisins européens qui garantissent en gros un remboursement intégral, la Belgique prévoit pour la majorité des produits un remboursement partiel pour les patients chroniques par l'assurance maladie avec donc des suppléments pour les patients (ceux-ci sont en principe illimités, mais ne dépassent pas 25% pour les produits les plus utilisés) ;
- le rôle officiel attribué en Belgique aux soins infirmiers en stomathérapie est minime en comparaison avec les pays étrangers ;
- la notion de dotation périodique avec un nombre fixe de produits (poches et éventuellement plaques) est unique ; on ne la retrouve pas dans les autres pays qui ne limitent pas le nombre de produits remboursés. Les opinions divergent quant à l'adéquation entre les nombres de produits de la dotation belge et les besoins du patient. Concrètement, nous manquons malheureusement de données chiffrées.
- Avec ses pharmaciens, ses fournisseurs à domicile (bandagistes) et ses points de vente spécialisés en matériels médicaux, la Belgique est parmi les pays étudiés celui qui compte le nombre le plus élevé de canaux de distribution potentiels pour le matériel de stomie.

Message clé

- **Sur le plan international, la réglementation belge semble être peu flexible et n'accorde pas suffisamment de compétences officielles aux stomathérapeutes.**

Analyse fonctionnelle du marché belge pour le matériel de stomie

Un examen de l'organisation et de la distribution des produits de stomie, au sujet desquelles des patients, des (para)médicaux, des fabricants, des distributeurs (finaux), des mutualités et des décideurs ont été interrogés, dévoile quelques points névralgiques importants :

- le système semble être trop rigide, tant pour le choix de produits par le patient que pour la possibilité de lancement de nouveaux produits par le producteur ;
- le financement actuel implique le risque de livraison de quantités inutiles, incite à proposer des produits onéreux inutiles et offre, par contre, trop peu de garanties en matière de services, de qualité et de livraison flexible en fonction des besoins réels du patient ;
- il y a un manque de transparence, tant au niveau de la fixation des prix et de la traçabilité des produits que du processus décisionnel, ce qui empêche un fonctionnement efficace du marché du point de vue d'une assurance maladie rationnelle ;
- un code déontologique est indispensable pour mieux garantir le choix et la fourniture de produits de stomie à l'hôpital et en dehors ;
- la nécessité de données de base épidémiologiques et économiques fiables et complètes a été clairement démontrée au cours de l'enquête.

Message clé

- **La réglementation belge peut être optimisée en matière de flexibilité, de transparence et de service aux patients.**

Recommandations

Le Centre fédéral d'expertise formule quelques recommandations, tant à court terme qu'à plus long terme.

À court terme :

- les patients ayant des besoins médicaux exceptionnels (radiothérapie, chimiothérapie, problèmes de mise en place durant les 3 premiers mois) devraient pouvoir obtenir une dotation supplémentaire sur simple prescription d'un médecin. Le suivi des profils de prescription est toujours possible, bien que les abus soient peu probables si le patient n'a pas de besoins réels. Du côté du patient, le fait de savoir qu'il a droit à une dotation supplémentaire si nécessaire l'incitera à ne pas faire trop de réserves de produits de stomie ;
- les producteurs et les distributeurs nationaux doivent s'expliquer sur la variance des prix observés et des coûts calculés pour les plaques de stomie, après quoi le prix des plaques peut être éventuellement adapté ;
- un code déontologique doit être élaboré par des stomathérapeutes en concertation avec des patients. Par ailleurs, une obligation d'information doit être prévue et la clarté doit être faite sur le comportement de prescription et de fourniture à l'hôpital, notamment le nombre d'échantillons que le patient reçoit gratuitement lors de son départ de l'hôpital ;
- la traçabilité des produits de stomie doit être garantie par l'introduction d'un code-barres sur l'emballage et le patient doit recevoir une facture détaillée de chaque dotation trimestrielle.

A plus long terme, le Centre fédéral d'expertise propose une réforme approfondie du système actuel dans laquelle une distinction claire serait faite entre le coût de prestation des soins médicaux, de livraison de matériel et du matériel lui-même. Une répartition claire des rôles des différentes parties prenantes doit y être associée :

- L'importance des stomathérapeutes doit être reconnue en tant qu'autorité paramédicale dirigeante et en tant que conseiller du patient le mieux placé en cas de problèmes avec une stomie ou avec le service du distributeur. Le choix du matériel de stomie doit être fait en concertation avec le patient et le médecin traitant. Une brève évaluation par un stomathérapeute, par exemple, tous les 2 ans, doit être envisagée pour vérifier la qualité des soins stomathérapeutiques et corriger la prescription si nécessaire.
- Le choix de produits fait à l'hôpital est déterminant pour le futur choix de produits du patient. La majorité des patients est particulièrement fidèle à une marque. Il n'est pas étonnant qu'il existe dans un certain nombre d'hôpitaux une politique d'échantillons gratuits et des conventions entre un fournisseur et l'hôpital. Cela limite la liberté de choix du patient sur la base d'arguments commerciaux et pas en fonction d'une utilisation rationnelle de l'assurance maladie. Tous les hôpitaux qui s'occupent de l'accompagnement initial des patients doivent obligatoirement proposer les produits de plusieurs fabricants. D'après les stomathérapeutes, c'est en effet une nécessité car une partie des patients a besoin d'une sélection de matériel spécifique ou d'une combinaison de matériel de plusieurs fabricants pour parvenir à la meilleure solution. Un simple suivi de profils permettrait en outre de détecter certaines pratiques exceptionnelles si on le souhaite.
- Vu le manque de transparence caractérisant la fixation des prix actuelle pour le matériel de stomie, on peut envisager un appel d'offres national ou une demande de prix. Sur la base d'un cahier des charges technique, les producteurs seraient invités à introduire un devis. Ce principe peut être appliqué dans le cadre d'une demande de marché transparente, menant à un remboursement de référence (montant du forfait matériel, cf. infra). Une

autre option consiste à une application dans les officines des hôpitaux. De cette manière, les producteurs seraient incités à mener une politique de prix compétitive. Bien sûr, un tel système ne conduit pas à couvrir tous les patients au prix de la soumission. Les produits des autres producteurs devront continuer à pouvoir être achetés à un prix non-réglementé (cf. supra).

- Les distributeurs finaux doivent être indemnisés pour les frais de matériel et pour le service. À ce niveau, deux options sont possibles : deux forfaits distincts ou un seul forfait intégrant le matériel et le service. D'un point de vue budgétaire, il s'agirait d'une évolution du système actuel de dotation trop rigide. Aucun coût supplémentaire immédiat ne serait prévu :

- Option 1: Forfait matériel et forfait service

Avec son forfait matériel (directement monétaire ou virtuel), le patient pourrait en grande partie choisir lui-même (avec l'aide du stomathérapeute) le nombre et le type de produits de stomie nécessaires. Cette liberté encouragerait un choix plus réfléchi et permettrait une plus grande flexibilité en matière de type et de nombre de produits. Cela favoriserait ainsi les distributeurs les plus performants proposant le meilleur service.

Le forfait services serait attribué aux distributeurs finaux sur la base du nombre de patients qu'ils gèrent par trimestre. Les patients seraient liés pour une période maximale de 3 mois à un distributeur final agréé. Le forfait services éviterait que les distributeurs finaux ne soient trop guidés par les intérêts commerciaux de la livraison de produits de stomie.

- Option 2 : Forfait tout compris

Avec cette option, le patient pourrait également changer de fournisseur tous les trois mois ou à chaque livraison. Son forfait (réel ou virtuel) lui permettrait de payer le matériel et le service. Cette option favoriserait les fournisseurs proposant principalement des produits de stomie et des services et entraînerait probablement quelques mouvements de concentration spontanés. Selon toute vraisemblance, ils pourraient obtenir de meilleurs prix chez les producteurs. Leur chiffre d'affaires dépendrait encore plus de la satisfaction des patients.

- Les limitations légales imposées aux distributeurs finaux doivent être repensées de façon à garantir un meilleur service au patient (notamment en matière de livraison). Les monopoles existants et pratiquement institutionnalisés sont peu susceptibles de stimuler la qualité et le service au patient : la livraison directe au patient est possible dans un marché plus libéralisé. Une condition annexe importante est que le stomathérapeute ait un rôle plus central.
- Les patients, les stomathérapeutes et les producteurs doivent être mieux associés au processus décisionnel pour mieux en garantir la transparence. Donner des informations objectives aux stomisés sur la qualité et le service est essentiel. Les associations de patients et de stomathérapeutes doivent donc avoir un rôle plus important.
- Les stomathérapeutes, surtout dans les centres académiques, doivent mettre en place une étude clinique prospective sur les facteurs qui déterminent la satisfaction des patients par rapport aux produits de stomie du patient belge moyen.
- Les données de base épidémiologiques doivent être rassemblées de manière longitudinale. Ces données concerneraient tant les patients dans un environnement de soins ambulatoire qu'hospitalisés.

Message clé

- Les recommandations du Centre d'expertise visent à favoriser la flexibilité dans le choix de matériel, la transparence du processus décisionnel et le fonctionnement compétitif du marché au profit du patient.

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I. CHAPTER I GENERAL INTRODUCTION

I.1. PURPOSE AND SET-UP OF THE REPORT

I.1.1. Description and Specification of the research subject

The present report aims at assessing the Belgian market for ostomy appliances from the patient and healthcare system perspective. Ideally, therapeutic needs of patients in relation to technical and economic features of available ostomy products are analyzed. This analysis is then fitted in the general economic framework, including the current regulatory framework.

I.1.2. Relevant research topics

The general research would ideally deal with the correspondence between the price structure applying to the Belgian situation and scientific evidence on respective effectiveness as well as costs for production, distribution, etc. If no sufficient data should be available with regard to reported effectiveness, research will be limited to an international cost analysis and institutional evaluation.

Two underlying topics are relevant for the analysis of the research subject.

Scientific background on Cost-Effectiveness

What are the differences in costs and/or effectiveness as reported by scientific literature? Is it feasible to develop a comprehensive cost-effectiveness analysis based on available publications? If so, how can the relevant findings be interpreted for the Belgian situation?

Price structure applying to the Belgian market

By “price” the authors refer to total cost for society, i.e. patients’ individual contributions AND (state-funded) reimbursements. The price consequently covers the costs for production and distribution, including all mark-ups and required medical expertise.

Is relative price setting at a par with possible findings on differences in medical effectiveness? How should the Belgian price level be evaluated compared to international markets?

Key Messages

- The report deals with Belgian market and regulatory processes for ostomy appliances.
- Feasibility of assessing costs and related medical outcome will be verified.
- The analysis is written from patient and healthcare system perspective

1.2. LAY-OUT OF THE REPORT

A certain succession of research steps has to be respected in order to successfully identify the quintessential decision parameters for Belgian policymakers:

- a selection among the vast array of ostomy appliances of those products that are of overriding relevance to Belgian patients;
- a comprehensive background search of scientific evidence on the cost-effectiveness of these selected (types of) products;
- a technical product(ion) analysis of these (types of) products, laying bare those factors that determine their cost;
- an assessment of the interplay between regulation and the terms of supply for ostomy products.

The final part of the report will serve as an external audit, identifying shortcomings in the current Belgian regulation and suggesting ways of mending those.

1.3. SCOPE OF THE REPORT

In 2003 the reimbursed expenses for bandaging products represented 59.839.000€ in Belgian ambulatory care. Ostomy products accounted for 19.240.419€ in this category. The lump sum daily reimbursements³ for appliances during hospital stays for ureterostomy, colostomy and ileostomy added up to a reported 532.024€ for 2003. As a result, Belgian health insurance reimbursed a total of 19.822.444€ for ostomy products or 0,13% of the overall budget for reimbursed medical expenses in Belgium⁽¹⁾. This amount does not take into account possible out-of-pocket payments patients made. These figures give readers an inkling of budgetary proportions at stake and demonstrate the modest financial impact ostomy products, who serve a vital purpose for patients, have on the overall government budget for health care.

The different products (and corresponding categories) that constitute this set of medical appliances are further limited to assure that research will prioritize in as efficient as possible a way, i.e. successfully balancing the trade-off between topical exhaustiveness and realistic research efforts. Likewise, the detail to which observed price level will be dissected into constituent components is limited by operational feasibility.

1.3.1. Ostomy products

Ostomy care includes nowadays a wide range of products and services for patients with a stoma. Every manufacturer presents a broad range of pouches and plates, each with their specific features, addressing every type of stoma patient. Most of them are available in different sizes and colours, mostly beige and transparent. In addition a whole variety of accessories such as barrier creams, protective films, belts, deodorants and other odour neutralizers, pouch covers, etc. is available.

An Ostomy appliance is defined as a “device that consists of a bag that is attached to the patient’s skin by an adhesive material that is intended for use as a receptacle for collection of faecal material or urine following an ileostomy, colostomy or ureterostomy, (2).” The main distinction made in the typology of ostomy appliances is the difference between one-piece and two-piece appliances. Both kinds of products are available for colostomy, ileostomy and ureterostomy patients (see figure 1), the latter appliance having flange and pouch as two separate items. Built-in filters, skin-friendly layers on the body side are but a few of the features that characterize modern-day’s ostomy pouches. Often (and commonly in the first year after surgery³) patients suffer

³ Reimbursement by health insurance to hospitals of surplus costs related to (patients needing) ostomy products is dealt with by lump sum daily reimbursements. Three nomenclature codes, 641465, 641480, 641502 correspond to a fixed sum attributed on a daily basis for registered patients with a colostomy, ileostomy or ureterostomy (in respective order).

from various conditions worsening the general state of their stoma. If the stoma for instance were to retract, ostomy appliances with convexly shaped can offer a solution. Documents introducing readers to more technical aspects of stoma care abound and are a rich source of information for the layman and trained clinician⁽⁴⁻¹¹⁾.

Table I offers an overview of the ostomy products this report will focus on. Readers will find the official Dutch and French labels aside their English translation in the annex to Chapter I. The 8 “nomenclature codes” are billing codes referring to the different types of appliances that are reimbursed by the Belgian state and concern reimbursements for devices in ambulatory care. The aggregate expenses for these products make up over 91% of the government budget for ambulatory care. It should be emphasized that patients could be requested to make out-of-pocket payments for certain devices. Therefore, the monetary amounts mentioned in table I do not represent the full cost of ostomy appliances to society.

The products belong to three distinct categories as identified by the Belgian healthcare system:

- appliances for colostomy and/or ileostomy and bowel fistulae,
- appliances for ureterostomy and/or cystostomy and fistulae on the urinary tract,
- appliances for exceptional stomies and/or bowel/urether fistulae.

The analysis includes both 1 and 2 piece pouches for colostomy and ileostomy patients. Both for technical⁴ reasons and in view of the general research scope⁵ the evaluation of ostomy appliances for ureterostomy appliances was limited to 2 piece pouches. Flanges for 2 piece products (including attached skin barriers), both regular and convex, are also assessed in this report.

The licensed national distributors for 6 important producers were asked by researchers to identify their most commonly sold products corresponding to the selected nomenclature codes. The companies contracted by researchers included the 4 main producers for the Belgian market⁶ (BBraun (Biotrol Braun), Coloplast, ConvaTec (Bristol-Myers Squibb), Hollister-Dansac) and two minor companies (Welland Medical and Eurotec) that mostly offer products at the bottom of the price range for the analyzed product scope.

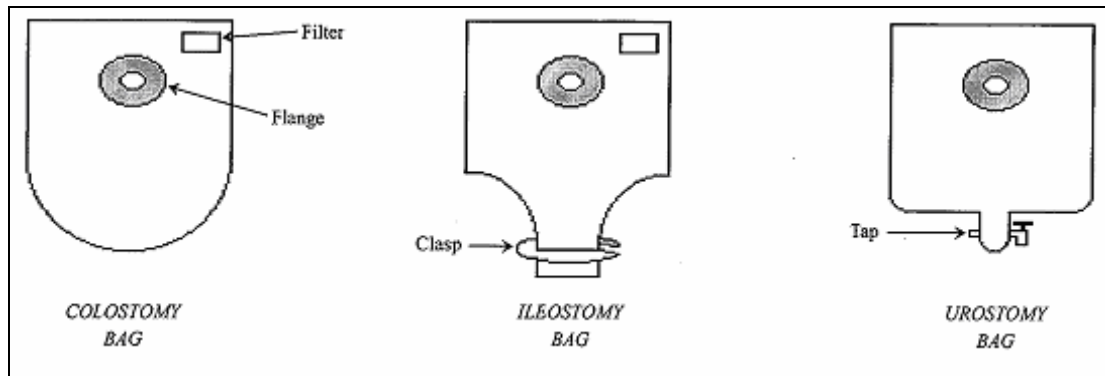
The listed products for 4 producers who responded to our request for information can be found in the annex to Chapter I. These specific products served as the basis for the technical analysis (regarding production costs) and international price comparison in this report.

⁴ The presence of drain valves or drain spouts and anti-reflux valves in ureterostomy pouches proved hard to integrate into the production cost analysis of appliances for ostomies and ileostomies.

⁵ In 2003 booked amounts for nomenclature code 640813 (one-piece ureterostomy appliances) added up to 25.295€, as compared to 3.353.418€ for two-piece ureterostomy appliances (amounts for flanges and pouches added).

⁶ Combined market share of 4 main producers is well over 99% (% of billed amounts) in 2005 as estimated by survey results obtained from 32 bandagers.

Figure 1 Schematic representation of ostomy products



Source ⁽³⁾: based on D, Garattini L, 2002 (referring to Corsi F 1999, p.9)

Key messages

- The reimbursement for ostomy appliances represents a small share of overall government health expenditures.
- A vast array of ostomy appliances is available to suit patients' needs, obliging researching to narrow the scope of the report.

Table 1 Selected Nomenclature Codes: 1 and 2 piece pouching appliances in ambulatory care for ostomy patients with original Dutch code labels

N-CODE	LABEL N-CODE (Official label (Dutch version), for English version see annex 1.1.1)	AMOUNT BOOKED IN 2003 (€)	% IN AMBULATORY CARE	# CASES	€/CASE	REIMBURSEMENT 2005
640275	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Eëndelig systeem</i> - Gesloten, Zelfklevend opvangzakje, voorzien van een peristomale beschermlaag, ongeacht de bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere systemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0275	6.244.068	32%	2.426.235	2,57 €	2,62 €
640393	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Gesloten zakje met bevestigingssysteem (bv. oplijring), ongeacht de overige bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere opvang- of continentiesystemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0393	2.732.910	14%	1.765.522	1,55 €	1,57 €
640371	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Peristomale beschermerschijf met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden(ileostomie) 35 stuks/3 maanden (colostomie) Lijst 0371	2.474.724	13%	415.876	5,95 €	6,05 €
640872	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Peristomale beschermerschijf, voorzien van een bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 0872	1.808.694	9%	303.906	5,95 €	6,05 €
640894	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Ledigbaar urine-opvangzakje met bevestigingssysteem (bv opklikring) en antirefluxklep, ongeacht de overige bijbehorende produktattributen Dotatie : 60 stuks/3 maanden Lijst 0894	1.544.724	8%	495.498	3,12 €	3,17 €
641351	Stomamateriaal - Verzorgingssystemen voor uitzonderlijke toestanden bij stomiekuil minstens 1 cm diep ligt, in ruglithouding gemeten - <i>Tweedelig systeem</i> - Convexe peristomale beschermerschijf met een minimum plaatdikte van 3 mm in het centrum, met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 1351	1.527.822	8%	191.152	7,99 €	8,11 €
640290	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Eëndelig systeem</i> - Ledigbaar zelfklevend opvangzakje voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0290	634.996	3%	180.739	3,51 €	3,57 €
640415	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Ledigbaar zakje met bevestigingssysteem (bv. opklikring) voorzien van een sluitklem, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/maanden Lijst 0415	493.439	3%	325.937	1,51 €	1,54 €
		17.461.377	91%			
		19.240.419				

1.3.2. General economic framework

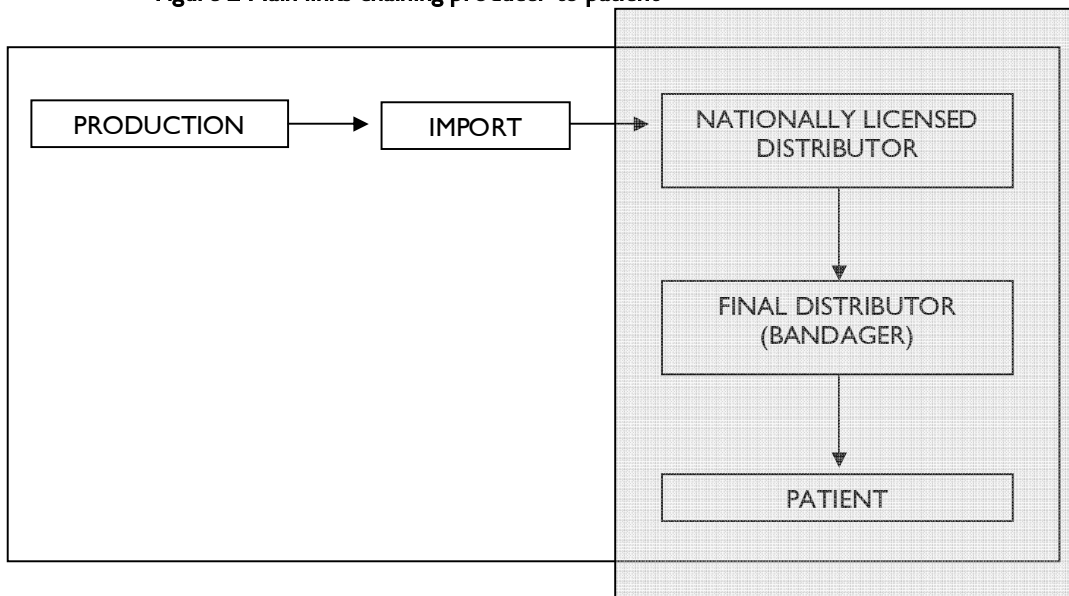
The price and cost analysis will be limited to those products corresponding to the relevant nomenclature categories (cf. supra). Those categories encompass the bulk of ostomy products used by Belgian patients. Furthermore, the price and cost analysis will focus on the products identified as the most commonly sold by 6 major producers for the Belgian market.

A further limitation will apply with regard to the main components in the wider economic frame (see figure 2) that will be analyzed. As by price the full cost to society is understood it seems logical to identify the principal constituents of this overall cost:

- Production cost
- Import cost
- Distribution cost
 - “Wholesale” distribution
 - “Retail” distribution (including costs for medical care)

In the present report plausible production costs will be gauged and a producer mark-up added. This way a purchase price for nationally licensed wholesaler (i.e. importer) is estimated. Next, a reasonable mark-up is added covering comprehensive costs for distribution and compared to final retail prices (6% VAT included). Discussions regarding the break-up of costs for medical expertise will not be broached in the technical analysis, as these are matters of a more ethical/political nature. This technical analysis also includes an international comparison of price levels, price variance and other relevant market factors.

Figure 2 Main links chaining producer to patient



As production for the selected appliances in Western Europe is centralized on a few sites (situated in Denmark, France, the UK) servicing several national markets, all ostomy appliances for the Belgian market are imported and production as such cannot easily be regulated by the Belgian government.

The grey area of figure 2 concerns the elements that fall under the regulatory discretion of Belgian policymakers. A detailed analysis of the regulatory framework will be made. A brief overview of salient regulatory characteristics will be highlighted from an international perspective.

The choice of international benchmarking countries will be concurrent (as concurrent as researchers found possible) for both the regulatory and technical market analysis. The interplay between legislation and market conditions may lead to interesting conclusions.

Key messages

- **Cost of production and medical effectiveness are factors applying internationally.**
- **The regulatory framework affects factors within the grasp of Belgian policy makers.**

2. CHAPTER II SCIENTIFIC BACKGROUND

2.1. INTRODUCTION

The previous chapter introduced readers to the various topics this study addresses. Furthermore, the scope of the report was set and priorities were elucidated. The types of ostomy products (see Chapter I, Table I and the annex to Chapter I) that were selected for further review, are now submitted to an exhaustive analysis of available scientific literature.

2.2. PUBLISHED LITERATURE

Setting up criteria for selecting available literature proved rather straightforward (Table I). Consulted databases are listed in Table 2 and relevant results in Table 3.

2.2.1. General background

Standard medical literature mostly deals with surgical indications and ostomy techniques, surgical complications and outcome of surgery, dietary or pharmaceutical issues especially for ileostomy patients *Nursing care & enterostomist literature* provides literature on quality of life, dietary aspects in enterostomy care, general nursing & patient care as well as product reviews or new product presentations.

2.2.2. Specific medical assessments of relevant product types

Few *Systematic Reviews*^{12, 13} and one *Randomized Controlled Trial*¹⁴ were published in relevant fields. One *comparative study* was published in Czechia in 1996¹⁵: in three surgical centres three modern two-piece colostomy systems, available in the Czech republic, were compared, to assess how they influence the quality of life of the patients. As the article was published in Czech researchers were not able to take its findings into further account. Another publication¹⁶, sponsored by ConvaTec®, reported findings of a randomized crossover comparison of adhesively coupled colostomy pouching systems in six outpatients clinics in Germany.

2.2.3. Specific socio-economic analysis' of relevant product types

Specific cost and market studies are also scarce^{2, 17-20}, with only one study²⁰ comparing the markets in five European countries. The findings of this study inspired the international analysis of the regulatory framework of ostomy appliances reported in Chapter IV of this report.

2.3. NON-PUBLISHED LITERATURE

Manufacturers for the 6 evaluated makes were invited to send relevant research papers to KCE. Two manufacturers replied favorably and posted an information package including in-house clinical trials. Agreements on confidentiality, however, do not allow authors to publish a formal assessment of this material.

Key messages

- The published literature on medical effectiveness of ostomy appliances is limited.
- The published literature on the economic background of ostomy appliance is limited.
- Unpublished literature could not be assessed in this report due to confidentiality.

2.4. CONCLUSION

Medical literature on this subject proved to be very limited and presents to a high extent with problems of internal validity. Given the absence of noteworthy scientific information on reported differences in medical effectiveness, evaluating the scientific justification of relative price structures will prove impossible. It seems evident that prospective research, more precisely in the field of crossover Comparisons between products of different make, constitute a prerequisite for future assessments of (cost-)effectiveness. Differences in patient satisfaction should be assessed according to standardized score sheets; relevant topical items including:

- risk of leakage,
- stickiness,
- odour (regarding to appliances with filters),
- skin-related problems,
- wear time.

Time and budget constraints prohibited researchers to engage the formidable effort of examining these factors for the selected products: 6 different makes, one- and/or two-piece appliances for ureterostomies, colostomies and ileostomies. Consequently, the formal evaluation of ostomy appliances will be restricted to a cost analysis in this report.

Table I : Search strategy

All MeSH Categories

1. Analytical, Diagnostic and Therapeutic Techniques and Equipment Category

- o Surgical Procedures, Operative [E04]
 - Ostomy
 - Cecostomy
 - Colostomy
 - Ileostomy
 - Ureterostomy
 - Urogenital Surgical Procedures
 - Urologic Surgical Procedures
 - Urinary Diversion
 - Ureterostomy
- o Equipment and Supplies
 - Surgically-Created Structures
 - Stomas
- o Investigative Techniques
 - Evaluation Studies
- o Subheadings Category
 - Instrumentation

2. Health Care Quality, Access, and Evaluation

- o Health Services Research
 - Health Care Surveys
- o Delivery of Health Care
 - Health Care Costs

3. Health Care Economics and Organizations

- o Health Planning
 - Health Services Research
 - Health Care Surveys
 - Health Services Needs and Demand
 - Needs Assessment
- o Economics
 - Costs and Cost Analysis
 - Cost Control
 - Cost Savings
 - Health Care Costs
 - Direct Service Costs
 - Health Expenditures
 - Capital Expenditures

Limits

- o Last 10 years
- o Humans
- o All languages
- o All ages

Focusses

- o Systematic reviews & meta-analyses, (editorial) reviews
- o RCT's, randomized trials, controlled trials
- o Multicentre, comparative studies
- o Health services research, health care surveys & needs assessment

Exclusions

- o Studies on surgical indications & techniques
- o Studies on surgical complications & outcome
- o Studies on QoL
- o Studies on dietics
- o General nursing & patient care
- o Patient info
- o (New) product presentation

Table 2 : Searched databases

1. Medline, PubMed (SumSearch),
2. Medline, PubMed (Clinical Queries, RCT's & SR's)
3. NLM, TOXLINE,
4. NLM, ClinicalTrials.gov
5. NLM, HSRProj
6. NLM, HSDB
7. NLM, PubMed
8. National Guideline Clearinghouse™
9. Embase
10. Cochrane Reviews, CDSR, DARE, CCTR
11. CINAHL
12. British Nursing Index
13. Econlit

Table 3 : Search Results					
Database	Search query	Found	Relevant	Subject	Feature(s)
Medline, PubMed (SumSearch)	Colostomy or cecostomy or ileostomy or ureterostomy or stomas and instrumentation (Focus: TREATMENT, ages: all, subjects: HUMAN, last 10 years)	21	3	Disposable plastic liners for a 2-piece colostomy appliance ²¹	Randomized, crossover trial with follow-up surveys
				Colostomy plug devices ²²	Randomized, prospective study
				The evolution, current status, and regulation of ostomy products in the United States ²	Review
Medline, PubMed (Clinical Queries, SR's)	(colostomy OR cecostomy OR ileostomy OR ureterostomy OR stomas) AND systematic[<i>sb</i>] Publication Date from 1995/01/01 to 2005/06/15, Humans	55	0		
NLM, TOXLINE	((((((@all colostomy) or (@all cecostomy)) or (@all ileostomy)) or (@all ureterostomy)) or (@all stomas)) and (@range yr 1995 2005))	17	0		
NLM, ClinicalTrials.gov	colostomy [ALL-FIELDS] OR cecostomy [ALL-FIELDS] OR ileostomy [ALL-FIELDS] OR ureterostomy [ALL-FIELDS] OR stomas [ALL-FIELDS]	3	0		
NLM, HSRProj	(((((("colostomy" <IN> ProjectTitle OR "colostomy" <IN> State OR "colostomy" <IN> KeywordList OR "colostomy" <IN> MeshHeading OR "colostomy" <IN> AbstractText OR "colostomy" <EXACT> <IN> DescriptorName <IN> MeshHeading OR "colostomy" <IN> SupportingAgency OR "colostomy" <IN> PerformingOrganization) OR ("cecostomy" <IN> KeywordList OR "cecostomy" <IN> SupportingAgency OR "cecostomy" <IN> State OR "cecostomy" <EXACT> <IN> DescriptorName <IN> MeshHeading OR "caecostomy" <IN> PerformingOrganization OR "caecostomy" <IN> AbstractText OR "caecostomy" <IN> SupportingAgency OR "cecostomy" <IN> ProjectTitle OR "caecostomy" <IN> KeywordList OR "cecostomy" <IN> MeshHeading OR "caecostomy" <IN> MeshHeading OR "caecostomy" <IN> State OR "cecostomy" <IN> PerformingOrganization OR "caecostomy" <IN> ProjectTitle OR "cecostomy" <IN> AbstractText)) OR ("ileostomy" <IN>	1	0		

	AbstractText OR "ileostomy" <IN> SupportingAgency OR "ileostomy" <IN> KeywordList OR "ileostomy" <IN> PerformingOrganization OR "ileostomy" <EXACT> <IN> DescriptorName <IN> MeshHeading OR "ileostomy" <IN> State OR "ileostomy" <IN> MeshHeading OR "ileostomy" <IN> ProjectTitle)) OR ("ureterostomy" <IN> AbstractText OR "ureterostomy" <IN> PerformingOrganization OR "ureterostomy" <IN> MeshHeading OR "ureterostomy" <EXACT> <IN> DescriptorName <IN> MeshHeading OR "ureterostomy" <IN> ProjectTitle OR "ureterostomy" <IN> State OR "ureterostomy" <IN> KeywordList OR "ureterostomy" <IN> SupportingAgency)) OR ("stomas" <IN> State OR "stomas" <IN> AbstractText OR "stomas" <EXACT> <IN> DescriptorName <IN> MeshHeading OR "stomas" <IN> ProjectTitle OR "stomas" <IN> MeshHeading OR "stomas" <IN> KeywordList OR "stomas" <IN> PerformingOrganization OR "stomas" <IN> SupportingAgency)) AND (1995 <IN> ALL_YEARS OR 1996 <IN> ALL_YEARS OR 1997 <IN> ALL_YEARS OR 1998 <IN> ALL_YEARS OR 1999 <IN> ALL_YEARS OR 2000 <IN> ALL_YEARS OR 2001 <IN> ALL_YEARS OR 2002 <IN> ALL_YEARS OR 2003 <IN> ALL_YEARS OR 2004 <IN> ALL_YEARS OR 2005 <IN> ALL_YEARS))				
NLM, HSDB	(((((@all colostomy) or (@all cecostomy)) or (@all ileostomy)) or (@all ureterostomy)) or (@all stomas))	5	2	Sterculia gum & guar gum	Hazardous Substances Data Bank reports
NLM, PubMed	(((((("colostomy" [MeSH Terms]) OR (colostomy [Text Word])) OR ((cecostomy [Text Word]) OR (caecostomy [Text Word])) OR ("cecostomy" [MeSH Terms])) OR ((("ileostomy" [MeSH Terms]) OR (ileostomy [Text Word])) OR ((ureterostomy" [MeSH Terms]) OR (ureterostomy [Text Word])) OR ((("stomas" [MeSH Terms]) OR (stomas [Text Word])))) AND ((1995/01/01 [PDAT]) : (2005/06/15 [PDAT]))))	4.165	2	Randomized crossover comparison of adhesively coupled colostomy pouching systems ^{14, 16} Product tolerance for 3 appliances, patient preference & skin status ¹⁵	Multicentre comparative study
National Guideline Clearinghouse™	colostomy or cecostomy or ileostomy or ureterostomy or stomas	0	0		
Embase	('colostomy'/exp/mj OR 'colostomy') OR ('ileostomy'/exp/mj OR 'ileostomy') OR ('cecostomy'/exp/mj OR 'cecostomy') OR ('ureterostomy'/exp/mj OR	2.589	0*		

	'ureterostomy') OR ('ostomy'/exp/mj OR 'ostomy') AND [2001-2005]/py AND [humans]/lim				
Cochrane Reviews, CDSR, DARE, CCTR	colostomy or cecostomy or ileostomy or ureterostomy/all fields	9	0		
CINAHL British Nursing Index	(colostomy or ileostomy or enterostomy or cecostomy or ureterostomy or stomas).mp. [mp=title, subject heading word, abstract, instrumentation]. Limit to (abstracts and yr=1995 - 2005)	275	1	Evaluation of patient's stoma cost ²³	Prospective , double blind, peer reviewed
Econlit		0	0		
* no additional relevant studies found					

Table 4 : Components of internal and external validity of controlled clinical trials

Internal validity - extent to which systematic error (bias) is minimised in clinical trials

- Selection bias: biased allocation to comparison groups
- Performance bias: unequal provision of care apart from treatment under evaluation
- Detection bias: biased assessment of outcome
- Attrition bias: biased occurrence and handling of deviations from protocol and loss to follow up

External validity - extent to which results of trials provide a correct basis for generalisation to other circumstances

- Patients: age, sex, severity of disease and risk factors, comorbidity
- Treatment regimens: dosage, timing and route of administration, type of treatment within a class of treatments, concomitant treatments
- Settings: level of care (primary to tertiary) and experience and specialisation of care provider
- Modalities of outcomes: type or definition of outcomes and duration of follow up

3. CHAPTER III COST ANALYSIS OF OSTOMY PRODUCTS

3.1. INTRODUCTION

The initial ambition of the cost analysis of ostomy products consisted in presenting an accurate and reliable cost assessment for different kinds of ostomy products as defined by the study outline in chapter I.

To attain this result and execute the study in a transparent and open way, researchers involved the industry (six companies). A questionnaire that contained elements for the development of the cost model was sent to all of them. As a result of the little information given by the industry, the resulting cost model can only approximate this initial ambition. The production cost presented here gives an idea on the order of the costs without claiming to give the exact cost of each item.

3.2. GENERAL METHODOLOGY

3.2.1. Involvement of manufacturers / local distributors

Manufacturers were largely solicited in the information gathering for this study.

Product information

In a first stage, contacts were initiated with local distributors or representatives, who were requested to provide identification numbers, samples and information on their products within the pre-defined product scope. Samples of products were received from all local distributors. Technical information and a list of representative products were received from most of them. Reactions were very diverse, ranging from general marketing material explaining the advantages of the products to product data sheets giving a rough idea on the raw materials used. The information collected here was therefore valuable, but not substantial.

Information meetings

During several interviews, representatives from the Belgian distributor of the selected firms were given the opportunity to present themselves and their product range and to discuss with the research team the challenges they are facing on the Belgian market.

Survey on ostomy appliances

Certain information could not be obtained directly from the local distributor. Therefore, in agreement with these local distributors, the decision was taken to address headquarters on these matters. A questionnaire was developed aiming at providing more information on:

- the importance of ostomy appliances for the company;
- the production type of the company (tailor-made versus standard production);
- the market share in a selection of countries;
- the general cost structure – cost elements in the production cycle;
- research & development indicators (budget, number of people, patents, development time, success rate);
- raw materials used and their cost impact;
- the manufacturing process (production sites, products, personnel involved, capital versus labour intensive, production organisation, manufacturing equipment, production steps, mark-up for sustainable activity).

It was agreed that confidential information would only be used for the study experts and would not be reported in the study as such.

The complete questionnaire can be found in the annex for chapter III.

Two reactions on this questionnaire were received. A first firm indicated not to dispose of the cost price information and was therefore not returning the questionnaire. A second firm did send the questionnaire back, but with little information, mentioning that most of the information is not publicly disclosed. From all other firms no reaction at all was received.

Visit production site

The research team took the opportunity to visit the Coloplast production site in Denmark.

Feedback on the cost model and international price comparison

The manufacturers and/or local distributors had the opportunity to give remarks on the aggregated cost model.

Key message

- **Manufacturers and/or local distributors were invited to participate in the information gathering process by means of product information exchange, information meetings, a survey and a feedback session.**

3.2.2. Desk research

Public health obligations

In the countries included in the scope of the study it was not found that the government imposes specific rules on the production process for ostomy appliances.

Nevertheless every manufacturer of medical devices that wants to sell these products on the European market should follow the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The Council of the European Communities was well aware that the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different. Moreover, certification and inspection procedures for such devices differ from one Member State to another and such disparities constitute barriers to trade within the Community.

Medical devices are grouped into four product classes. Ostomy appliances are, as all non-invasive devices, Class I products. The conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products.

The manufacturer must draw up a written declaration of conformity to the directive and the products themselves must bear the CE marking of conformity when they are placed on the market.

Some of the essential requirements imposed by this Medical Devices directive that should be taken into account in the production of ostomy appliances are (amongst others):

- attention to the choice of materials used (e.g. as regards toxicity and flammability)
- elimination or reduction of the risk of infection
- choice of the packaging systems (keeping non-sterile devices clean)
- packaging and label should distinguish between sterile and non-sterile similar devices
- patient information requirements (information on the label, instructions for use)

Key message

- **Except for the Council directive concerning medical devices, no specific product regulation is found in the Belgian situation.**

Economic and market information

Annual reports and other financial information on the manufacturers have been studied to gain the necessary knowledge on the firm's structure and key financial figures including information on the turnover and operational costs of the manufacturers.

For this study we also had access to Deloitte's **Life Sciences Global Benchmark Study** (24). This benchmark study provides information on business performance, customer service, inventory, sourcing, manufacturing, distribution and product innovation in the life sciences industry. Especially the information on the medical devices industry sub segment was of interest.

Other sources

The research team gathered some more information from a wide range of sources including:

- decomposition, analysis and study of finished samples of finished products;
- information from product data sheets, catalogues, brochures describing the (main) product components, and the principal raw materials (ingredients) used for the manufacturing of each component;
- general and specific information received on the product life cycle, the current manufacturing process, the (global) amount of investments made, the quality control activities and organisation, ... during the interviews with the manufacturer's local representatives;
- information received from machine constructors concerning the purchase, operational and maintenance costs for the typical machines used in these manufacturing processes (injection moulding, extrusion, pouch assembly, ...);
- information obtained from suppliers about the main raw materials and their average market price levels;
- general industry, manufacturing and distribution knowledge: average labour personnel costs, transport costs, sales and distribution, ...

Particularly the cooperation of a material expert, the VKC Vlaams Kunststofcentrum (a technological knowledge centre) and Fechiplast (the association of the plastics converters in Belgium) was very valuable.

Key message

- **Desk research was performed in order to provide accurate information to build the cost model.**

3.3. DEVELOPMENT OF A COST MODEL

3.3.1. Steps in the development of the model

The methodology followed for the development of a cost model consists of four different steps.

In a first step **the production process** is represented **schematically**. To assure that all cost drivers are covered, the cost model is built according to this generic production process. Cost drivers for the production process include raw materials, machinery, direct and indirect labour, manufacturing overhead, warehousing, distribution, transport, clinical tests, research and development, wholesale, sales, services provided, etc.

In a second step the **calculation model** is built, mapping the relationships between and the calculations behind the different cost drivers. Here also the production process was used as guidance. This cost model is developed using a spreadsheet application. The focus of the calculation is based on the costs incurred by the product as it leaves the factory of the producer, referred to as the price FOB (i.e. Free On Board). This estimate is referred to as "price" FOB, since it includes a mark-up for producers and therefore it is the estimated purchase price domestic importers supposedly pay for ostomy products. With this price an estimate can be made on a reasonable total price of the product when bought at the pharmacy or bandager's, including both the reimbursement tariff and an eventual surplus paid by the patient.

In the third step the **calculation model** is **applied and filled out**. All cost elements involved are quantified using a number of hypotheses. Information for this quantification

exercise is obtained by contacts with the industry, desk research, contacts with experts in the field, contacts with other companies (e.g. suppliers, similar products or production types) and industry knowledge. For every cost driver to be quantified a low, a medium and a high estimate is used. These help to give a better idea of the sensitivity of the result.

The last step is the **validation of the result**. A draft of the model is reviewed by the experts (31/08/2005) involved in the study and adapted accordingly before finalisation. Manufacturers/local distributors also have the possibility to share comments on the aggregated cost model.

Key message

- **The development of the cost model consisted of four steps**
 1. **Presenting the production process schematically**
 2. **Building the calculation model**
 3. **Applying and filling out the calculation model**
 4. **Validation of the resulting cost model**

3.3.2. Reactions from the industry

Researchers received 4 written reactions from the industry:

- One firm declares the figures for the one-piece system would appear reasonable, although the firm's own cost structure by item is different. The price for two-piece products seems low according to them.
- Another firm states the cost data presented are not in correspondence with the reality as seen from their point of view.
- A third firm writes that the figures are not realistic.
- UNAMEC ⁽²⁵⁾, representing the industry, underlines that the industry has not participated to the elaboration of the cost model and, therefore takes some distance from it because some elements presented are based on assumptions that its members are not able to control. UNAMEC has no information on manufacturing costs.

An additional feedback session was organised for UNAMEC members in order to present and discuss the results (16/09/2005).

3.3.3. Description of the cost model

Production steps

The production of ostomy products at the manufacturing site can typically be split into the following steps:

- weighing and mixing of raw materials;
- coating;
- rolling;
- adhesive elements;
- filter production;
- injection moulding;
- assembly of finished products;
- packaging;
- shipping;
- warehousing;
- picking;
- distribution.

The costs incurred in these production steps are divided into the following components including:

- raw material used in the production step;
- direct labour such as operating and packing;
- indirect labour such as engineering and quality assurance;
- machine cost (depreciation, maintenance, repair, energy, facilities).

For all of the components of a selection of ostomy appliances (1-piece pouches, 2-piece pouches and 2-piece flanges) these are described and calculated.

Assumptions used

Given the confidential information and insights received from several sources and used in this model, it is unfortunately not possible to disclose all estimates and hypotheses in this public report.

The assumptions used can be divided into two broad categories. General assumptions are presented here with figures. Some more detailed assumptions related to specific production steps and machines are only explained in brief in this report.

General assumptions

R&D, warehousing, profit and general overhead are expressed as a mark-up of the total manufacturing costs. Considering that the products are manufactured in very large quantities, we do not differ between fixed and variable costs.

The medium estimate of the **percentage of sales spent on research and development** is 4%. This is based on the annual accounts of the manufacturers. For this purpose only the players whose core business is the production of stoma material were taken into account. Other manufacturers are part of a bigger pharmaceutical group which obviously have higher R&D spending due to the high research focus in this industry.

The medium estimate of the **percentage of sales spent on warehouse operations** of 1,6% and on distribution and transport of 2,40% are based on the Deloitte Global Benchmark Study on Life Sciences (August 2004), indicating this data for the sector of medical devices.

The medium estimate of the **percentage of sales that represents the overall profits** is set at 15%, based on the annual accounts of the manufacturers. There is a lot of variation in the range of profits presented in the annual accounts, so the estimate is mainly focused on a representative percentage for companies where the production of ostomy appliances is their core business.

Assumptions for processes and machines

Estimated costs of raw material are based upon the most frequently used ingredients of the components. Especially the more expensive ingredients or the ones with the highest share in the ingredient mix determine the cost of the raw materials. Prices were based on sector information from the plastics industry and firms from the chemical industry, who are suppliers for the ostomy industry. The weight of the raw material was determined from the product samples. Waste of raw material during production was taken into account to determine the cost.

Concerning the use of **machinery** a medium estimate of 48 weeks per year, 5 days per week and 3 shifts of 8 hours per day was taken into account, based on the operation hours of recent high technological plants like the production site visited.

An estimated **occupation rate** for every step in the production cycle takes into account for not-occupation of the machine because of different reasons like adjustments, failure, etc.

Depreciation is typically 5 years for the kind of machines used, although the life time is much longer. An estimated **lifetime** of 8 years was therefore used in the calculations.

Energy costs are added also in the cost calculation and vary for every production step, since some machines or manipulations typically use more energy than others.

An estimated number of **pieces produced** per time unit makes the attribution of these and other production costs to the individual product pieces possible.

Labour cost is very dependent on the wage level in the country of production. For this study European industry averages of 25 € per hour for operators and maintenance

technicians, 40 € per hour for quality assurance and 55 € per hour for engineering were considered.

Key messages

- The production steps are described and used as guidance to determine the cost model and calculate the costs.
- Costs incurred in the production steps are divided into the following components: raw material, direct labour, indirect labour and machine cost.
- R&D, warehousing, general overhead and profit are determined as a mark-up of the previous result (total manufacturing cost).
- The assumptions used are divided into two categories.

General assumptions are used when applicable on the cost model as a whole (all production steps).

Assumptions for processes and machines varying for the different production steps.

Calculation of production cost

For confidentiality reasons only an aggregated cost model is presented in the table below. The full cost model was reviewed by the project partners, experts involved in the study and external evaluators, who all signed a confidentiality agreement.

The aggregated model gives an overview of the different cost types added over the subsequent production steps. To get a clear view on the weight of every cost component, the cost as a percentage of the total price FOB is also indicated.

Table 1: Aggregated cost model

	1-piece pouch			2-piece pouch			2-piece plate		
	Cost (€)	%	%	Cost (€)	%	%	Cost (€)	%	%
Raw material	0,27 €	32%	23%	0,22 €	47%	33%	0,07 €	12%	9%
Direct labor (operating, packing)	0,29 €	34%	24%	0,10 €	21%	15%	0,24 €	40%	29%
Indirect labor (engineering, quality assurance...)	0,05 €	6%	4%	0,03 €	7%	5%	0,03 €	6%	4%
Machine cost (depreciation, maintenance, repair, energy, facilities)	0,24 €	29%	20%	0,11 €	24%	17%	0,24 €	42%	30%
Total manufacturing costs	0,85 €	100%		0,46 €	100%		0,59 €	100%	
General overhead (accounting, insurance, security, ...)	0,09 €		8%	0,05 €		8%	0,07 €		8%
Research & Development	0,05 €		4%	0,03 €		4%	0,03 €		4%
Warehousing	0,02 €		2%	0,01 €		2%	0,01 €		2%
Profit	0,18 €		15%	0,10 €		15%	0,12 €		15%
Total price FOB	1,18 €		100%	0,65 €		100%	0,82 €		100%

The model focuses on basic models of colostomy and ileostomy pouches, where the latter could cost a little extra in reality. The price of these ileostomy pouches depends on the specific closure (an extra clamp or Velcro closure used) and the type of filter used, which might be a little more expensive than a regular filter. To obtain an estimate price for ureterostomy pouches the main differentiating factors would be to deduct the costs of a filter and add a tap system and anti-reflux valve.

Key messages

- Due to our assumptions (R&D, general overhead, warehousing and profit as a mark up of total manufacturing cost), total manufacturing cost represents $\pm 70\%$ of total price FOB.

- The importance of the components raw material, direct labour, indirect labour and machine cost vary for the different ostomy products:

Raw material represents 12 to 47 % of total manufacturing costs

Direct labour represents 21 to 40 % of manufacturing costs

Machine costs represent 24 to 42 % of manufacturing costs

Indirect labour represents 6 to 7 % of total manufacturing costs

The total price FOB of a one piece pouch is estimated at 1,18€. Total price (FOB) of a two piece system (plate and pouch) is estimated at 1,47€.

Sensitivity analysis

To have an idea of the sensitivity of the model a sensitivity analysis was performed. The sensitivity of the following four factors is presented below: general overhead, research and development, warehousing and profit.

Table 2: Sensitivity analysis cost model

	estimates			measure for sensitivity
	low	medium	high	
General overhead	5%	8%	10%	7%
Research & Development	3%	4%	5%	3%
Warehousing	1,4%	1,6%	1,9%	1%
Profit	7%	15%	22%	21%

The measure for sensitivity calculated here is defined as:

$$\sigma = \frac{\text{priceFOB}(\text{high}) - \text{priceFOB}(\text{low})}{\text{priceFOB}(\text{medium})}$$

With:

priceFOB (high)= the total price FOB using the high estimate for this variable, ceteris paribus (i.e. medium estimates for all other variables)

priceFOB (low)= the total price FOB using the low estimate for this variable, ceteris paribus

priceFOB (medium)= the total price FOB using the medium estimate for this variable, ceteris paribus, i.e. the price FOB as calculated above

These figures indicate that changing the profit margin and cost for warehousing will respectively have the highest and lowest impact on the price when looking at these four factors.

Calculation of distribution cost

To have an idea of the price the patient will eventually pay for the product over the counter (**price local patient**), the total price FOB is multiplied with factor 2,5.

The multiplication with factor 2,5 covers services provided by different stakeholders:

- services provided by the local distributor: housing, personnel, taxes, education of health care providers, logistics, taking care of special needs for the Belgian market, service to patients,...;
- services provided by the bandager or wholesaler and pharmacy: personnel, shop, transport, warehousing, service to patients,...

The estimate is based on interviews we had with manufacturers/local distributors:

- several distributors gave indications that if the market price was referenced to 100, their average sales prices was approximately 60 and the average purchase price from the manufacturing site was 40. The range from 40 to 100 is equivalent to the factor 2,5. It also means that the FOB production price of ostomy material represents approximately 65% of turnover of the local distributor.

The estimation was also cross-checked with the data found in the income statements of the Belgian distributors of a number of the manufacturers:

- the average cost of raw materials, services and other goods amount from 75 to 80% of turnover. The 65% mentioned in the previous point seems consistent with these percentages, as some local purchase costs for materials and services should be added to the costs of raw materials mentioned in income statements for domestic distributors.
- UNAMEC, the interest group of the producers, declares that the proposed factor 2,5 used to translate the price FOB to a patient price seems insufficient to them⁷. However, during a meeting was said that this 2,5 factor would be enough if delivery is optimised.

3.3.4. Conclusion

Calculation of total price

Applying the 2,5 factor, the calculated price the patient will eventually pay for the product on the counter (**price local patient**) is:

- 2,96€ for one-piece pouches

⁷ In a registered letter, dated 16-8-2005, UNAMEC considers that the 2,5 factor is too low to cover all types of appliances and types of patients, educational needs, personnel qualifications, special taxes, packaging costs, margins for bandagers and transport costs.

- 1,62€ for two-piece pouches
- 2,06€ for two-piece flanges

In the model it is not specified who delivers the medical services. This point of discussion, however, is broached in the final chapter of the report.

Comparison with reimbursement tariff

In table 3 a comparison is made between the calculated price for the local patient as obtained from the cost model, and the reimbursement tariff RIZIV-INAMI from January 2005.

Table 3: Comparison between cost model and Belgian reimbursement tariff (26)

Calculated price		Reimbursement tariff RIZIV -INAMI	
one-piece pouch	2,96 €	one-piece colostomy pouch	2,62 €
		one-piece ileostomy pouch	3,57 €
two-piece pouch	1,62 €	two-piece colostomy pouch	1,57 €
		two-piece ileostomy pouch	1,54 €
two-piece plate	2,06 €	regular plate	6,05 €
		convex plate	8,11 €

For the **one-piece pouch** the cost model is especially focused on the colostomy pouches. For this kind of pouch the reimbursement tariff is close to the calculated price. The reimbursement tariff for the one-piece ileostomy pouch is almost one euro more. This price difference can be explained firstly by an extra clamp or Velcro closure used and secondly by a slightly more expensive type of filter. The difference in the reimbursement tariff between colostomy pouches and ileostomy pouches seems therefore acceptable.

For the **two-piece pouches** we also notice a similarity between calculated price and the reimbursement tariff.

For the regular **two-piece flanges** we are confronted with a remarkable difference between calculated price and reimbursement tariff. Based on the existing information it is not possible to bridge the gap of 4€.

Moreover, the international price comparison in the next chapter shows that this kind of flanges can be found cheaper in Denmark, France and the United Kingdom. The French reimbursement tariff, indicating the maximum price, for these regular flanges is only 3,67€.

The specificities of convex flanges were not taken into account in the model

Key message

- Based on the estimated total price FOB (cost model) and the 2,5 factor, representing services from local distributors and bandagers / wholesaler-pharmacy, the estimated prices to local patients (calculated prices) are:
 2,96 € for a one-piece pouch,
 3,68 € for a two-piece system (plate and pouch).

4. CHAPTER IV INTERNATIONAL PRICE COMPARISON

4.1. INTRODUCTION

To have a better view on the cost for patients and health insurers of ostomy appliances on the Belgian market, an international price comparison in five different European countries was performed. Price data for Belgium are taken as a baseline and compared to corresponding data for Denmark, France, the Netherlands and the United Kingdom. These countries were chosen for their geographic proximity (rendering the hypothesis of comparable purchase prices for domestic importers more realistic) and the institutional characteristics of the regulatory framework for ostomy appliances in those countries. Consequently, these countries will also be discussed in the following chapter on institutional traits for varying countries.

For every country the methodology describes the data used and how they should be interpreted. Where possible, reference is made to relevant chapters (e.g. on institutional analysis), to explain the choice of the data. The international price comparison as presented here is related to the Belgian market. Foreign prices are therefore always compared with Belgian prices for similar products. Accordingly, the price information for Belgium is presented as such. For every other country both a general comparison and a comparison based on a certain type of patient is made.

4.2. GENERAL METHODOLOGY

4.2.1. Involvement of manufacturers / local distributors

Manufacturers Product information

Manufacturers were contacted through their domestic branches and requested to provide information regarding the international comparability of their various products. No replies were received by researchers.

Feedback on the cost model and international price comparison

The manufacturers and/or local distributors had the opportunity to give remarks on the international price comparison before, during and after a feedback session with UNAMEC members on September 16th 2005. One manufacturer reacted, claiming that higher retail mark-ups in the UK and higher discounts for Dutch health insurers should be allowed for in the price comparison. So far, desk research and contacts with foreign experts did not confirm this claim.

4.2.2. Desk research

Information on prices

Sources on exact price levels are clearly identified for varying countries. Limitations and interpretability of price data are elucidated. Precise prices are shown in the overview tables in the annex to chapter IV.

Selected products

The (specific) products selected for price comparison are clearly identified for varying countries. Underlying hypotheses are specified. Product labels are shown in the overview tables in annex to chapter IV.

Price comparisons for products

Prices for selected foreign products were compared with corresponding Belgian ones in the following way:

$$C_{1,FG} = \frac{\text{price}_{BE} - \text{price}_{FG}}{\text{price}_{BE}}$$

where

price_{BE} = price of the product in Belgium

price_{FG} = foreign price of the product

Hence, if the resulting figure is positive, the product is more expensive in Belgium and cheaper abroad. By contrast, if the resulting figure is negative, the product is cheaper in Belgium and more expensive on the foreign market. The amount indicates how much the price abroad is different compared to the Belgian price, as a percentage.

Secondly, the difference in overall price levels between the countries was eliminated in the comparison calculation in order to allow for differences in general purchasing power between countries. Comparative price levels (CPL) published by the OECD for June 2005 were used for these calculations (27). These comparative price levels are defined as the ratios of purchasing power parities to exchange rates.

$$C_{2,FG} = \frac{\text{price}_{BE} - \text{price}_{FG} \cdot \frac{CPL_{BE}}{CPL_{FG}}}{\text{price}_{BE}}$$

where

price_{BE} = price of the product in Belgium

price_{FG} = foreign price of the product

CPL_{BE} = comparative price level for Belgium (=100, Belgium as basis)

CPL_{FG} = foreign comparative price level

Calculated price differentials C₁ and C₂ are shown as percentages, rounded down to integer values, for the different countries compared to Belgium and can be found in the overview tables in the annex for chapter IV.

Price comparisons for patient profiles

The average yearly cost in euro (covering reimbursed costs and possible patient copayments), based on a non-weighted average of the selected products and the Belgian fixed allowances as an average indicator for the quantities purchased, is compared for the following patients:

- A colostomy patient using the one-piece system (Colo 1 p)
- An ileostomy patient using the one-piece system (Ileo 1 p)
- A colostomy patient using the two-piece system (Colo 2p)
- An ileostomy patient using the two-piece system (Ileo 2p)
- A ureterostomy patient using the two-piece system (Uro 2p)

This way the overall cost, combining flange and pouch for two piece systems and making allowances for set posology, can be assessed on an annual basis. To give a correct idea of the real cost for foreign patients, prices were corrected for general purchasing power to reflect the actual price level.

Key messages

- The product scope set in Chapter I is taken as a baseline for price comparisons.
- Sources and hypotheses for price comparisons are clearly elucidated throughout this chapter.

4.3. BILATERAL COMPARISONS

4.3.1. Belgium: baseline for comparisons

Obtained price information

As mentioned in the chapter on institutional analysis, the article 27 § 10 of the health care nomenclature stipulates that all products for ostomy care, for which an insurance intervention is foreseen, should be placed on a limitative list approved by the Assurance Committee. This limitative list is issued twice a year by the National Institute for Sickness and Invalidity Insurance (RIZIV-INAMI) and includes tariffs for ostomy products. For this study the list applicable from 1st January 2005 was used. We indicate two prices:

- The supplier price⁸: price at which on average the supplying bandager is supposed to buy the product
- The patient price: i.e. the indicated supplier price multiplied with factor 1,64 (Walkiers-coefficient). This is the price at which the patient is supposed to buy the product from the bandager.

We have to note that these prices should be considered with care. Different information sources, including patient prices in a manufacturer's product list, indicate that the real price for the patient is in some cases lower than the here presented patient price. Nevertheless, these are the official market prices as reported by the manufacturers to RIZIV-INAMI.

Reimbursement by RIZIV-INAMI is based on the nomenclature categories of ostomy products. For every category there is a certain reimbursement tariff. Some products (with reimbursement status "A") are sold at this tariff and therefore have full reimbursement by the third-party payer. When buying products with reimbursement status "B" or "C" (i.e. more expensive products), the patient should pay a surplus to the provider of respectively maximum and more than 25%. However, some cases in which the patient is not asked to pay the supplement above the reimbursed price were reported for these last products.

Products chosen for comparison

The products chosen in the Belgian list would be the basis for further comparison. Within the product scope, as defined in (the annex to) chapter I, a representative product was chosen for every manufacturer.

For Biotrol Braun, ConvaTec and Coloplast, the choice of this product is based on their respective sales figures, selecting the most bought products on the Belgian market. Also for Hollister a specific product choice was made.

⁸ Supplier price: in Dutch 'prijzen verstreker'; in French: 'prix prestataire'

Nevertheless, we will just indicate the price levels for Eurotec and Welland. These last two manufacturers provide “A” products’ on the Belgian market, meaning they are integrally reimbursed. That is why we just indicate this reimbursement tariff without specifying the product name itself.

The price list for selected products in Belgium, used as reference for the other countries, is found in table I (annex to chapter IV).

Key message

- **Prices for the product set are taken from RIZIV-INAMI data and should be interpreted with due care.**

4.3.2. Denmark

Obtained price information

According to the Danish Social Services Act, providing ostomy products is the responsibility of the municipalities⁹. In practice most municipalities have an agreement with one or more suppliers for delivering the products to the patients. Normally, the users do not have to pay and the local authority completely finances.

Ostomy products are part of the assistive devices category ‘particularly personal devices’. For these devices the applicant can if he/she wishes choose another supplier than the one chosen by the municipality and can have all expenses reimbursed up to the price the municipality would have paid to their supplier. If there is no agreement between a supplier and the authority, the applicant can choose freely. Accordingly, there is no general price or reimbursement list for ostomy products. By contrast the framework contracts between municipalities and suppliers are defining the price level.

Since there are no figures that generally indicate the price level of certain ostomy products in Denmark, another method had to be used to give an idea on the Danish price level. For this purpose, a major supplier, Kirudan A/S, who is involved in framework contracts with several municipalities, was selected. This firm is one of Denmark’s leading companies in health care products and provides them in the whole country. Clients are not only hospitals and health care professionals, but also individual patients through the agreements they have with the municipalities. Prices are found at the company’s website. Kirudan presents both prices in EUR and in DKK, for orders of one box or at least 3 boxes. Supposing that patients who are faithful to a particular product will probably purchase several boxes at once and additionally that the municipalities will not pay a higher price, the price in EUR for purchase orders of at least 3 boxes was used to calculate the unit price of products.

Products chosen for comparison

Products from the following four manufacturers were chosen for comparison: BBraun, Coloplast, ConvaTec and Hollister. The brands Eurotec and Welland were not found in the catalogue. Two of the convex flanges were not taken into consideration because they were either not found or a combination of a flange and a convex ring was used instead. According to the consulted ostomy experts, this combination is not used anymore in Belgium.

In a first step the objective was to match the products on the Belgian reference list with a corresponding product in Denmark. This correspondence check has been product name-based, hence assuming that products with the same name in both countries are the same product. For many of the products a match was found between product names.

⁹ Denmark is divided into (13 counties and) 271 municipalities (28).

In a second step, for products that had no initial match, it was analysed if there was another candidate product on the Belgian limitative list from RIZIV-INAMI that matched a product in the Danish catalogue. For manufacturers that shared information on the market shares of their products, the occurrence of the products was taken into account, leading to the most sold products to be selected. Also here the correspondence check was product name based, assuming that products with the same name in both countries are the same product.

In a third step, were no name-based match between Danish products and the Belgian limitative list was found, another product from the same type was selected in Denmark and the product from the Belgian limitative list was used.

In table 2 of the annex to chapter IV, an overview of these products is presented. In the first and second column the Belgian representative products for which a match was found in Denmark are listed (first step). In the second and third column a Danish selection is listed for which identical Belgian products were found (step 2). The second and fourth column shows results for products for which we suppose they are similar (third step).

For all products prices in the respective countries are indicated. For the Belgian products a comparison with the Danish prices was added. This percentage indicates how much the product is cheaper (negative number) or more expensive (positive number) in Belgium compared to Denmark. Considering the match of the products, the price comparison between products that are the same has a higher confidence than the price comparison of similar products.

Given the big difference in VAT rate for ostomy products sold in Belgium (6%) and Denmark (25%), the comparison was both made inclusive and exclusive of VAT.

Comparison of product prices

In absolute terms, prices for ostomy products are generally higher in Denmark, compared to Belgium. One of the explanatory factors is a substantial difference in taxes applied. Whereas Belgium has a 6 % value added tax rate on ostomy products, this is 25% in Denmark. In this study prices including value added tax are compared.

In the resulting table both the basic comparison (C_1) using the Danish and Belgian prices as such and the more elaborate comparison (C_2), eliminating the difference in price level between both countries, are shown. For further analysis here only the latter one is used.

One-piece systems are generally more expensive in Denmark compared to Belgium:

- 6 out of 8 products (75%) are more expensive in Denmark, ranging from -35% to -13%;
- 2 out of 8 products (25%) are less expensive in Denmark, ranging from 14% to 26%.

For two-piece pouches there are both more and less expensive products in Denmark compared to Belgium:

- 8 out of 12 products (67%) are more expensive in Denmark, ranging from -60% to -7%;
- 4 out of 12 products (33%) are less expensive in Denmark, ranging from 1% to 34%.

Although most normal two-piece flanges have a higher price in Denmark, this price difference is mainly explained by the difference in price levels between both countries. Hence more elaborate comparison shows that most of the two-piece flanges are less expensive in Denmark compared to Belgium.

- 1 out of 4 products (25%) are more expensive in Denmark: -4%;
- 3 out of 4 products (75%) are less expensive in Denmark, ranging from 9% to 33%.

Two-piece convex flanges are more expensive in Denmark compared to Belgium

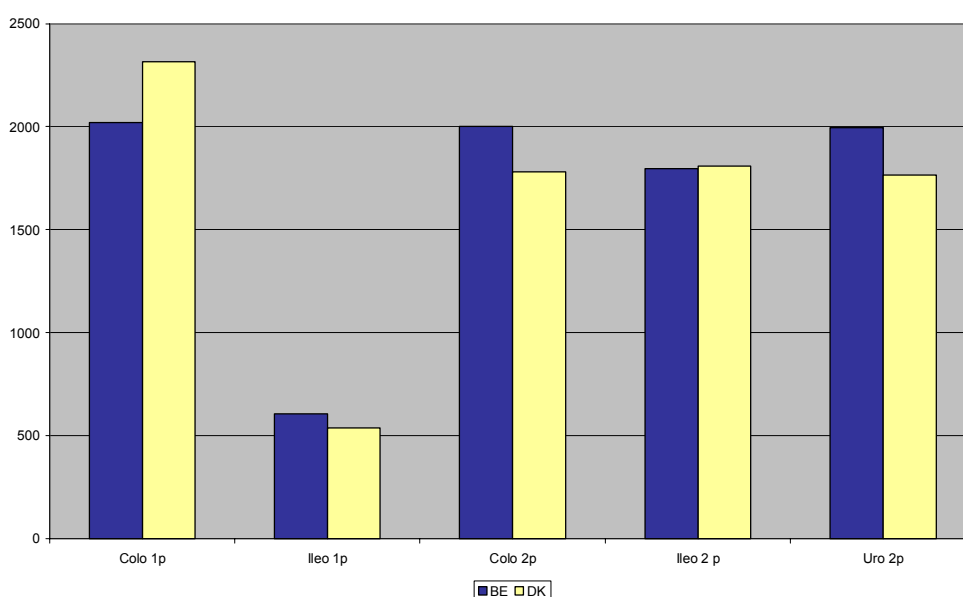
- 3 out of 3 products (100%) are more expensive in Denmark, ranging from -60% to -42%;

When having a look at the different brands it can be concluded that the compared products for B Braun are all cheaper in Denmark and that the compared products for Hollister are all more expensive in Denmark (except for one product which is only slightly cheaper).

Comparison of patient profiles

Allowing for differences in general purchasing power between Danish and Belgian patients clearly eliminates a considerable part of the higher item price found for products sold in Denmark. Purchasing the reimbursed quantity of comparable product items Belgian patients are entitled to is more expensive on annual basis for Belgian patients using two piece appliances for colostomies and ureterostomies and one piece ileostomy appliances.

Figure I Patient profiles Denmark - Belgium



Key messages

- **General analysis of the different price level between Denmark and Belgium:**
 - One-piece systems are generally more expensive in Denmark
 - For two-piece pouches there are both more and less expensive products in Denmark.
 - Most of the two-piece flanges are less expensive in Denmark.
 - Two-piece convex flanges are more expensive in Denmark.
- **Patient profiles:**
 - The real cost is higher in Belgium for ileostomy one-piece, colostomy two-pieces and ureterostomy two-piece systems, comparable for ileostomy two-piece systems and lower for colostomy one piece-systems, compared with Denmark.

4.3.3. France

Obtained price information

For an official price list of ostomy appliances in France, the Ministry of Health refers to the LPP (liste des produits et prestations remboursables). The LPP is a list of reimbursable products, together with their reimbursement conditions and tariffs. This list is publicly available at the web site of the French Medical Insurance (Assurance maladie on www.ameli.fr). For this study the 9th May 2005 version was used. Information leaflets from a local distributor indicated that they are using these prices as advised maximal public price, resulting in a total reimbursement for the patients involved.

Products chosen for comparison

In this official LPP list no reference to brands or product names is made, yet there are several different nomenclature categories describing the product in general. An example of this product description for a certain type of one-piece colostomy pouches looks as follows: 'Digestive, collector of faeces, pouch with adhesive flange and filter. Pouch with integrated adhesive flange that assures the attachment, with integrated filter, not drainable'. Each nomenclature has a corresponding nomenclature number and tariff (including VAT). The nomenclature category depends on the quantity of the product that is sold in a box whilst the reimbursed price of a single piece is independent of the quantity purchased.

Accordingly no distinction was made between the different manufacturers or products when defining the French equivalent for product prices in Belgium. To define the right nomenclature categories needed, the correspondence was checked with a price list of one of the manufacturers. The price list for the French product categories is found in table 3 of the annex to chapter IV.

Comparison of product prices

For France only the reimbursement tariff is compared with the Belgian reimbursement tariff for the same product. In the resulting table both the basic comparison (C_1) using the French and Belgian reimbursement tariffs as such and the more elaborate comparison (C_2), eliminating the difference in price level between both countries, are

shown. For further analysis here only the latter one is used. While in France this reimbursement tariff is considered as a maximum price, Belgian patients pay surplus out-of-pocket payments for certain products. Therefore, actual price differences between France and Belgium can even be bigger than presented here.

One-piece systems are cheaper in neighbouring country France compared with Belgium:

- 7% for colostomy products;
- 8% for ileostomy products.

For two-piece pouches there is some differentiation between the different types:

- colostomy pouches are cheaper in France: 6%;
- ileostomy pouches are more expensive in France: -51%;
- ureterostomy pouches are more expensive in France: -19%.

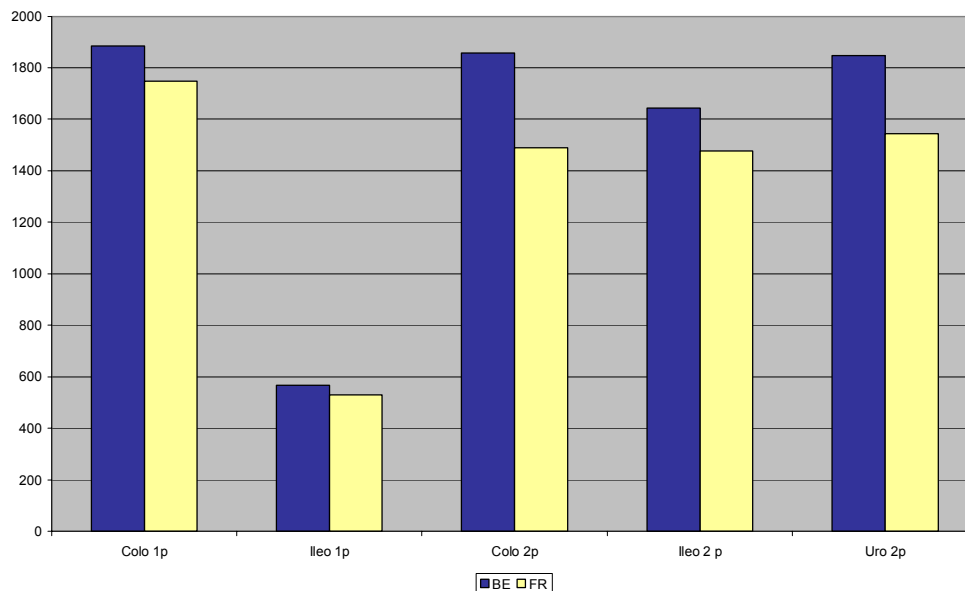
Flanges are cheaper in France:

- 41% for regular flanges;
- 38% for convex flanges.

Comparison of patient profiles

Patient profiles indicate that Belgian patients, regardless of the type of ostomy they have, pay more on an annual basis than their French counterparts would for comparable product sets.

Figure 2 Patient profiles France - Belgium



Key messages

- **General analysis of differences in price level between France and Belgium:**
French reimbursement (also seen as maximum tariff) is lower for the one-piece systems, colostomy two-piece pouches and regular and convex flanges than the Belgian reimbursement (a de facto price minimum).
- **Patient profiles: real cost in France is lower for all patient profiles.**

4.3.4. The Netherlands

Obtained price information

The quest for obtaining price information for ostomy appliances in the Netherlands started out with considerable difficulties as the medical equipment shop realizing the largest market share refused to provide researchers with price information and data on average patient material needs. After contacting the Dutch Ministry of Health, Welfare and Sports, the organisation “Z-index” resulted to be the most reliable provider of price information.

Z-index lists the public price of ostomy products in the ‘G-Standaard’. Originally starting from a medicine database, the G-Standaard now also covers medical devices, self care products and homeopathic products. This database is used by pharmacists, general practitioners and care insurers and Z-index is therefore well placed to give price information for the Netherlands.

For comparison with other countries, it has to be noticed that the reimbursement level of ostomy appliances, i.e. the price paid by the insurers to the pharmacy or medical equipment shop, is generally set at 85% of the public price listed by Z-index (see Chapter V – Institutional analysis).

Products chosen for comparison

The Netherlands is the only country where products from all manufacturers included in this study are found. Therefore, products similar to the Belgian selection were chosen from these six companies. Only for Welland the two piece uropouch and convex flange could not be easily identified from the products lists and are therefore not mentioned. The price list for selected products in the Netherlands is included in table 4 of the annex to this chapter.

Comparison of product prices

Comparing the Dutch prices on a product base with the Belgian listed prices, we can see that the Dutch patient prices appear to be consistently above the Belgian ones.

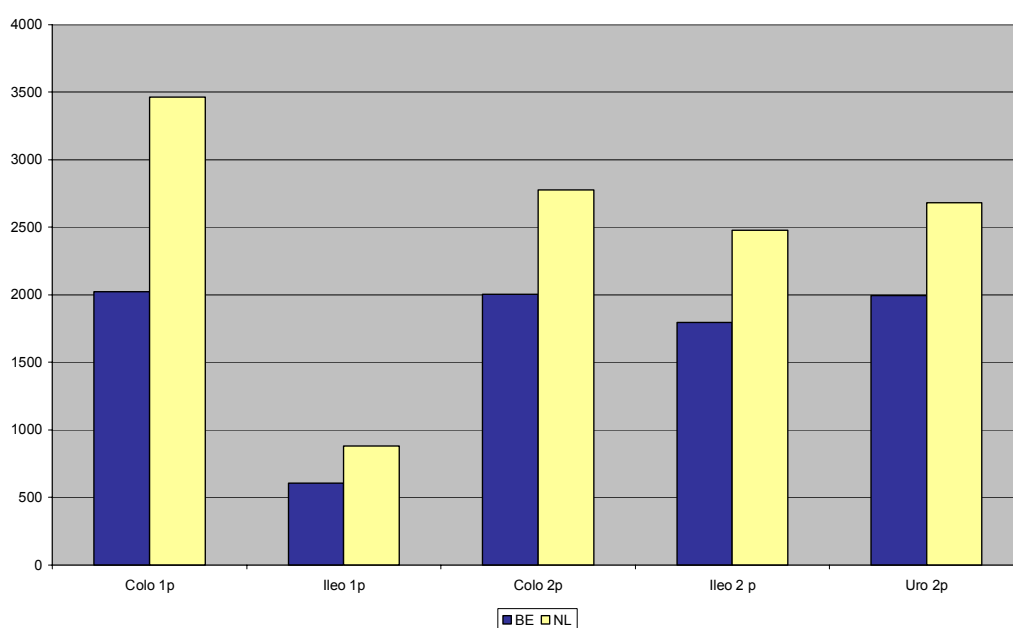
- One-piece colostomy pouches, ranging from -45% to -97%;
- One-piece ileostomy pouches, ranging from -30% to -112%;
- Two-piece colostomy pouches, ranging from -25% to -57%;
- Two-piece ileostomy pouches, ranging from -19% to -90%;
- Two-piece ureterostomy pouches, ranging from -29% to -60%;
- Two-piece regular flanges, ranging from -20% to -43%;
- Two-piece convex flanges pouches, ranging from -60% to -79%.

We should however note that the Dutch insurers on average only pay about 85% of the official patient price.

Comparison of patient profiles

The analysis of patient profiles shows that Belgian patients, regardless of the type of ostomy they have, pay less on an annual basis than their Dutch counterparts would for comparable product sets.

Figure 3 Patient profiles the Netherlands - Belgium



Key messages

- **General analysis of differences in price level between the Netherlands and Belgium:**
All product categories are more expensive in the Netherlands based on the Z index.
- **Patient profiles:**
as a consequence calculated real cost is higher in the Netherlands for all patient profiles.

4.3.5. United Kingdom

Obtained price information

One of the functions of the Prescription Pricing Authority (PPA) within the National Health Service (NHS) is to produce the Drug Tariff containing the reimbursement prices of a range of prescribed items and remuneration rules. This Drug Tariff is electronically available and provides access to the current edition of the National Health Service Drug Tariff for England and Wales, compiled on behalf of the Department of Health by the Prescription Pricing Authority.

Part IXC of this Drug Tariff covers ostomy appliances. Products not included in the list do not qualify for prescription.

Products chosen for comparison

Products similar to the Belgian selection from the following manufacturers were chosen for comparison: BBraun, Coloplast, ConvaTec, Hollister and Welland. Eurotec products are not included in the Drug Tariff. The price list for selected products in England is found in table 5 of the annex to this chapter.

Comparison of product prices

For most of the products, prices in England are rather comparable. Some types are a little cheaper than the Belgian ones, where others are more expensive. For the flanges, however there is a remarkable difference: Belgium turns out to be much more expensive.

In the resulting table both the basic comparison (C_1) using the Belgian and UK prices as such and the more elaborate comparison (C_2), eliminating the difference in price level between both countries, are shown. For further analysis here only the latter one is used.

For one-piece systems there is a remarkable difference between colostomy and ostomy pouches. All selected colostomy pouches are more expensive in the United Kingdom, whereas almost all ileostomy pouches are cheaper in the United Kingdom:

- 5 out of 5 one-piece colostomy pouches (100%) are more expensive in the United Kingdom, ranging from -30% to -17%;
- 4 out of 5 one-piece ileostomy pouches (80%) are cheaper in the United Kingdom, ranging from 1% to 19%.
- 1 out of 5 one-piece ileostomy pouches (20%) is more expensive in the United Kingdom, -11%.

For two-piece pouches most products are more expensive in the United Kingdom compared to Belgium:

- 11 out of 15 products (73%) are more expensive in the United Kingdom, ranging from -15% to -2%;
- 4 out of 15 products (27%) are cheaper in the United Kingdom, ranging from 1% to 46%.

Almost all normal convex flanges are cheaper in the United Kingdom:

- 1 out of 4 products (25%) is more expensive in the United Kingdom: -4%;
- 3 out of 4 products (75%) are cheaper in the United Kingdom, ranging from 33% to 38%.

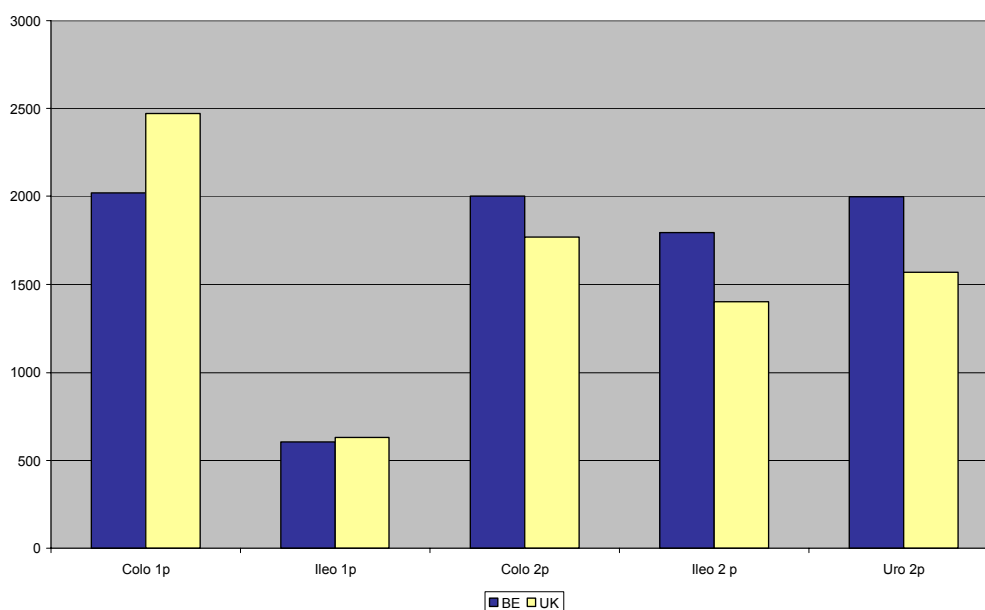
Two-piece convex flanges are all cheaper in the United Kingdom compared to Belgium:

- 4 out of 4 products (100%) are cheaper in the United Kingdom, ranging from 49% to 52%;

Comparison of patient profiles

The analysis of relevant patient profiles indicates that Belgian patients using one piece appliances pay less on an annual basis than their English counterparts. The real annual cost for patients using two piece appliances, however, is higher for Belgian patients.

Figure 4 Patient profiles United Kingdom - Belgium



Key messages

- **General analysis of differences in price level between the United Kingdom and Belgium:**
 - One-piece colostomy pouches are more expensive in the UK.
 - One-piece ileostomy pouches are generally cheaper in the UK.
 - For two-piece pouches most products are more expensive in the UK.
 - Most of the regular two-piece flanges are cheaper in the UK .
 - All selected two-piece convex flanges were cheaper in the UK.
- **Patient profiles:**
 - The real cost is substantially lower in Belgium for colostomy one-piece systems and just a little lower for ureterostomy one-piece systems. The real cost for all two-piece combinations is higher in Belgium.

4.4. MULTILATERAL COMPARISONS

In the previous sections the Belgian price was compared bilaterally to the other countries. To draw overall conclusions on this price setting, we present the obtained prices here per product type. The specific RIZIV-INAMI reimbursement tariff is included in all price charts. For colostomy pouches and two piece flanges the calculated price (see previous chapter) is added to the price charts.

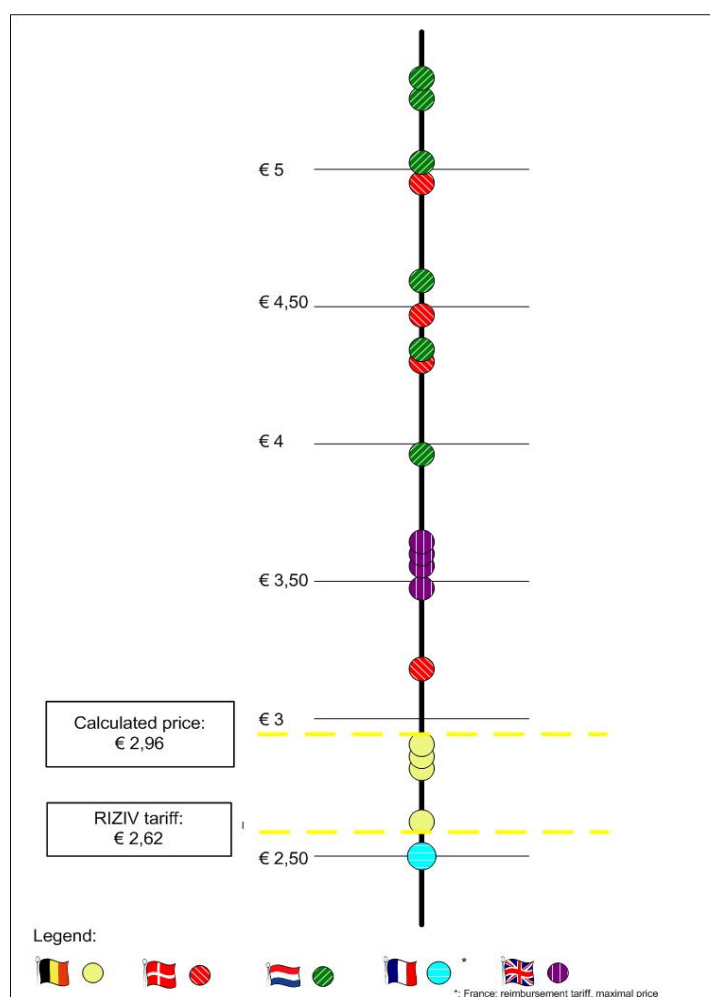
In the following figures the price of the selected products in the different countries is presented. For Belgium the initial selection is used.

4.4.1. One-piece colostomy pouches

For one-piece colostomy pouches the calculated price is 2,96€, while the RIZIV-INAMI reimbursement tariff is 2,62€.

The price of the selected Belgian products is in between this tariff and the calculated price and seems therefore reasonable. In other countries prices are higher for this kind of products. However, the French reimbursement tariff is lower.

Figure 5 Price chart one-piece colostomy pouches



Key message

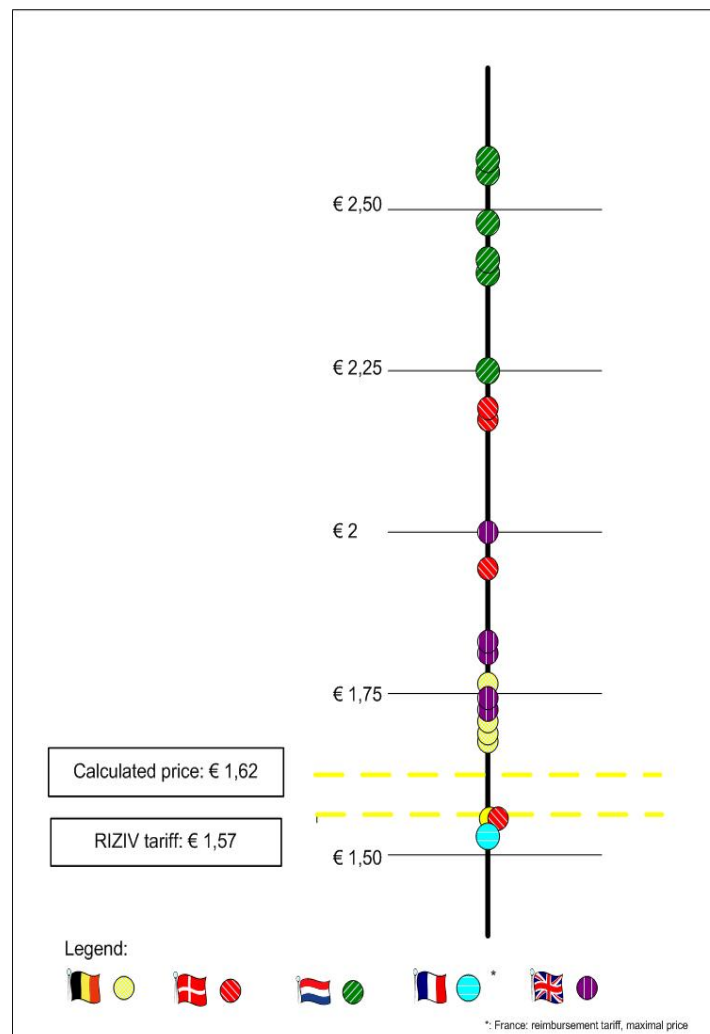
- Belgian prices for one-piece colostomy pouches concur with research estimates and are among the cheapest of the compared product sets.

4.4.2. Two-piece colostomy pouches

For two-piece colostomy pouches the calculated price is 1,62€, while the RIZIV-INAMI reimbursement tariff is 1,57€. The calculated price is therefore slightly higher than the RIZIV-INAMI reimbursement tariff.

The price of the selected Belgian products is just above the calculated price for most products, with A-category products as an exception. In most other countries the price is higher. The French reimbursement tariff is lower and one of the selected products in Denmark is also cheaper.

Figure 6: Price chart two-piece colostomy pouches



Key message

- **Belgian prices for two-piece colostomy pouches are slightly above research estimates and are among the cheapest of the compared product sets.**

4.4.3. One-piece ileostomy pouches

For one-piece ileostomy pouches the RIZIV-INAMI reimbursement tariff is set at 3,57€. Products sold in Belgium are cheap compared to other European countries, with the notable exception of France. Moreover, the figure illustrates a wider price range was found for this particular product category.

Figure 7: Price chart one-piece ileostomy pouches



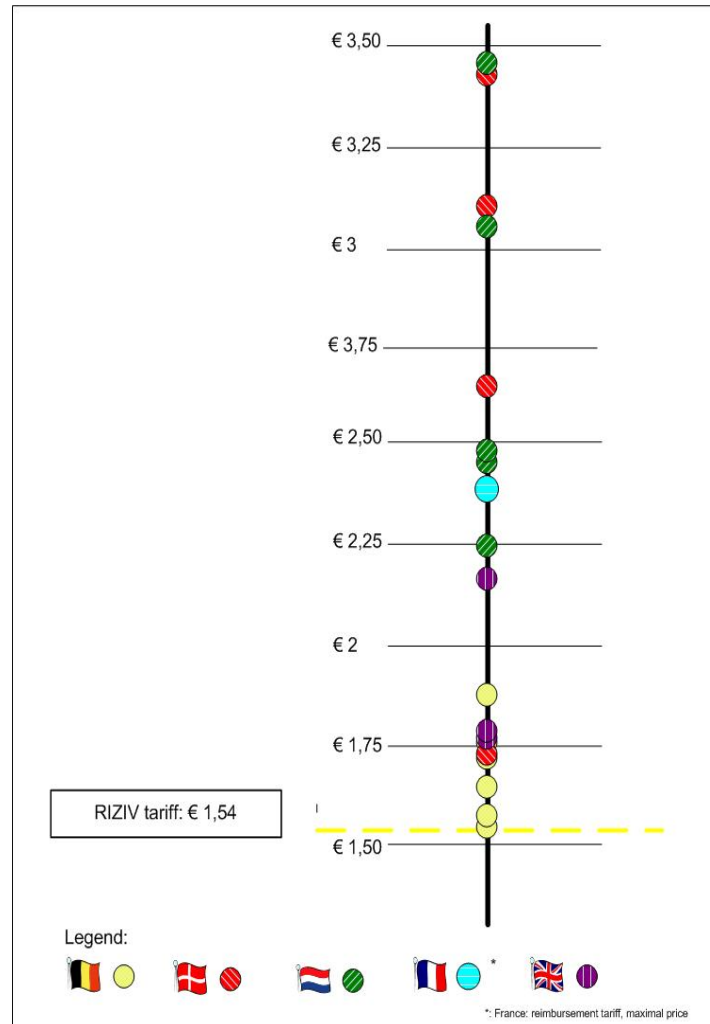
Key message

- Belgian prices for one-piece ileostomy pouches are comparable to English ones, more expensive than French products and generally cheaper than Dutch and Danish products.

4.4.4. Two-piece ileostomy pouches

For two-piece ileostomy pouches the RIZIV-INAMI reimbursement tariff is set at 1,54€. Products sold in Belgium are cheap compared to other European countries.

Figure 8: Price chart two-piece ileostomy pouches



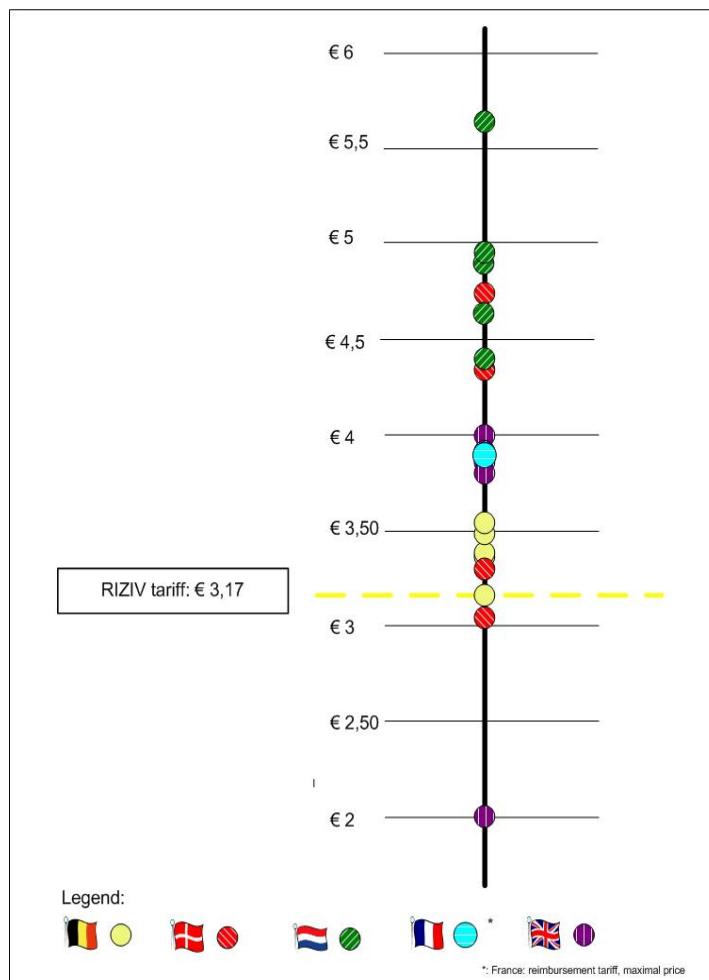
Key message

- **Belgian prices for two-piece ileostomy pouches are among the cheapest of the compared product sets.**

4.4.5. Two-piece ureterostomy pouches

For two-piece ureterostomy pouches the RIZIV-INAMI reimbursement tariff is set at 3,17€. Products sold in Belgium are cheap compared to other European countries, with two Danish and 1 English product sold at a lower or comparable price.

Figure 9: Price chart two-piece ureterostomy pouches



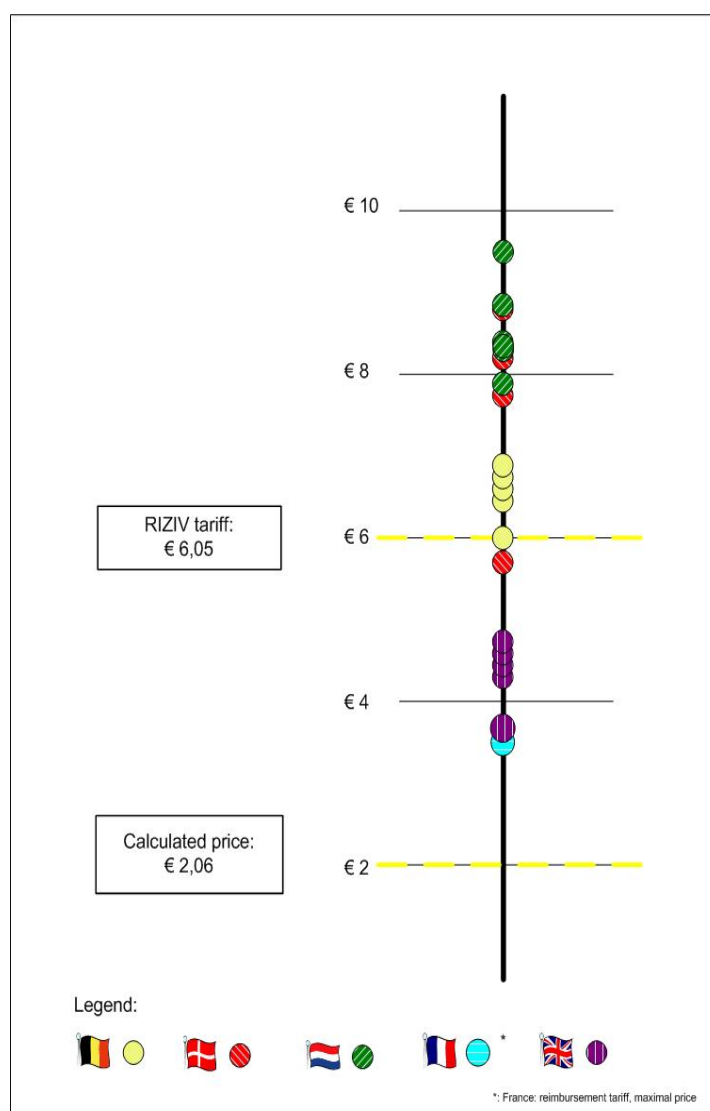
Key message

- Belgian prices for two-piece ureterostomy pouches are among the cheapest of the compared product sets.

4.4.6. Two-piece flanges

For two-piece regular flanges the calculated price is 2,06€, while the RIZIV-INAMI reimbursement tariff is 6,05€. This means there is an important gap between both. It is not clear how to explain this price difference. Of course the calculated price is an approximation of the real cost price. The gap between the RIZIV-INAMI reimbursement tariff in Belgium and the reimbursement tariff in the United Kingdom and France is smaller, but stays unexplained as these products can not be sold with loss. This observation is corroborated by the wide price range found for this product category (with product prices clustering per country), raising questions regarding the factors determining price levels for these various countries.

Figure 10: Price chart two-piece flanges



Key messages

- Belgian prices for two-piece flanges are well above research estimates.
- Belgian prices for two-piece flanges are well above English and French prices.
- A large overall price range is observed for this product category.

4.5. GENERAL CONCLUSIONS

Researchers emphasize that all made price comparisons should be interpreted with due methodological reservation. Sources and underlying hypotheses in connections to the price comparisons have been elucidated and highlighted throughout this chapter.

4.5.1. Bilateral product comparisons

When making bilateral comparisons between Belgian and foreign products at first (according to C1 values) Belgian patients appear to enjoy low prices: 71 out of 93 overall product comparisons would indicate the compared product is cheaper in Belgium.

This conclusion needs to be reconsidered, however. After correcting for general purchasing power (C2 values) this ratio drops down to 59 out of 93 product comparisons, especially for Denmark (ratio dropping from 22 to 14 out of 29 comparisons) and the UK (ratio dropping from 17 to 13 out of 29 made comparisons).

Moreover, when comparing annual real cost for patients purchasing a product set corresponding to the reimbursed quantity Belgian patients are entitled to, it becomes clear that, partially due to relatively expensive two-piece flanges, Belgian patients seem to be facing average overall costs when compared to neighbouring countries:

- they enjoy an overall lower real cost than their Dutch counterparts;
- they face an overall higher real cost than their French counterparts;
- they face higher or lower real costs according to their profile when compared to their English and Danish counterparts with patients using 2-piece appliances on the whole facing higher costs in Belgium.

4.5.2. Multilateral product comparisons

The multilateral price charts refine the bilateral analysis by visualising overall price range and highlighting the RIZIV-INAMI and calculated price within the framework of the overall price comparison:

- wide overall price ranges were observed for one-piece ileostomy pouches and two piece flanges;
- the calculated prices (see previous chapter) are at a par with observed Belgian market prices for colostomy pouches;
- a wide gap between the calculated price for two-piece flanges and market prices is observed.

The hypothesis formulated in chapter III that market prices are mainly determined by domestic distribution chains seems to be confirmed by the price analysis. The 2,5 factor, applied for the calculated price would even appear to underestimate most of the observed market prices. The following chapter will deal with domestic regulatory frameworks. The countries analysed in the following chapter will include the countries analysed in chapter IV.

Key messages

- **Belgian patients appear to be facing average overall real costs when compared to patients in neighbouring countries.**
- **The observed market prices seem to confirm the considerable impact domestic distribution chains have on final retail prices.**

5. CHAPTER V INSTITUTIONAL ANALYSIS: AN INTERNATIONAL PERSPECTIVE

5.1. INTRODUCTION

The comparison made in the preceding chapter between estimated costs for importers and final market prices, “patient prices”, demonstrates the impact domestic factors have on market prices. Consequently, a detailed analysis of regulatory traits of the market for ostomy appliances seems to be a logical next step in assessing the market for ostomy products for Belgian patients and health insurers.

This chapter describes the institutional setting of the ostomy appliance market in Belgium and in a number of European countries (Denmark, France, the Netherlands and England (the United Kingdom)). These countries were selected for their geographic proximity to Belgium and because they provide insight into the variety of regulatory mechanisms that govern domestic ostomy appliance markets. Ontario (Canada) was added to the review as this province has adopted grant-based reimbursement of ostomy appliances, a system of reimbursement that has not been implemented in European countries to date.

5.2. METHODOLOGY

Ostomy appliance markets were investigated by examining the following institutional features: domestic legislation surrounding registration, pricing and reimbursement; delivery channels and distribution margins; and the prescribing process of ostomy appliances.

Three approaches were used to review the institutional setting of national ostomy appliance markets: a review of the international peer-reviewed literature, an analysis of legal texts, and a questionnaire completed by national experts.

A review of the international literature confirmed the lack of research on ostomy appliance markets. The review generated one study that compared ostomy appliance markets across five European countries (Cornago and Garattini, 2002). However, this article did not cover Belgium, the Netherlands and Canada, countries that have organised their domestic ostomy appliance markets in different ways. Moreover, recent reforms of the ostomy appliance market in, for instance, France were not incorporated. Finally, institutional features such as registration procedures, distribution margins and the distinction between pricing and reimbursement were not considered.

Information about institutional features was gained by accessing documents setting out national legislation and local publications. Additionally, a qualitative questionnaire was filled in by correspondents from governmental and regulatory agencies, major ostomy appliance manufacturers (Coloplast, Convatec, BBraun and Hollister-Dansac), patient organizations, health insurance funds and INAHTA (International Network of Agencies for Health Technology Assessment). Each country-specific section of the chapter was validated by a national expert. Contact details for these experts and further background references can be found in the annex to chapter V.

Key messages

- **The analysis of domestic regulatory factors will complete the assessment of the Belgian market for ostomy appliances.**
- **Scientific literature on the topic proved to be scarce and was completed by researchers through the perusal of legal text and the analysis of survey results.**

5.3. BELGIUM

5.3.1. Registration

Ostomy appliances are registered as medical devices in Belgium and are included in a "Limitative List of Ostomy and Incontinence Appliances". This limitative list is made up of a number of product classes that are defined according to the characteristics of the ostomy appliance: one/two-piece appliances with open/closed pouches. Within each product class, the various appliances of different manufacturers are listed. If a manufacturer wishes to register a ostomy appliance, the manufacturer submits an application for either inclusion of the appliance in an existing product class or creation of a new product class.

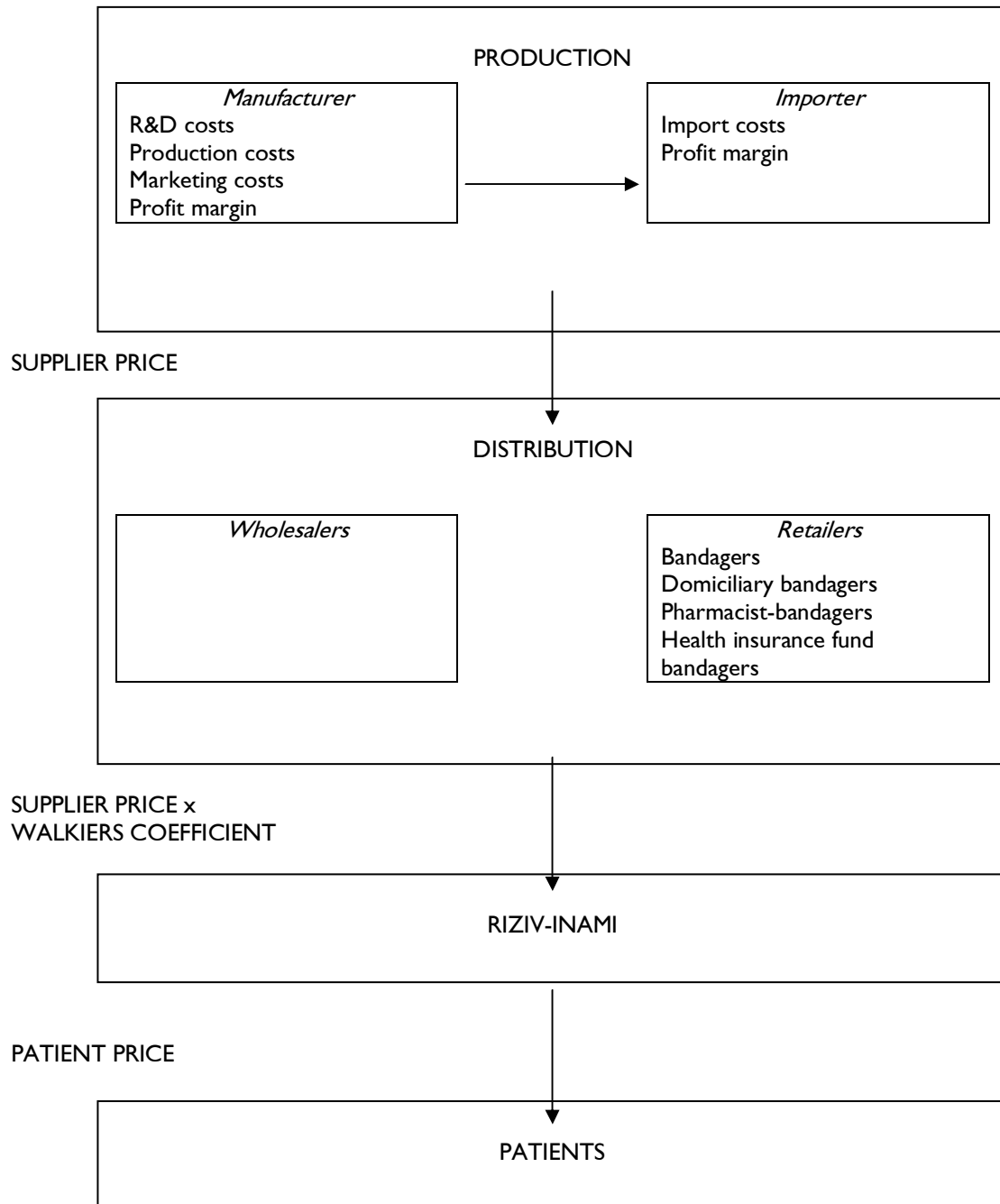
If the appliance falls within an existing product class, the manufacturer submits a dossier to the RIZIV-INAMI, the Secretariat of the study group "Bandagers" of the "Agreement Committee" of Bandagers and Health Insurance Funds, and the members of this study group. This dossier consists of a sample, description of appliance, proposed code of product class, appliance name, therapeutic indication, price to distributor and EU-conformity declaration. The dossier can be complemented by scientific evidence on the use of the appliance. If approved by the Committee, a notification letter is forwarded to the manufacturer and a circulatory letter is sent to (pharmacist-)bandagers and health insurance fund distributors (bandagers working at device shops affiliated to insurance funds). The list of reimbursable ostomy appliances is updated once a year and can be found on the website of RIZIV-INAMI.

If the manufacturer feels that the ostomy appliance does not fall within an existing product class, the manufacturer can apply for the creation of a new product class. A description of the new product class in terms of the estimated needs, nature of the appliance, price, reimbursement and number of appliances that are reimbursed within a specific time period, is proposed by the Committee of Bandagers and Health Insurance Funds. The proposal for a new product class is sent in the form of a draft Royal Decree to the Committee for Budgetary Control which examines the budgetary impact of adding a new product class for reimbursement. If the Committee for Budgetary Control gives a positive advice, then the Insurance Committee will decide whether or not to forward the draft Royal Decree to the Policy Cell of the Minister of Social Affairs and Health. Subsequently, the proposal needs to be approved by the Inspector of Finances, the Minister of Budgeting and the State Council prior to its publication as a Royal Decree in the Belgian State Monitor. (Pharmacist-)bandagers and health insurance fund distributors are notified of the new product class by means of a circulatory letter. If the Committee of Bandagers and Health Insurance Funds does not support the creation of a new product class, the manufacturer can ask for the ostomy appliance to be allocated to an existing product class. This will be accepted if the submitted dossier fulfils the criteria and the ostomy appliance conforms to the description of the product class.

5.3.2. Pricing

The public price of ostomy appliances is made up of a number of components (see Figure I).

Figure 1. Pricing of ostomy appliances



A number of major international manufacturers are supplying ostomy appliances to the Belgian market, the six most important of which are included in this study: Coloplast, ConvaTec, Biotrol Braun, Dansac-Hollister, Welland and Eurotec. The supplier price charged by manufacturers typically covers costs of research and development, production, marketing, import and a profit margin. This supplier price is a mean price taking into account that manufacturers are free to, for instance, give larger discounts to high-volume distributors and grant smaller discounts to low-volume distributors. In practice, mean prices to bandager are around 35-40% below catalogue prices. Ostomy appliances are distributed to patients by recognized bandagers through various delivery channels (cfr. infra). The distribution margin is determined by the so-called 'Walkiers coefficient', although this does not have a legal foundation. The Walkiers coefficient that is used by the Committee of Bandagers and Health Insurance Funds is currently set at 1.64. This factor covers a pay-off for general costs, wages and costs of materials. The supplier prices multiplied by 1.64 is used as the basis for reimbursing ostomy appliances by the RIZIV-INAMI. The public price of ostomy appliances tends to be equal to or higher than the reimbursement tariff.

On the 1st January of each year, manufacturers can augment prices if this is economically justified by, for example, rising production costs. Such price changes are likely to have implications for the reimbursement status of the ostomy appliance and the level of patient co-payments (cfr. infra).

5.3.3. Reimbursement

The reimbursement tariff of each ostomy product class is reported in the "limitative list of ostomy and incontinence appliances". The reimbursement tariff would be derived from the multiplication of the supplier prices by the Walkiers coefficient. Depending on the extent to which the ostomy appliance meets the medical indication, it is allocated to one of three reimbursement categories. If the appliance corresponds to an absolute medical indication, it is awarded reimbursement status "A", implying full reimbursement by the third-party payer. Each product class is expected to have at least two appliances with "A" status. If the appliance meets a relative medical indication – meaning that its features surpass those required by the medical indication – the third-party payer reimburses the same amount as if the appliance had "A" status and a supplement of up to 25% of the tariff of the product class can be charged to the patient (reimbursement status "B"). Reimbursement status "C" is offered to appliances whose features substantially exceed those of the medical indication. In this case, free pricing prevails, but reimbursement is limited to the amount paid as if the appliance had "A" status.

Nowadays, allocation to reimbursement category is no longer determined by medical indication, but depends on the difference between the patient price of the ostomy appliance and the reimbursement tariff. If the patient price is set equal to the reimbursement tariff of the product class, the appliance is granted reimbursement status "A". If the patient price surpasses the tariff of the product class by a maximum of 25%, the appliance receives reimbursement status "B". "C" status is awarded to appliances priced more than 25% above the tariff of the product class. Most products tend to have reimbursement status "B".

If this can be accomplished within prevailing budgetary constraints, the Committee of Bandagers and Health Insurance Funds can adjust the reimbursement tariff to take account of the evolution of the Health Index on the 1st January of each year. In addition to this, manufacturers, physicians, health insurance funds, distributors and patients can submit a dossier requesting a change in reimbursement tariff. This requires an adjustment of the relevant product class and has to go through the same approval procedure as for the creation of a new product class.

It should be noted that, for appliances with status "B" or "C", bandagers can but do not have to ask for a patient co-payment. If a distributor decides not to charge or partially

charge patients, this corresponds to the distributor receiving a lower margin. Moreover, manufacturers can offer discounts to distributors, thus increasing the margin of the distributor.

Limits have been set on the quantity of ostomy appliances that are reimbursed to a given patient during a specific time period in ambulatory care. Depending on the product class and the type of ostomy (colostomy, ileostomy or ureterostomy), up to 180 one-piece appliances per three months and up to 45 two-piece appliances (45 flanges and 180 pouches) per three months are reimbursed. If patients use more appliances, they incur the full costs of their additional consumption.

In the hospital setting, a system of fixed reimbursement¹⁰ is in operation. This means that the third-party payer reimburses the hospital for an amount of 3.27 € (for 2005) per day for those days on which at least one appliance has been used by the patient. Within this context, pricing of ostomy appliances by manufacturers is free. Patients do not have to make use of ostomy appliances provided by the hospital, but can continue to draw on their allowance of ostomy appliances in ambulatory care. Alternatively, if patients choose to use ostomy appliances provided by the hospital, the period of time that is used to calculate the allowance of reimbursed ostomy appliances in ambulatory care is extended by the length of stay in hospital.

5.3.4. Delivery channels

In order to be reimbursed by the third-party payer, ostomy appliances need to be delivered to ambulatory patients through one of the following channels: private medical device shops managed by bandagers, domiciliary bandagers, community pharmacies or medical device shops affiliated to health insurance funds. According to article 27, §16 of the Belgian reimbursement nomenclature only ostomy appliances delivered personally by a recognized bandager qualify for reimbursement to patients in ambulatory care. As a consequence, ostomy appliances acquired by patients on the internet do not qualify for reimbursement. Pharmacists distributing ostomy appliances are required to have an additional recognition as a bandager. Medical device shops affiliated to health insurance funds employ officially recognised (pharmacist-)bandagers for the distribution of ostomy appliances.

The market share of bandagers, community pharmacies and medical device shops (tends to be 55%, 25% and 20%¹¹, respectively. In the hospital setting, ostomy appliances are provided by the hospital pharmacy. With respect to delivery by bandagers, they are compelled to apply third-party-payer regulation if the cost of ostomy care delivered by the bandager exceeds 310 €. This means that the patient does not pay the full amount to the bandager, but only his/her co-payment, if there is one. Subsequently, the bandager is reimbursed by the health insurance fund for the remainder or the total of the amount. If the reimbursable value is lower than 310 €, the bandager can choose whether or not to apply third-party-payer regulation. If the bandager opts not to apply this regulation, the patient has to pay the full amount to the bandager and then seek reimbursement from the health insurance fund.

Delivery of ostomy appliances by community pharmacies is subject to the pharmacist obtaining a formal recognition as a pharmacist-bandager. Community pharmacies need to apply third-party-payer regulation if reimbursement of products sold by the

¹⁰ This lump sum reimbursement corresponds to three nomenclature numbers: 641465, 641480, 641502 for patients with respectively a colostomy, ileostomy or ureterostomy.

¹¹ . In a registered letter dated 16-8-2005, UNAMEC, the professional association of nationally licensed wholesale distributors representing ConvaTec, Coloplast and BBraun estimated respective market shares (% of turnover in €) at 21,4%, 72,2% and 6,4% for pharmacy/wholesale traders, bandagers and hospitals in 2004. Given the fact that appliances bought at medical device shops are officially prescribed by bandagers the UNAMEC figures tally with figures quoted by experts: 22,9% of turnover in ambulatory care realized by pharmacist-bandagers, leaving a remainder of 77,1% for medical device shops and other (independent) bandagers.

pharmacy is channelled through a tarification service or if costs of ostomy appliances exceed 310 €. In contrast to bandagers, community pharmacies generally require patients to disburse their co-payment. An additional distributor (wholesaler) may be involved in the community pharmacy delivery channel. This is because most community pharmacies purchase their ostomy appliances from a wholesaler. In this case, the distribution mark-up based on the Walkiers coefficient (64% of price to distributor) is split up between the wholesaler and the community pharmacy: the community pharmacy usually obtains the same margin as on drugs (a maximum of 31%, with a limit on the absolute amount of 7.44 €) and the wholesaler receives the remainder.

5.3.5. Prescribing process

Reimbursement of ostomy appliances requires that the first prescription is issued by a physician. Typically, patients receive their first prescription from a specialist following a surgical procedure with colostomy, ileostomy or ureterostomy in hospital. There are few regulations as to how the ostomy appliance is identified on the prescription form and these regulations are currently being discussed by the study group “Bandagers” of the Committee of Bandagers and Health Insurance Funds. Present regulations state that the prescription form needs to provide a description of the type of ostomy appliance. In practice, this implies that the physician can specify the type of ostomy (colostomy, ileostomy or ureterostomy), the code of product class or a specific brand name on the prescription. If the prescription states the type of ostomy or the code of product class, the bandager in agreement with the patient decides which specific appliance within the product class is used. Upon discharge from hospital, patients may receive a number of appliances to cover their initial needs for free. With respect to repeat prescriptions, general practitioners do not need to certify the continuing needs of ostomy patients or renew their prescriptions. A certificate delivered by (pharmacist-)bandagers specifying code of product class and product number suffices for reimbursement purposes.

Key messages

- **Ostomy appliances are registered as medical devices on the “Limitative list of ostomy and incontinence appliances”.**
- **The reimbursement tariff of ostomy appliances would be derived from adding a distribution mark-up of 64% (determined by the Walkiers coefficient) to the supplier price.**
- **In practice reimbursement status depends on the difference between the patient price of the ostomy appliance and the reimbursement tariff set by RIZIV-INAMI.**
- **There is little regulation governing the prescribing of ostomy appliances.**

5.4. ONTARIO (CANADA)

Canada was included in this ostomy market analysis because some provinces/territories have adopted grant-based reimbursement of ostomy appliances, a system of reimbursement that has not been implemented in European countries to date.

The institutional setting of the ostomy appliance market varies between provinces/territories. After setting out national procedures governing registration of ostomy appliances, the remainder of this section focuses on registration, pricing,

reimbursement, distribution and prescribing of ostomy appliances in Ontario, one of the provinces that has introduced a grant-based reimbursement system.

5.4.1. Registration

In Canada, manufacturers of ostomy appliances need to obtain an Establishment License from the Health Products and Food Branch Inspectorate of Health Canada. A license entails that the ostomy appliance meets safety and effectiveness requirements and is appropriately labelled. Moreover, manufacturers need to have in place procedures for distribution records, complaint handling, mandatory problem reporting and recall. Establishment Licenses need to be renewed on an annual basis.

Ontario does not have any additional requirements regarding registration of ostomy appliances. This means that the Assistive Devices Program of the Ontario Ministry of Health and Long-Term Care does not evaluate ostomy appliances and does not maintain a list of manufacturers' appliances.

5.4.2. Pricing

Manufacturers and distributors are free to determine prices in Ontario. In general, distributors comply with retail prices as suggested by manufacturers, although some distributors offer discounts to patients.

5.4.3. Reimbursement

Reimbursement of ostomy appliances in Ontario is limited to patients who have a permanent colostomy, ileostomy or ureterostomy. The Assistive Devices Program does not reimburse supplies for patients with a temporary ostomy. The reimbursement grant is currently set at Can\$ 600¹² per year per ostomy. This grant increases to Can\$ 800 for patients who benefit from social assistance benefits and patients living in nursing homes. The Assistive Devices Program reviews grant amounts every five years. Grants aid patients in paying for their ostomy appliances, but are not intended to cover the full costs of ostomy appliances. Payment of the grant is made in installments every six months.

Patients need to renew their application for reimbursement of ostomy appliances every two years. Renewal does not require a physician visit. The Assistive Devices Program can audit invoices for two years after purchase and can contact physicians to corroborate the ongoing need of ostomy appliances. If the patient requires a higher quantity of ostomy appliances than that covered by the reimbursement grant, the additional expense is paid by the patient. Some private insurance plans cover this additional expenditure.

5.4.4. Delivery channels

Ostomy appliances in Ontario can be distributed by any business or non-profit organization (e.g. community pharmacies and medical equipment shops). Distributors are allowed to advertise their ability to sell ostomy appliances. The distribution margin depends on negotiations between distributors and manufacturers.

5.4.5. Prescribing process

¹² Exchange rate on 15/09/05: 1 CAD = 0,6897 € (The Economist on-line currency converter at www.economist.com), implying that the equivalent of 600CAD and 800CAD at 413,85€ and 551,76€ respectively (nominal rate, purchasing power correction excluded)

Prescriptions of ostomy appliances in Ontario are issued by a specialist physician, general practitioner or nurse practitioner who provides a diagnosis and certifies that the patient has a permanent ostomy. Ostomy appliances tend to be identified on the prescription by their brand name. There is no need for health care professionals to issue repeat prescriptions. Instead, patients apply for a two-year extension of reimbursement (cfr. supra). Patients are free to change appliances without prior notification of the Assistive Devices Program.

Key messages

- **There is free pricing of ostomy appliances.**
- **Reimbursement of ostomy appliances is limited to an annual grant.**
- **Annual grant is not intended to cover full costs of ostomy appliances, implying some level of patient co-payment.**

5.5. DENMARK

5.5.1. Registration

The Danish Health Service registers ostomy appliances as medical devices in the List of Ostomy Appliances as set out in the 1997 Act of the Ministry of Social Affairs. In order to gain registration, the manufacturer needs to submit information about product characteristics and need to follow EU rules governing labelling of packaging.

5.5.2. Pricing

Prices of ostomy appliances are set freely in Denmark through a process of public procurement at the regional/local level of the municipality, of which there are 271 throughout Denmark. This tendering process aims to enable municipalities to negotiate competitive prices for ostomy appliances with distributors. Furthermore, the distributor that wins the tendering process needs to guarantee delivery of ostomy appliances to the home of the patient.

5.5.3. Reimbursement

Ostomy appliances are fully reimbursed by the Danish Health Service to chronic patients with a permanent ostomy. In the case of a temporary ostomy, appliances are paid for by the hospital. Reimbursement is based on the price that emerges from the public tendering process.

5.5.4. Delivery channels

Ostomy appliances are provided by distributors, community pharmacies or the municipality. Generally, ostomy appliances are delivered at home by the distributor that has won the local tendering process. The distribution margin is the difference between reimbursement and the wholesale price negotiated between distributors and manufacturers. Ostomy appliances are also provided by community pharmacies. However, this tends to be a minor distribution channel as pharmacies find it more difficult to offer competitive prices to municipalities that take into account the legal requirement of home care delivery. Finally, some municipalities deliver ostomy appliances directly to patients from their own stock.

5.5.5. Prescribing process

For patients who have undergone an ostomy procedure in hospital, a prescription is filled in by a specialist physician or ostomy care nurse. This prescription specifies the type of appliance or a specific brand name. Also, the required quantity is stated. The prescription form is forwarded to the municipality for reimbursement approval and to the local distributor that has won the tendering process. Upon reimbursement approval, the patient receives a voucher from the municipality allowing him/her to obtain free ostomy appliances at home. General practitioners do not need to certify the needs of ostomy patients following hospital discharge or issue repeat prescriptions.

Key messages

- **Prices of ostomy appliances are determined through a process of public procurement at the level of the municipality.**
- **Distributors are required to deliver ostomy appliances to the home of the patient.**

5.6. FRANCE

5.6.1. Registration

Registration of ostomy appliances is the responsibility of the Products and Services Assessment Committee of the French Agency for the Safety of Health Products. This committee examines the justification for registering or renewing the registration of a ostomy appliance and specifies the conditions for reimbursement. To this effect, manufacturers need to submit a dossier that sets out product characteristics, clinical studies, improvement of service rendered compared to other registered products, target population and sales volume forecasts of the ostomy appliance that is to be registered.

5.6.2. Pricing

In principle, manufacturers are free to set prices, although the Economic Committee for Health Products has the right to set sales price limits by decree. Price fixing considers trends in charges, income and volume of activity.

5.6.3. Reimbursement

The Medical Devices Department of the Economic Committee for Health Products finalises conditions for reimbursement and determines the reimbursement tariff of ostomy appliances in the List of Reimbursed Health Products and Benefits. Appliances can only be reimbursed if they lead to an improvement in the service rendered or to cost savings. Reimbursement is withheld if it is likely to lead to unjustified expenditure. If reimbursement is granted, the ostomy appliance is included in the list of reimbursed products under the generic name of the appliance.

Tariffs are set taking into account (improvement in) the service rendered; tariffs and prices of comparable products on the list; sales volume forecasts; foreseeable and actual conditions of use; and health economic studies. For ostomy appliances that do not generate an improvement in service rendered, the tariff is set at the same level as that applicable to comparable products already registered. A higher tariff can be granted for products with an improvement in service rendered, although regulation does not specify the size of the increase in tariff. Furthermore, improvement in service rendered does not necessarily lead to a higher tariff. Indeed, such ostomy appliances can be reimbursed at a lower tariff than that of comparators. Additional conditions can be imposed on awarding a higher tariff to ostomy appliances with an improvement in service rendered. Such conditions limit the use of the appliance to those groups of patients for which the service rendered by the appliance has been well established. Finally, a procedure of annual revisions of tariffs exists to take account of the evolution of production costs of ostomy appliances.

Most ostomy appliances are fully reimbursed in ambulatory care by the French social insurance system as they qualify for recognition as a chronic condition, ie a condition lingering over more than 6 months (“ALD”, affection de longue durée, “vignette blanche barrée”). Patients whose conditions are deemed to be of a more temporary nature are entitled to a partial reimbursement amounting to 65% of listed tariffs (“vignette blanche”). In hospital, ostomy appliances are paid for by the institution.

5.6.4. Delivery channels

Ostomy appliances are distributed by community pharmacies and private medical device shops managed by bandagers. Distributors sell ostomy appliances to patients at the tariff specified in the List of Reimbursed Health Products and Benefits. The distribution margin derives from the difference between the reimbursement tariff and the wholesale price that distributors are able to negotiate with manufacturers and amounts to 30-40% of the reimbursement tariff. Community pharmacies dominate the market for ostomy appliances, with a market share attaining 93%.

5.6.5. Prescribing process

In hospital, the first prescription of ostomy appliances is generated by a specialist physician or a hospital ostomy care nurse. Ostomy appliances are generally referred to on the prescription by their generic name. General practitioners do not need to certify the needs of ostomy patients following hospital discharge. Prescriptions are renewed by the hospital ostomy care nurse. If the ostomy appliance does not fit, patients need to obtain a new prescription in order to switch to an alternative ostomy appliance, which will be fully reimbursed by the French social insurance system.

Key messages

- Free pricing of ostomy appliances prevails, although the Economic Committee for Health Products can set maximum prices.
- The reimbursement tariff is based on, among other things, the value added by the ostomy appliance.

5.7. NETHERLANDS

5.7.1. Registration

Ostomy appliances are registered as medical devices on a limitative list of ostomy appliances that is managed by the Dutch Ministry of Health, Wellbeing and Sports. Any new ostomy appliance that corresponds to the description of an existing category within the limitative list is automatically added to this category. The Ministry of Health, Wellbeing and Sports can add new categories to the list each year on the advice incorporated in the “Signal Report Medical Devices” of the College of Care Insurances.

5.7.2. Pricing

Free pricing of ostomy appliances prevails in the Netherlands. Information about the price to distributors and the public price of ostomy appliances is listed in the “Z-index”. In practice, market forces ensure that public prices of similar appliances are set around the same level. As health insurance funds are free to decide which ostomy appliances to offer, they are able to exclude, for instance, expensive ostomy appliances. Two kinds of discounts on prices can be awarded. Manufacturers tend to give discounts to distributors depending on the volume of sales. In addition to this, health insurance funds may be able to obtain discounts from large-volume distributors.

5.7.3. Reimbursement

Reimbursement of ostomy appliances in ambulatory care is governed by the “1996 Medical Devices Regulation” under the Compulsory Health Insurance Act. The Medical Devices Regulation includes a limitative list of ostomy appliances that are reimbursed. It applies to the part of the Dutch population that is covered by public health insurance funds. Additionally, most private health insurance funds adhere to this regulation. Ostomy appliances for hospitalized patients and patients residing in long-term care institutions are paid for by the institution.

Ostomy appliances are fully reimbursed in the Netherlands. In order to gain reimbursement, ostomy appliances need to be delivered by a distributor who has a contract with a health insurance fund. Such contracts impose conditions on reimbursement and delivery of ostomy appliances. Contract conditions may vary between health insurance funds, but in general tend to relate to the following aspects. The contract may specify the reimbursement tariff of ostomy appliances. This tariff is generally set at a certain amount below prices listed in the Z-index. Usually, the reduction amounts to around 15% or more of Z-prices. Moreover, distributors may have to satisfy a number of quality conditions, for example, distributors are able to deliver a representative range of ostomy appliances in sufficient number out of stock on a 24 hour / 7 day basis; distributors do not provide excessive quantities of ostomy appliances (in practice, a quantity corresponding to no more than two months of supply); distributors employ a ostomy care nurse. Distributors may be obliged to contribute to promoting an efficient use of ostomy appliances. If distributors

persistently fail to do so, they run the risk of losing their contract with the health insurance fund.

Generally, no restrictions are placed on the quantity of ostomy appliances that is used by patients. However, in their insurance regulations, health insurance funds are free to impose limits on the number of appliances that is used during a certain time period. Patients who have special needs requiring them to use a higher quantity of ostomy appliances are exempted from these rules. Also, health insurance funds monitor prescribing patterns with a view to encouraging efficient use of ostomy appliances. Health insurance funds may draw on the co-operation of patients to check that the number of delivered ostomy appliances equals the number of appliances for which reimbursement is sought.

5.7.4. Delivery channels

Ostomy appliances are delivered in the Netherlands through either medical equipment shops or community pharmacies. Medical equipment shops receive a distribution margin of 40% of the public price (VAT excluded). As the reimbursement level of ostomy appliances is generally set at 85% of the public price listed in the Z-index, medical equipment shops in practice obtain a margin of 25%. The distribution margin of pharmacies is set at 25% of the public price (VAT excluded). If community pharmacies purchase their ostomy appliances from a wholesaler, a distribution margin of 20% flows to the wholesaler.

The market share of medical equipment shops and community pharmacies has changed dramatically over time, with the market share of medical equipment shops rising from 50-70% in 1992 to 95% in 2003 (College voor Zorgverzekeringen, 2004). The Dutch experience with medical equipment shops is somewhat specific as one player, Combicare B.V., covers roughly 65-70% of the market. The success of medical equipment shops derives from their ability to gain larger discounts from manufacturers. Moreover, patients benefit from a 24-hour service and can draw on the assistance of a ostomy care nurse if needed. Finally, medical equipment shops increasingly assist health insurance funds in checking consumption of ostomy appliances.

5.7.5. Prescribing process

Following a colostomy, ileostomy or ureterostomy in hospital, a specialist physician in collaboration with a ostomy care nurse issues a prescription for ostomy appliances. Prescriptions refer to ostomy appliances by a specific brand name or by their generic name. Renewal of prescriptions resides with bandagers. Bandagers deliver a certificate for ostomy appliances which is valid for a period of one year. Depending on the contract with the health insurance fund, this certificate in itself may suffice for reimbursement purposes. Alternatively, the certificate needs to be joined by the original prescription issued by the specialist physician. An exception is made for the first delivery of ostomy appliances to a (new) patient. This delivery requires neither an authorized certificate nor the prescription by the specialist physician. Prescribing regulation allows patients to switch to an alternative ostomy appliance to the one specified on the prescription form if the original ostomy appliance does not suit the patient.

The prescribing process is supported by the publication in 2002 of the "Ostomy Appliances Compass", a book targeted at prescribers to improve the quality of the ostomy care process. To this effect, the compass sets out guidelines regarding the choice, delivery and evaluation of ostomy appliances.

Key messages

- Information about prices of ostomy appliances is publicly available.
- Health insurance funds can exclude expensive ostomy appliances from reimbursement.
- Health insurance funds negotiate contracts with distributors that impose conditions on reimbursement and delivery of ostomy appliances.
- Health insurance funds monitor prescribing patterns in order to encourage efficient use of ostomy appliances.

5.8. ENGLAND

5.8.1. Registration

The Prescription Pricing Authority on behalf of the Secretary of State compiles a list of ostomy appliances that can be supplied to patients in ambulatory care under the National Health Service (NHS) Act 1977. This national list - Part IX C of the Drug Tariff – enumerates the ostomy appliances that benefit from NHS reimbursement and that can be prescribed for any patient or condition for which the appliance is considered appropriate. The Department of Health grants approval for inclusion of ostomy appliances in Part IX C if the appliances are safe and of good quality; if they are appropriate for general practitioners and designated nurses to prescribe; and if they are cost-effective. Ostomy appliances that carry a CE marking are generally considered safe and of acceptable quality by the Department of Health. Appliances that can be administered by the patient, with or without the help of a health care professional, are considered appropriate for general practitioners and designated nurses to prescribe. In considering the cost-effectiveness of a new ostomy appliance, the cost of the new appliance is compared with the cost of similar products and with the cost of the most effective alternative products or treatment regimes.

5.8.2. Pricing

Prices are determined separately for ostomy appliances dispensed in ambulatory care and in hospitals. With respect to ambulatory care, free pricing prevails and prices are negotiated between manufacturers and distributors. With respect to hospitals, ostomy appliances are purchased by the NHS Purchasing and Supply Agency through a European tendering process. An advert is placed in the Official Journal of the European Union to notify suppliers from within Europe of the forthcoming contract. Suitable suppliers are shortlisted and tender documents issued. The completed tenders are then evaluated based on criteria as stated in the advert and tender documents, and the most economically advantageous award is made based on the results. If during the life of the contract a supplier applies for a price increase, the supplier needs to submit a full reasoning for the request (i.e. an increase in utility bills or manufacturing costs). Acute Trusts within the NHS can then use the national contract to purchase ostomy appliances for use within the hospital.

5.8.3. Reimbursement

Ostomy appliances are fully reimbursed by the NHS. In ambulatory care, reimbursement is determined on the basis of the tariffs listed in Part IX C of the Drug Tariff. The entry tariff of ostomy appliances is determined as follows. If the ostomy appliance is similar to products listed in Part IX C, the Prescription Pricing Authority

attempts to set a tariff around the same level of tariffs of listed products. Manufacturers have the opportunity to suggest which products they consider appropriate for comparison with their new ostomy appliance. Tariffs are therefore negotiated between the Prescription Pricing Authority and the manufacturer, and each product is awarded its individual tariff. Additionally, manufacturers can request a different tariff from that of listed products if they can point to differences in the use and patient benefits between products that have a financial impact (e.g. differences in quantities required, comfort, ease of disposal). If the ostomy appliance is not similar to previously listed products, manufacturers need to demonstrate that the requested tariff is in line with the benefits to patients and the NHS.

Regulation governing tariff rises of ostomy appliances is set out in an agreement that is not legally binding between the Department of Health, the Prescription Pricing Authority and the Part IX Drug Tariff Forum, which represents manufacturers marketing products listed in Part IX. Manufacturers can request tariff rises once a year or any longer period which they choose. The tariff rise is limited to a maximum of the forecast of the gross domestic product deflator minus 0.75% (this currently equals 1.77%). This maximum rise is generally awarded by the Prescription Pricing Authority, unless the manufacturer applies for less. Furthermore, manufacturers can apply for additional tariff rises for a category of ostomy appliances if they can establish that cost pressures are being incurred in exceptional circumstances due to, for instance, shortages of raw materials.

There are no restrictions on, for instance, the number of appliances that are reimbursed in a given time period. As community pharmacies may be able to obtain discounts from manufacturers, tariffs of ostomy appliances are discounted using a sliding scale depending on the number of prescriptions. Unlike for pharmacies, reimbursement of ostomy appliances delivered by appliance contractors is fixed and does not take into account any discounts that appliance contractors may gain.

5.8.4. Delivery channels

Ostomy appliances are provided by community pharmacies. The remuneration of community pharmacies for delivering ostomy appliances consists of a fee per prescription. Pharmacies may receive additional fees depending on the number of prescriptions. Alternatively, ostomy appliances are delivered at home by appliance contractors. Appliance contractors can only dispense appliances listed in Part IX of the Drug Tariff. Their remuneration amounts to 15-25% of the reimbursement tariff of the appliance, depending on the number of prescriptions. This implies that appliance contractors are generally paid more than community pharmacies, particularly on the more expensive appliances. Focusing on the proportion of ostomy appliances dispensed by community pharmacies and appliance contractors, the market share of appliance contractors has increased over time from 37% in 1993 to 55% in 1996 and 64% in 2001 (Department of Health, 2003).

5.8.5. Prescribing process

The original prescription of ostomy appliances to a patient is generated by a specialist physician or a hospital ostomy care nurse. Ostomy appliances are generally identified on the prescription form by their brand name. If the prescribed ostomy appliance does not fit, the patient in consultation with the ostomy care nurse switches to an alternative appliance and a corresponding prescription is written. Any additional expense caused by a switch to a more expensive ostomy appliance is incurred by the NHS.

A particular feature of the prescribing process of ostomy appliances in hospital is the contributions in cash or in kind to NHS ostomy care by some of the larger appliance contractors and manufacturers. This sponsorship takes the form of funding the employment of ostomy care nurses or even the provision of the ostomy nursing service by the appliance contractor. Such commercial relationships may favour the prescription of ostomy appliances of the sponsor, although no data are available on this issue.

In ambulatory care, general practitioners and designated nurse prescribers are responsible for managing repeat prescriptions of ostomy appliances listed in Part IX of

the Drug Tariff. They are not required to certify the needs of ostomy patients following discharge from hospital.

Key messages

- **Prices of ostomy appliances are negotiated between manufacturers and distributors.**
- **The reimbursement tariff is negotiated between the Prescription Pricing Authority and manufacturers, and is set around the level of similar ostomy appliances.**
- **The remuneration of community pharmacists for delivering ostomy appliances consists of a fee per prescription.**

5.9. INTERNATIONAL MARKET ANALYSIS

Institutional features of the ostomy appliance market for outpatients in the six countries studied are presented in Table I.

Ostomy appliances are registered as medical devices in the six countries. In order to gain a registration, ostomy appliances are evaluated in terms of a number of criteria that vary between countries but tend to include safety, quality, effectiveness, and expected budgetary impact in Belgium, Ontario (Canada), Denmark, France and England. In the Netherlands, it suffices for a manufacturer to demonstrate that a new ostomy appliance fits in an existing category to obtain a registration.

Registration of a ostomy appliance implies that it will be reimbursed in Belgium, Denmark, France, and England. In the Netherlands, health insurance funds can choose to exclude expensive ostomy appliances from reimbursement. When an appliance is registered in a limitative list of ostomy appliances, this automatically determines the reimbursement tariff in France and England as tariffs are set at the same level for comparable products.

Prices of ostomy appliances are set freely in Belgium, Ontario (Canada), Denmark, France, the Netherlands and England. However, market mechanisms are unlikely to exert downward pressure on prices in a market that is dominated by a few international manufacturers and that is characterized by the high brand loyalty of patients. Moreover, competition in this market takes the form of successive cycles of product innovation rather than price competition. In order to strengthen price competition, prices in Denmark are determined by a system of public procurement at the level of the municipality. In France, maximum prices can be fixed as a function of charges, income and volume of activity.

The relationship between prices and reimbursement tariffs tends to differ between countries. In Belgium, prices tend to be higher than or equal to the reimbursement tariff. If the price of a ostomy appliance exceeds the tariff, the supplement is paid by distributors or patients. A similar system operates in France, although the fixing of maximum prices limits the difference between the price and tariff of a ostomy appliance. This system is intended to create price competition between manufacturers, whilst restricting reimbursement borne by French social insurance. In Ontario (Canada), public reimbursement is limited by setting the grant amount at a level that does not suffice to cover all costs of ostomy appliances. The ability of distributors to obtain discounts from manufacturers in countries where free pricing prevails, is incorporated into the reimbursement system in different ways. In Denmark and the Netherlands, reimbursement is set at 100% or less of the price to take account of discounts granted by manufacturers. In England, reimbursement is based on a discounted tariff.

Ostomy appliances are fully reimbursed in Denmark, France, the Netherlands and England, irrespective of the quantity of appliances consumed. Therefore, public expenditure on ostomy appliances is open-ended in these countries. To ensure an

efficient use of ostomy appliances, health insurance funds and distributors monitor consumption patterns of appliances in the Netherlands. Belgium follows a mixed system of full or partial reimbursement depending on the price of ostomy appliances. Moreover, the quantity of ostomy appliances that benefit from reimbursement is restricted. If patients require more appliances, they incur the full costs of their additional consumption. Ontario (Canada) has opted for partial reimbursement in that patients do not tend to be able to purchase the required quantity of ostomy appliances with the grant amount.

Ostomy appliances are distributed by community pharmacies and medical equipment shops in Belgium, Ontario (Canada), France and the Netherlands. The market share of each type of distributor within a country depends on the distribution margin, the ability of the distributor to gain discounts from manufacturers and provide ostomy care to patients. In countries that place an emphasis on home care delivery such as Denmark and England, domiciliary distributors dominate the market to the detriment of community pharmacies which do not seem to be able to offer this service at a competitive price.

Various approaches are used in the six countries to remunerate distributors. Distributors receive a proportion of the price of ostomy appliances in Belgium, the Netherlands and England. In Denmark and France, the remuneration of distributors depends on the difference between the reimbursement tariff and the wholesale price negotiated between distributors and manufacturers. A third system applies to community pharmacies in England, which are paid by fee-for-service. In Ontario (Canada), distributors and manufacturers negotiate to determine wholesale and retail prices and, thus, the distribution margin.

The prescription of ostomy appliances can be initiated by a specialist physician in the six countries. In this respect, Belgian nurses enjoy less official competences than their counterparts. Ostomy appliances are identified by either their brand or generic name in Belgium, Denmark and the Netherlands. This contrasts with Ontario (Canada) and England where the brand name of ostomy appliances is generally used, and France where use of the generic name dominates. Repeat prescriptions are managed by bandagers in Belgium and the Netherlands, by ostomy care nurses in France, and by general practitioners and nurse practitioners in England. Repeat prescriptions do not need to be issued in Ontario (Canada) or Denmark.

Table I. International regulation governing distribution of ostomy appliances in ambulatory care

Features	Belgium	Ontario (Canada)	Denmark	France	Netherlands	England
Pricing:						
- Free market	X	X	X	X	X	X
- Price fixing				X		
Reimbursement system:						
- National public procurement						
- Regional public procurement			X			
- National tariffs	X			X	X	X
- Grant		X				
Reimbursement by:						
- National Health Service			X			X
- Social insurance	X	X		X	X	
Reimbursement level:						
- Full reimbursement ¹³			X	X	X	X
Delivery channels:						
- Community pharmacies	X	X	X	X	X	X
- Medical equipment shops	X	X		X	X	
- Domiciliary distributors	X		X			X
Prescription by:						
- Brand name	X	X	X		X	X
- Generic name	X		X	X	X	
Repeat prescription by:						
- General practitioner						X
- Nurse practitioner						X
- Ostomy care nurse				X		
- Bandager					X	
- no repeat prescriptions	X	X	X			

¹³ Applying to chronic patients with a permanent stoma.

Key messages

- Ostomy appliances are registered as medical devices in the six countries.
- Registration of an ostomy appliance implies reimbursement, except for the Netherlands where health insurance funds can exclude ostomy appliances from reimbursement.
- To contain prices of ostomy appliances, a public procurement system or the imposition of maximum prices have been implemented in some countries.
- Ostomy appliances are fully reimbursed, with the exception of Belgium and Ontario (Canada) where there can be some level of patient co-payments.
- Reimbursement can be contained by introducing grant-based reimbursement or monitoring prescribing patterns of ostomy appliances.
- There are no limits on the quantity of ostomy appliances that are reimbursed in a specific time period, except in Belgium.
- The market share of distributors depends on the distribution margin, the ability of distributors to gain discounts from manufacturers and provide ostomy care to patients.

6. CHAPTER VI POLICY ANALYSIS

6.1. METHODOLOGY

Researchers contacted experts and representatives from various stakeholders:

- National distributors for Coloplast, ConvaTec, BBraun, Hollister-Dansac, Welland and Eurotec: both individually and through the professional federation UNAMEC
- The Belgian federation of bandagers, BBOB-UPBOB, was contacted through meetings with representatives and a survey was held among their members (cf. annex to this Chapter)
- Experts from RIZIV-INAMI
- The university hospital of Gasthuisberg (Katholieke Universiteit Leuven)
- The university hospital of Saint-Luc (Université Catholique de Louvain)
- Representatives of the two major Belgian sickness funds
- The expert group counselling the researchers
- Representatives from patients' associations

Interviews were held and requests for data and other information formulated. Related documents can be found in the annex to Chapter VI. An important aim underlying these contacts was to assess shortcomings of the current Belgian economic and regulatory framework for ostomy products as defined by the outlined scope in chapter I. This chapter will present the various shortcomings stated by different stakeholders, verify their validity if possible and propose policy measures to remedy confirmed shortcomings.

6.2. FINDINGS

6.2.1. Current Belgian Regulatory Framework for Ambulatory Care

Assessment of product categories in the current "Limitative Lists"

The so-called "Limitative List" lists products into three distinct categories for every product class:

- Category "A": category corresponding to a product of absolute medical and social necessity to patients. Every product class should have at least 2 products in the "A" category. Full reimbursement for these "A" category products is provided by Belgian health insurance, i.e. patients do not pay out-of-pocket contributions ("supplementen").
- Category "B": this category encompasses products with a "relative" medical-social necessity. A personal contribution of up to 25% can be billed to the patient. The reimbursed amount is the same as products from the "A" category adhering to the same "limitative list".
- Category "C": this category includes products that are priced well above their medical / social necessity and do not warrant higher reimbursement. Reimbursement is limited to the reimbursed amount for products in the "A" category. There are no limits on the personal contribution patients make.

At present the classification of products into three categories no longer seems to adhere to the initial criterion of medical/social necessity. It would appear a de facto lump sum contribution is accorded per product class.

Firstly, it should be noted that the number of ostomy products for main producers in the “A” category is limited. In 2005 only 7 out of 378 products for these companies classified as category “A” products, implying that category “A” products primarily concern appliances of smaller producers (eg. Welland, Eurotec). Secondly, it would appear most maximum prices for product ranges in categories “A” and “that the main criterion for classifying a product into a distinct category would be the average purchase price for retail distributors and not per se the perceived medical or social necessity. This claim was confirmed by various experts.

As bandagers currently are compensated for their medical expertise by a 64% mark-up based on a de facto lump sum implicitly set by the mean purchase price of (cheaper) “A” category products, they have a direct interest in seeing these prices rise. A possible strategy to raise the de facto lump sum is by boycotting the sale of (cheap) “A” category products. The disappearance of these products off the Belgian market would make current “B” category products the cheapest available patient alternatives seeing that that A-B-C categories are primarily determined by price levels. Moreover, it is stipulated that every product class of the “limitative list” should contain at least 2 “A” category products. Thus, current “B” category products would become new “A” category products. A higher de facto lump sum would come into existence, yielding higher absolute revenues for bandagers. It should be clear that spurring retailers to favour certain products for other than medical reasons is not judicious on the part of health insurance officials.

Fixed quantities of ostomy appliances

The Belgian system appears to be exceptional in the way it sets the amount of reimbursed ostomy products patients are entitled to. The comparison of institutional settings for a selected number of countries (see previous chapter) confirmed the unique nature of this regulation. Periodical “dotations”, allowances/endowments, are granted, meaning that for instance every colostomy patient, regardless of the individual nature of his condition is entitled to the same amount of ostomy products on a three-monthly basis.

Arguably this system lacks flexibility. Depending on the nature of each patient’s ostomy, varying amounts of ostomy products could be required. Temporary ostomy patients, patients going through the first months of living with an ostomy, patients suffering from various complications, multiple ostomies or interfering treatments such as e.g. chemotherapy could benefit from a less rigorous way of supplying ostomy appliances.

Moreover, this particular regulation applying exclusively to Belgian patients requires producers to tailor their packaging specifically for the Belgian market, incurring certain surplus costs.

Introduction of new products within an existing product class

The introduction of a new ostomy product filing for reimbursement under the Belgian regulation is possible on an annual basis only (cf. chapter V): the launch of new ostomy products for the Belgian market therefore could be delayed. As major multinational companies have production facilities operating on an international scale this delay could temporarily hamper optimal scales of production and thus incur certain costs. At present insufficient data was provided by the industry (cf. production survey in previous chapter) to assess this claim.

Introduction of new products within a new product class

The fact that the introduction of innovative products on the Belgian market in principle would require the introduction of new product categories in the Belgian reimbursement scheme (ie nomenclature code) can in theory be disadvantageous to the needs of Belgian patients. New and advanced products are launched for the Belgian market at a somewhat later stage of their product cycle, thus potentially diminishing the relative quality of medical treatment Belgian patients receive. Patients' organisations did, however, not confirm the gravity of this claim.

Traceability of ostomy products

The traceability of supplied ostomy products cannot be guaranteed under current supplier practices. The applied allowance system could entail too generous allowances for certain types of patients. This would imply either that surplus materials are stocked or re-enter the (domestic or foreign) distribution chain. Traceability of products could be raised by introducing barcodes (or a sticker system) on every supplied and reimbursed package in order to prevent products from re-entering the domestic (or foreign) distribution chain. This system is already in force for pharmaceutical products. Alternatively, or corroboratively, suppliers should be required to present patients with a duplicate of their three-monthly bill.

Conflicts-of-interest

Given the interests both bandagers and health insurance funds both have as suppliers of ostomy products, the presence of these parties in the RIZIV-INAMI "agreement committee" (Overeenkomstcommissie / Commission de Convention) is rather surprising from an outsider's point-of-view. As far-reaching decisions regarding the reimbursement of new and existing products are made by the committee, the presence of two main distributors¹⁴ could skew proper market clearing.

Key messages

- **The current regulation is proving too rigid for patients and producers.**
- **The current regulation lacks transparency, with regard to price setting, traceability of products and decision processes.**
- **As a result, the current regulation on reimbursement no longer corresponds to on-the-field reality.**

6.2.2. Market dynamics

A recurrent claim is that (licensed national distributors for) major manufacturers negotiate prices with bandagers on the basis of the number of patients they supply. Reductions of over 40% on official catalogue prices would be attributed to major bandagers. The result would be an ongoing consolidation of market share by a few dominant bandagers. Higher price reductions allow retailers not to bill patients the

¹⁴ In a registered letter by UNAMEC dated 16-8-2005 Coloplast, ConvaTec and BBraun estimate the aggregate market share of bandagers at 72,2% of turnover in 2004, implying bandagers account for 77,1% of turnover on the ambulatory market. In a mail sent by UNAMEC 15/09/2005 the percentage of turnover for bandagers working at "mediotheken", medical devices shops associated to health insurance funds, is estimated at 11% of total turnover for bandagers in 2004 (25).

legally foreseen out-of-pocket payment (“supplement”) for “B” category products, thus removing incentives for patients to act in a more economical way.

A questionnaire on ostomy products was sent to members of the federation of bandagers (BBOB-UPBOB). The federation has members throughout the three Belgian regions. The response rate for the questionnaire was 40%. Out of the bandagers that returned filled out forms 66% claim to sell ostomy products in 2005. This percentage corresponds to 21 firms, out of which respectively 4, 4, 11 and 2 firm(s) claim their sales of ostomy products have either increased / remained stable / diminished / did not answer this question. A more detailed analysis of survey data can be found in the annex to this chapter.

UNAMEC members Coloplast, ConvaTec and BBraun reported¹⁵ that the overall market shares in ambulatory care for bandaging companies rose from 52,8% to 77,1% between 1998 and 2004. Further details on various market shares could not be provided. Consequently, no clear conclusions with regard to an ongoing market consolidation could be drawn. Further statistical analysis (e.g. on significance between geographical average differentials) was not explored due to the limited number of completed responses.

Table I contains figures derived from the “P-Documenten / Documents P” (29). These data are financial aggregates (financial year, booked amounts) split up by type of supplier. Qualification “201” refers to suppliers with an official profession code as a bandager limited to supplying ostomy and incontinence products as well as endotracheal tube retainers (“tracheacanules”). The remaining amount is booked for suppliers with further qualifications (supplying orthopaedic material, wheelchairs, etc.). A tendency towards specialisation in the supply of ostomy products cannot be observed for the period 1999-2003. If market shares for ostomy products are consolidated by a handful of large outfits, these retailers would probably also provide other products than ostomy appliances.

Table I Market shares according to qualification of supplier (€, %)

Year	Qual "201"	All Qualifications	Percentage
1999	6.341.546	13.132.489	48,29%
2000	6.347.274	13.677.924	46,41%
2001	6.888.940	15.359.049	44,85%
2002	6.753.047	16.077.474	42,00%
2003	7.573.918	17.439.842	43,43%

Nomenclature codes 640275, 640290, 640371, 640393, 640415, 640872, 640894, 641351 are included.

The two major sickness funds, associated with chains of medical devices shops, were requested to deliver longitudinal data regarding make of products sold and market consolidation. One sickness fund replied favourably, urging confidential treatment of data however.

Key messages

- **More detailed market data are needed in order to assess the reported claim of market consolidation as a possible result of non-transparent governance.**
- **These data could be obtained through sickness funds and should allow for a longitudinal follow-up on product make and market consolidation.**

¹⁵ Registered letter by UNAMEC dated 16-8-2005 (25).

6.2.3. Hospital setting

At present, prescriptions for ostomy products can mention either brand names or nomenclature codes. Proper rules for prescription should be laid down as well as with regard to information given to first time ostomy patients⁽³⁰⁾.

Furthermore, no guidelines exist on the product range available at hospitals and the amount of free sample products patients can take home upon discharge. Given the widely reported brand loyalty patients show toward ostomy products, due care should be given to sound prescription practices for first time ostomy patients' hospital stays.

Key messages

- **At present no clear hospital guidelines exist regarding prescription of appliances and needed patient information.**

6.2.4. Epidemiologic data

Estimates for patients' numbers can be derived indirectly through the number of appliances that have been prescribed to patients. This analysis can only allow for rudimentary insights regarding relevant stylized traits¹⁶. Both the possibilities (and limitations) such an analytic framework has to offer are shown in table 2. The derived patient numbers are obtained from the "Documents N" (RIZIV-INAMI). These data regard amounts of reimbursements and allowances (number of products) on a yearly basis. The limitations of the nomenclature data are apparent:

- Certain Nomenclature codes mentioning two different allowances based on a patient's individual profile (which cannot be determined by the database);
- Data do not allow for patients taking up their first or final allowance respectively after the first or before the last trimester of any given year. Therefore the derived patient numbers will imply a downward bias¹⁷.

These data nevertheless point to some important observations as proven by table 3:

- An overall increase of the (derived) number of patients can be observed for the period between 1995 and 2003;
- The nomenclature code "641351"¹⁸, relating to convex flanges has increased its patient number dramatically between 1995-2003 with over 1300%, implying an average exponential growth of over 39% annually.

A rudimentary cross-check of these estimates was performed by comparing them with data for the Belgian "Christian Sickness Fund" (MC-CM), a fund covering roughly 45% of all Belgian residents. Relevant data are shown in the annex to this chapter. The downward bias patient estimates based on nomenclature data entail appears to be confirmed and several questions (regarding gender differences, multiple ostomies with patients,...) are raised. It would seem obvious to dedicate further (longitudinal)

¹⁶ Data obtained through the questionnaire (data for 21 bandagers) divide ostomy patients up by category in the following way: 55% of colostomy patients, 14% of ileostomy patients, 31% of ureterostomy patients, whereas the MC-CM data indicate there are 22% of ureterostomy patients (annex I.4, 31).

¹⁷ The proportion of patients related nomenclature code "640275" receiving 4 trimestral allowances is estimated at 33% among CM-MC members in 2002.

¹⁸ The nomenclature code "641351" was introduced on April 1st 1992

research to the epidemiologic background of ostomy patients. Crucial factors that are insufficiently documented for the Belgian situation pertain more specifically to surgical treatments (number and type of temporary ostomies, number of Bricker operations, Hartmann operations, anterior resections, etc.) and more generally to the average further life expectancy of ostomy patients. Understanding these evolutions is an elementary prerequisite for making sound estimates of future evolutions. Moreover, linking the epidemiologic data to effectiveness of appliances requires prospective research on reported differences in medical outcome according to varying typology and make of material. This necessity is further illustrated by the conclusions of Chapter II.

Key messages

- **Detailed epidemiologic data are needed in order to adequately steer and fully gauge the future impact of possible regulatory reform.**
- **These data could be obtained through sickness funds and should allow for a longitudinal follow-up on patient-related data, regarding both hospital and ambulatory care.**

Table 2 Derived¹⁹ patient numbers (based on “Documents N”, RIZIV-INAMI, allowances for 1995-2003, ³²)

Nomenclature	Label (Dutch)	3-monthly] ²⁰ endowment	Annual Endowment	1995	1996	1997	1998	1999	2000	2001	2002	2003
640275	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen - Eéndelig systeem</u> - Gesloten, Zelfklevend opvangzakje, voorzien van een peristomale beschermlaag, ongeacht de bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden , indien niet gebruikt in combinatie met andere systemen 2. 90 stuks/3 maanden , indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0275	180	720	3.381	3.394	3.079	3.551	3.539	3.553	3.492	3.432	3.350
640290	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen - Eéndelig systeem</u> - Ledigbaar zelfklevend opvangzakje voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0290	90	360	369	389	370	442	459	450	463	483	496
640371	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen - Tweedelig systeem</u> - Peristomale beschermring met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden (ileostomie) 35 stuks/3 maanden (colostomie) Lijst 0371	45	180	2.100	2.117	1.740	2.081	2.119	2.147	2.217	2.243	2.301
640393	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen - Tweedelig systeem</u> - Gesloten zakje met bevestigingssysteem (bv. oplijlring), ongeacht de overige bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden , indien niet gebruikt in combinatie met andere opvang- of continentiesystemen 2. 90 stuks/3 maanden , indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0393	180	720	1.811	1.832	1.658	1.990	2.040	2.114	2.191	2.304	2.443

¹⁹ Data for expenditures (booked amounts) were converted to actual amounts following RIZIV-INAMI indications (32).

²⁰ Maximum allowance chosen when two possible allowances are mentioned in the nomenclature label

640415	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <i>Opvangsystemen - Tweedelig systeem</i> - Ledigbaar zakje met bevestigingssysteem (bv. opklikring) voorzien van een sluitklem, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0415	90	360	403	453	427	575	619	663	743	819	907
640872	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Peristomale beschermerschijf, voorzien van een bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 0872	45	180	1.190	1.215	1.092	1.362	1.413	1.439	1.532	1.640	1.674
640894	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Ledigbaar urine-opvangzakje met bevestigingssysteem (bv. opklikring) en antirefluxklep, ongeacht de overige bijbehorende produktattributen Dotatie : 60 stuks/3 maanden Lijst 0894	60	240	1.347	1.394	1.290	1.632	1.729	1.794	1.899	1.993	2.065
641351	Stomamateriaal - Verzorgingssystemen voor uitzonderlijke toestanden bij stomiekuil minstens 1 cm diep ligt, in ruglithouding gemeten - <i>Tweedelig systeem</i> - Convexe peristomale beschermerschijf met een minimum plaatdikte van 3 mm in het centrum, met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 1351	45	180	79	146	218	387	512	632	739	867	1.089

Table 3 Salient evolutions in derived patients' totals

Nomenclature	Label (Dutch)	Evolution Number of Patients 1995-2003
640275	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Eéndelig systeem</i> - Gesloten, Zelfklevend opvangzakje, voorzien van een peristomale beschermlaag, ongeacht de bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere systemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentie-systemen Lijst 0275	-0,92%
640290	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Eéndelig systeem</i> - Ledigbaar zelfklevend opvangzakje voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0290	34,43%
640371	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Peristomale beschermerschijf met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden (ileostomie) 35 stuks/3 maanden (colostomie) Lijst 0371	9,57%
640393	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Gesloten zakje met bevestigingssysteem (bv. oplirring), ongeacht de overige bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere opvang- of continentie-systemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0393	34,86%
640415	Stomamateriaal - Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel - <u>Opvangsystemen</u> - <i>Tweedelig systeem</i> - Ledigbaar zakje met bevestigingssysteem (bv. opklikring) voorzien van een sluitklem, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0415	125,33%
640872	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Peristomale beschermerschijf, voorzien van een bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 0872	40,64%
640894	Stomamateriaal - Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen - <i>Tweedelig systeem</i> - Ledigbaar urine-opvangzakje met bevestigingssysteem (bv opklikring) en antirefluxklep, ongeacht de overige bijbehorende produktattributen Dotatie : 60 stuks/3 maanden Lijst 0894	53,32%
641351	Stomamateriaal - Verzorgingssystemen voor uitzonderlijke toestanden bij stomiekuil minstens 1 cm diep ligt, in ruglithouding gemeten - <i>Tweedelig systeem</i> - Convexe peristomale beschermerschijf met een minimum plaatdikte van 3 mm in het centrum, met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 1351	1272,17%

6.3. POLICY MEASURES

A general conclusion following the problem analysis in the preceding paragraphs is that the Belgian regulatory framework would benefit from a balanced set of policy measures fulfilling several criteria:

- Raising flexibility in the product choice for patients, and emphasizing service and quality of care over the periodic delivery of a set number of appliances,
- Introducing incentives that encourage sound market principles and reduce unjustified monopolies from the health insurance point of view,
- Instilling transparency for various stakeholders, more particularly for patients, by guaranteeing a balanced representation of various stakeholders within the regulatory framework.,

The policy recommendations will concentrate on elucidating the interacting roles various stakeholders ideally would play.

6.3.1. Pivotal role for enterostomal therapy nurses as caretakers

Given the observed brand loyalty among patients the first hospital stay and ensuing discharge as an ostomy patient is crucial in determining patients' preferences in further life. The role stoma nurses fulfil at this point is of pivotal importance. The existence of so-called "sponsored stoma nurses" funded by the industry in the NHS constitutes a prime example of this observation. Policy makers should be aware of this and due care should be given to the way hospitals supply first time ostomy patients with appliances.

Government policies should aim at:

- Acknowledging and valorising the expertise enterostomal therapy nurses offer,
- Requiring a sufficient variety in available ostomy appliances and brands at the hospital,
- Emphasizing the importance of clear and unbiased information patients are entitled to at the moment of hospital discharge.

Enterostomal therapy ("ET") nurses should guide the choice of proper appliances in dialogue with medical practitioners and patients. This prescription would require a periodical renewal for chronic patients (e.g. every 2 years) to assure the appropriateness of the products and services provided by suppliers to the patients.

Furthermore, the range of ostomy appliances in hospital pharmacies should be diverse and encompass at least three alternative appliances from distinct brands. Discharged patients should be given a reasonable supply of ostomy products to take home, sufficient only to span a limited period. At present however, no funds are available for hospitals to provide first time ostomy patients with appliances at the time of discharge.

At the time of hospital discharge first time ostomy patients face a clear and pressing need for objective information⁽³³⁾. The government should see to it that clear and unbiased information on products, prices, reimbursement, distribution channels, and recognized enterostomal therapy nurses is offered to patients. Further information could include diet and exercise, physical and emotional adjustment to name but a few elements⁽³⁴⁾.

Reinforcing the authority ET nurses can exert also invokes a need for more accountability. At present, government officials are working out the formal educational qualifications Belgian ET nurses should dispose of. The professional associations for ET

nurses are currently laying down deontological guidelines for their profession. The effectiveness of this effort for self-regulation should subsequently be assessed by health insurance officials.

Key messages

- **ET therapists should be allowed to play a more active role in guiding patients.**
- **This increased authority should be accompanied by accountability and regulation.**

6.3.2. Transparency in prices: disentangling costs for services and products

As pointed out in the problem analysis the current price setting for patients and regulatory framework does not enable them to make price-aware decisions for various reasons. The following policy proposals are set up in an optional and modular way:

- proposal 1 can be combined with all other proposals;
- proposal 2 and 3 are mutually exclusive;
- proposal 4 can be combined with all other proposals.

Proposal 1: Tendering

In order to encourage competition, a tender could be set up. Producers of ostomy appliances would participate in a national bid. The bid would be organized by RIZIV-INAMI, the governmental organization specifying technical and medical features for each distinct product category (separate products or combinations of complementary products, e.g. pouch and compatible plate). This specification would require the expertise of patients' associations and ET therapists. Assessing (e.g. testing) whether the products offered correspond to the product specifications will require the further involvement of patient groups. All Belgian hospitals would be obliged to have the lowest bid products (or product combinations) in their product range of ostomy appliances. This way tenderers would be assured they would deliver a set percentage^u of all ostomy appliances in Belgian hospitals for a given period of several years. Year-to-year price increases should be linked to an agreed upon index over that period. This obligation would apply to all Belgian hospitals requesting a daily lump sum compensation for resident ostomy patients. It is assumed that for medical reasons (e.g. skin problems) certain patients would require products from a different make. Therefore the agreed upon percentage should allow for a certain leeway for addressing specific patient needs. This way, a powerful incentive is offered to producers willing to set prices at a competitive level.

Current regulatory practices already include a form of price bidding as producers are asked to make their supplier prices known to RIZIV-INAMI on an annual basis. It would, nevertheless, appear that the A-B-C categories for each limitative list are determined as an increasing (discrete) function of product prices. The vast majority of products being sold probably do not belong to the A category (cf. supra) and thus (theoretically) require some form of out-of-pocket payment made by patients. As stated in the preceding problem analysis often patients are not required to make a personal payment and the signal competitively set prices would otherwise emit is subdued and patients are not encouraged to make price-aware decisions. Therefore, a positive incentive should be attributed to competitively priced products that meet medically and technically required specifications.

^u In a registered letter by UNAMEC dated 16-8-2005 Coloplast, ConvaTec and BBraun estimate the aggregate market share of Belgian hospitals at 6,4% of turnover in 2004 (25).

Key message

- **Hospital tendering could prove a powerful incitement for producers to set competitive prices.**

Proposal 2: separate lump sum reimbursement

This proposal aims at disentangling the reimbursement for retail services and material cost. The goal is to empower patients in a price-aware manner and to thwart unsound commercial practices among distributors. It is assumed that the overall post-surgery costs for the Belgian health care budget are threefold:

- Costs for medical expertise of ET therapists and other practitioners,
- Costs for retail services by distributors,
- Costs for appliances.

Costs for medical expertise would be covered by reimbursement of patient consultations (cf. supra). Costs for retail services and appliances should be reimbursed separately.

Proposal 2a: Lump Sum per patient for retail services

In order to reduce any incentive for distributors to favour the supply of more expensive ostomy appliances, a lump sum system could be set up. Suppliers would receive a trimestral fixed sum per patient covering their expenses for providing services to patients. The actual costs for medical appliances would be reimbursed separately from costs for supplier services. Such a system would imply each patient choosing a regular supplier. If patients are dissatisfied with the service provided by their current supplier they should be allowed to change their supplier by means of a prescription renewal. A minimum period of three months of staying with a given supplier should be regarded by patients.

This system would require follow-up of the number of patient serviced by each distributor. In combination with a lump sum periodic material reimbursement according to various patient profiles (cf. infra), the necessary data would be available for health officials.

Proposal 2b: Lump sum for appliances

The separate reimbursement for medical appliances could be realized by means of the product equivalent of a fixed sum set at patients' disposal by means of a:

- Direct cash payment to patients or
- Third-party payment (e.g. health insurance funds) or
- By means of a voucher system.

Several patient profiles corresponding to various pathologies should be drawn up. Packages of appliances linked to these profiles can be put together. Patients would be allowed a package of ostomy appliances equivalent to their periodical appliances reimbursement. The size of the reimbursement would be the outcome of current price levels ("supplier prices" as indicated to RIZIV-INAMI by manufacturers) multiplied by the quantity of ostomy appliances required by a typical patient. These required quantities can be devised separately for a colostomy patient, an ileostomy patient and a ureterostomy patient. In case a prior tender is organised, the lowest price bid for each separate category will help to set the lump sum periodical reimbursement for a distinct patient profile. A relative value would be assigned annually to each product linked to a distinct pathology package^v. This product value would be fixed as the product's price share in the appliances lump sum. The main advantages of this system are clear: patients will choose those providers that offer most service, possible additional bags when needed and that allow an easy switch to other products. To ensure that distributors deliver the quantity of ostomy appliances as reported, the patient needs to countersign the delivery invoice or needs to obtain a copy.

If patients choose to exceed the allowed monetary value of their appliances package an out-of-pocket payment will be due. A system of transferable credits can be organised to allow patients to transfer any surplus of ostomy appliances during one period to the following period. General price inflation will not erode patients' accumulated credit shares, as these are determined in relationship to a physical package of required products. This system of transferable credits may not be necessary if the quantity of appliances required by a typical patient is set at the appropriate level. However, the required quantity is likely to be above the average for: a) patients during the first months after hospital discharge; b) for patients who experience acute problems; c) for patients who undergo radiotherapy or chemotherapy. Flexibility needs to be built into the system to raise the fixed allowance for these types of patients. A simple prescription by a medical specialist treating the intermittent condition (medical oncologist, surgeon, dermatologist, radiotherapist,...) should suffice for an additional allowance. From health insurance control perspective, follow-up can be done relatively easily by profiling and correlation for case load and number of ostomy patients.

Tables 5 and 6 illustrate this principle. After having launched a price bid or a hospital tender (cf. supra) for distinct product categories, RIZIV-INAMI, in consultation with patient associations, composes base packages for different patient profiles. The monetary equivalent of these trimestral product packages are 500€, 400€ and 360€ respectively in the hypothetical examples below. Each product belonging to a certain base package is then accorded a credit share (table 6). Credit shares are set by deriving relative product values from prices set by producers in the initial bid round. Product A for instance, is used by both colostomy and ileostomy patients and represents a credit share of respectively 0,8% and 1% in these patients' base packages. Surplus credit shares can be transferred and added to the next periodical allowance.

^v Nomenclature codes representing various patient profiles (and thus lump sums) should be linked to products on the Belgian market on an annual basis.

Table 5 Examples of Appliance packages (€)

Pathology	Periodical Allowance	Product		
		A	B	C
Colostomy	500 €	4 €	NA	25 €
Ileostomy	400 €		NA	
Ureterostomy	360 €	NA	3 €	

Table 6 Examples of Appliance packages (%)

Pathology	Periodical Allowance	Product		
		A	B	C
Colostomy	Ec	0,8%	NA	5%
Ileostomy	Ei	1%	NA	6%
Ureterostomy	Eu	NA	1%	7%

The advantages this system offers compared to the current situation are:

- Inciting price competition among producers (possibly both through the initial bid round and) by instilling price awareness in patients. In the present situation, legally foreseen out-of-pocket payments often remain unbilled to patients.
- Empowering patients to address their specific needs in a more tailored manner.
- Taking away the need for “hoarding behaviour” as physical stocks are now turned into credit accounts.

Disadvantages this system entails are:

- The arbitrary nature of setting allowances by composing homogenous packages valid for large groups of patients. This inconvenience, however, seems inevitable with every system capping individual patients' needs at a maximum amount. The introduction in the system of a specific allowance for the start period and for exceptional circumstances such as chemotherapy or radiotherapy upon simple prescription can in part solve the problem.
- The arbitrary nature of determining distributors' margins consisting of a trimestral fixed sum per patient.
- The necessity of keeping track of individual share accounts for each patients. This would require a considerable organisational effort. The decision whether or not to make package shares transferable is a trade-off between a more flexible system and organisational feasibility.

The notion of transferable credits can be nuanced. The system would then consist of a maximum periodical package allowance with a monetary equivalent determined by RIZIV-INAMI. The quintessential advantage of empowering patients by raising their freedom of choice and instilling price awareness would thus be maintained. Main crux, however, is to assure relative prices are not obstructed in practice by retail distributors. Therefore only products competing in the initial price bid or hospital tender will be

reimbursed. If the initial price bid yields competitive price levels, no substantial leeway should be left for producers to attribute the considerable price reductions to final distributors that currently seem to apply. Obviously, the legal ability of national distributors to attribute price reductions to retail channels is not questioned. The main concern of the proposed reform is to enable patients to tailor the available products to their individual needs, all the while guaranteeing price-awareness.

Key messages

- **Encouraging proper commercial practices among retailers can be done by establishing separate lump sum reimbursements for retail services and the cost of material.**
- **This system allows patients more freedom of choice and removes the current premium on unsound commercial practices.**

Proposal 3: all-inclusive lump sum

The “all-in” lump sum should cover expenses for retail services and cost of appliances. As a consequence, product prices include a mark-up for distributors. Overall lump sums could be determined based on prices including retail mark-ups for a combination of products for varying patient profiles. The specific organisation of this system with regard to periodicity, payment, credit transferability and higher lump sums for patients facing special needs could be designed in a similar way as set forth in proposal 2. It would seem logical to no longer define retail mark-ups as a set percentage of product value and to attribute a fixed sum per product for retail services.

This proposal has the advantage of requiring less administrative follow-up compared to the previous proposal though it should be noted an incentive is created for retailers to deliver low cost products in high volumes for a given overall lump sum. The fact that the type of appliances is chosen by ET therapists or other qualified practitioners in dialogue with patients should counteract this potential shortcoming.

Key message

- **Proposal 3 attributes an all-inclusive lump sums to patients, based on product prices that cover both the cost of appliances and the cost of retail services.**

Proposal 4: unchaining distribution

Taken into account a reinforcement of the role of the enterostomal therapy nurse and an increased patient choice towards those suppliers that offer most service and quality, the current rigid system of legally bound face-to-face supply by bandager or pharmacist can be optimized. Especially for chronic and stable ostomy patients, other delivery channels should be envisaged. The current chain of supply is costly, compared to the production price (cf. chapter III), and imposes several legal constraints. Direct-to-patient delivery by specialized retailers or postal delivery are certainly options to be considered. These systems are operational or are starting to emerge in neighbouring countries (see also chapter V). Paramount for these alternative delivery channels is that prescription (brand choice) and supply are separated and that clear conditions on the logistic level are imposed (service level agreement) : e.g. 24 hours patient help desk, sufficient supply, maximum delivery time, specialized personnel. Those involved in brand choice, should supply all major brands available on the Belgian market.

The increase in delivery channels will increase competition between suppliers, specifically on the level of patients' service and satisfaction and timely delivery of ostomy products. This, in theory, should lead to a market concentration towards highly specialised bandagers, pharmacists or other suppliers.

Key message

- Taking the lead of foreign examples, legal conditions for distributors should be redirected to the service level they provide as a retailer.

Table 5: overview of various proposals for price transparency

Proposal 1: Tendering	
What? Setting up a tender for hospital appliances	
Why? Providing a firm incentive for competitive price setting	
<p>Proposal 2: Seperate Lump sums (3-monthly allowances)</p> <p>Proposal 2a: Lump sum for Services</p> <p>What? Lump sum per patient for delivery service paid to provider</p> <p>Why? Taking away negative commercial incentives with providers</p> <p>Proposal 2b: Lump sum for Appliances</p> <p>What? Lump sum per patient for appliances paid to provider</p> <p>Why? Ensuring price-aware patient choice, Inducing price competition</p>	<p>Proposal 3: All-in Lump sum</p> <p>What? Lump sum per patient for delivery service and appliances paid to provider</p> <p>Why? Easier follow-up, sufficient price competition should be induced by patient choice</p>
Proposal 4: Distribution	
What? Loosening constraints on direct delivery	
Why? Bringing down unneeded cost in distribution	

(dashed lines concern modular options, full lines concern mutually exclusive proposals)

6.3.3. Empowering all stakeholders

Currently, only bandagers and sickness funds participate in the decision making process. As demonstrated by our research (cf. supra), both have vested interests in the supply chain of ostomy products. Theoretically, there is also a higher risk of market consolidation. Other major stakeholders have no formal role, not even an observational one, in the decision making process.

The complaints patients' associations express are tantamount to a plea for empowerment:

- Tailorizing the provision of appliances to their individual needs,
- Gaining access to clear and unbiased information,
- Acknowledgement as a prominent stakeholder.

By having patients dispose of their allowance and emphasizing the availability of clear and unbiased sources of information the first two of the above points are addressed. Moreover, patients' associations should be recognized as valuable stakeholders. Decisions regarding the availability and reimbursement of ostomy appliances on the Belgian market will gain in transparency and in patient satisfaction with prior counselling and more active participation of patients' associations in the decision process.

The outline and content of information packages presented to patients leaving the hospital should be discussed and decided upon both by associations of therapists and patients. Patient organisations, together with associations of ET therapists should, also be counselled in the composition of appliance profiles that determine the amount of lump sums. These appliance profiles should be made publicly available so patient scrutiny can fully be guaranteed.

The industry of ostomy products on the other hand now undoubtedly has many informal contacts with individuals involved in the decision taking but lack a formal and especially publicly more transparent way of communication, rendering them more accountable. Therefore industry officials should at least be allowed an observational role in the existing committees.

Key message

- **To assure a more representative and transparent decision process, patients, ET therapists and the industry should be allowed a more prominent role.**

6.3.4. Data Requirements

The various proposals presented by researchers entail various requirements regarding available data:

- Setting up a lump sum for the cost of appliances, would require the introduction of RIZIV-INAMI codes for different patient profiles (e.g. patient with ureterostomy/colostomy/ileostomy, patients requiring an increased lump sum). It is very likely that the number of newly introduced codes will be less than the current number of codes for appliances.
- Relevant products should be linked on annual basis to various patient profiles by RIZIV-INAMI. These lists would then be used by health insurance funds (this is comparable to the current system of limitative lists).
- The number of three-monthly appliances lump sums will indicate the number of retail service lump sums respective distributors are entitled to. These retail lump sums can be referred to by a single reimbursement code.

As RIZIV-INAMI does not dispose of data on actual patient numbers linked to reimbursement codes on a regular basis nor of reimbursement data linked to detailed product specifications, the task of controlling the system's effectiveness should be trusted to health insurance funds (as is currently the case). The necessity to control whether individual patients do not surpass their lump sums (on an annual basis) could imply an increase of administrative efforts on the part of sickness funds.

Key messages

- **Data requirements resulting from the various proposals are similar to existing ones and will diminish the number of needed reimbursement codes.**
- **Controlling whether individual appliances lump sums are not exceeded will require an extra administrative effort.**

7. VALIDATION

The methodology applied in the report for chapter I to chapter V was assessed by three external validators. Their main comments concerned the necessity to:

- clarify the report's scope, emphasizing the analysis of cost factors and regulatory factors and dealing with medical effectiveness only to a lesser extent;
- univocally distinguish the various monetary aggregates: government reimbursement, either for ambulatory or hospital care, patient's out-of-pocket payments, various taxes, etc;
- univocally distinguish factor(coefficient), mark-up and margin in the analysis of price data;
- limit the content of technical analyses (literature research, cost/price analysis, regulatory analysis) to reporting the applied methodology and ensuing findings. Policy recommendations should be reserved to the final chapter.

All of the above points of interest were taken into consideration in the final report.

8. ANNEXES

ANNEXES CHAPTER I

SELECTED NOMENCLATURE CODES: 1 AND 2 PIECE POUCHING APPLIANCES FOR OSTOMY PATIENTS, OFFICIAL LABELS (DUTCH AND FRENCH) AND TRANSLATED CODE LABELS (TRANSLATION SUGGESTED BY KCE).

N-CODE	OFFICIAL DUTCH LABELS	OFFICIAL FRENCH LABELS	ENGLISH LABELS (TRANSLATION BY KCE)
640275	Stomamateriaal Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel Opvangsystemen Eéndelig systeem Gesloten, Zelfklevend opvangzakje, voorzien van een peristomale beschermlaag, ongeacht de bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere systemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentie-systemen Lijst 0275	Matériel pour stomie Système de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en une partie Collecteur, adhésif fermé muni d'une couche protectrice péristomale, quels que soient les accessoires Dotation : 1. 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes 2. 90 pièces/3 mois, si utilisé en combinaison avec d'autres systèmes collecteurs ou de continence Liste 0275	Ostomy Appliances - Appliances for colostomies and/or ileostomies and bowel fistulae - Retainer Appliances - One piece appliance - Closed, Cleaving pouch, peristomal protective layer, regardless of complimentary attributes. Allowance: 1. 180 items/3 months, if not applied in combination with other appliances 2. 90 items/3 months, if applied in combinations with other appliances List 0275
640290	Stomamateriaal Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel Opvangsystemen Eéndelig systeem Ledigbaar zelfklevend opvangzakje voorzien van een peristomale beschermlaag, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/3 maanden Lijst 0290	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en une partie Collecteur adhésif à vider mini d'une couche protectrice péristomale, quels que soient les autres accessoires Dotation : 90 pièces/3 mois Liste 0290	Ostomy Appliances - Appliances for colostomies and/or ileostomies and bowel fistulae - Retainer Appliances - One piece appliance - emptiable cleaving pouch with peristomal protective layer, regardless of complimentary attributes Allowance: 90 items/3 months List 0290
640371	Stomamateriaal Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel Opvangsystemen Tweedelig systeem : Peristomale beschermring met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden (ileostomie) 35 stuks/3 maanden (colostomie) Lijst 0371	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en deux parties Disque protecteur péristomal avec système de fixation (par exemple anneau-clip), quels que soient les autres accessoires Dotation : 45 pièces/3 mois (iléostomie) 35 pièces/3 mois (colostomie) Liste 0371	Ostomy Appliances - Appliances for colostomies and/or ileostomies and bowel fistulae - Retainer Appliances - Two piece appliance - Peristomal protective flange with attachment (eg clicking ring), regardless of complimentary attributes Allowance: 45 items/3 months (ileostomy) 35 items/3 months (colostomy) List 0371
640393	Stomamateriaal Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel Opvangsystemen Tweedig systeem : Gesloten zakje met bevestigingssysteem (bv. oplilring), ongeacht de overige bijbehorende produktattributen Dotatie : 1. 180 stuks/3 maanden, indien niet gebruikt in combinatie met andere opvang- of continentie-systemen 2. 90 stuks/3 maanden, indien gecombineerd gebruikt met andere opvang- of continentiesystemen Lijst 0393	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Systèmes collecteurs Système en deux parties : Poche fermée avec système de fixation (par exemple anneau-clip), quels que soient les autres accessoires Dotation : 1. 180 pièces/3 mois, si pas utilisé en combinaison avec d'autres systèmes collecteurs ou de continence 2. 90 pièces/3 mois, si utilisé en combinaison avec d'autres systèmes collecteurs ou de continence Liste 0393	Ostomy Appliances - Appliances for colostomies and/or ileostomies and bowel fistulae - Retainer Appliances - Two piece appliance - closed pouch with attachment (e.g. clicking ring), regardless of complimentary attributes Allowance: 1. 180 items/3 months, if not applied in combination with other appliances 2. 90 items/3 months, if applied in combinations with other appliances List 0393

86	HTA Matériel de Stomie		KCE reports vol. 21A
640415	Stomamateriaal Verzorgingssystemen voor colostomie en/of ileostomie en fistels van het darmstelsel Opvangsystemen Tweedelig systeem : Ledigbaar zakje met bevestigingssysteem (bv. opklikring) voorzien van een sluitklem, ongeacht de overige bijbehorende produktattributen Dotatie : 90 stuks/maanden Lijst 0415	Matériel pour stomie Systèmes de soins pour colostomie et/ou iléostomie et fistules du système intestinal Système en deux parties : Poche à vider avec système de fixation (par exemple anneau-clip) muni d'une agrafe de fermeture, quels que soient les autres accessoires Dotation : 90 pièces/3 mois Liste 0415	Ostomy Appliances - Appliances for colostomies and/or ileostomies and bowel fistulae - Retainer Appliances - two piece appliance - emptiable pouch with attachment (eg ring) and fastening clip, regardless of complimentary attributes Allowance: 90 items/3 months List 0415
640872	Stomamateriaal Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen Tweedelig systeem Peristomale beschermerschijf, voorzien van een bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 0872	Matériel pour stomie Systèmes de soins pour urétérostomie et/ou cystostomie et fistules des voies urinaires Disque protecteur péristomal muni d'un système de fixation (par ex. anneau-clip), quiles que soient les autres accessoires Dotation : 45 pièces/3 mois Liste 0872	Ostomy Appliances - Appliances for urostomies and/or cystostomies and urinal tract fistulae - Two piece appliance - Peristomal protective flange with attachment (eg clicking ring), regardless of complimentary attributes Allowance: 45 items/3 months (ileostomy) List 0872
640894	Stomamateriaal Verzorgingssystemen voor ureterostomie en/of cystostomie en fistels van de urinewegen Tweedelig systeem Ledigbaar urine-opvangzakje met bevestigingssysteem (bv opklikring) en antirefluxklep, ongeacht de overige bijbehorende produktattributen Dotatie : 60 stuks/3 maanden Lijst 0894	Matériel pour stomie Systèmes de soins pour urétérostomie et/ou cystostomie et fistules des voies urinaires Système en deux parties Collecteur d'urine à vider avec système de fixation (par ex anneau-clip) et valve anti-reflux, quels que soient les autres accessoires Dotation : 60 pièces/3 mois Liste 0894	Ostomy Appliances - Appliances for urostomies and/or cystostomies and urinal tract fistulae - Two piece appliance - emptiable urine pouch with attachment (eg ring) and anti-reflux valve, regardless of other complimentary attributes Allowance: 60 items/3 months List 0894
641351	Stomamateriaal Verzorgingssystemen voor uitzonderlijke toestanden bij stomiekuil minstens 1 cm diep ligt, in ruglithouding gemeten : Tweedelig systeem Convexe peristomale beschermerschijf met een minimum plaatdikte van 3 mm in het centrum, met bevestigingssysteem (bv. opklikring), ongeacht de overige bijbehorende produktattributen Dotatie : 45 stuks/3 maanden Lijst 1351	Matériel pour stomie Systèmes de soins pour situation exceptionnelle en cas de stomie et/ou fistules des voies urinaires et du systèmes intestinal Pour stomies rentrées, où la base de la fosse de la stomie a au moins 1 cm de profondeur, mesurée en position dorsale : Système en deux parties Plaque protectrice péristomale convexe, avec une épaisseur minimale de la plaque de 3 mm au centre avec système de fixation (p ex. anneau-clip) quels que soient les autres accessoires Dotation : 45 pièces/3 mois Liste 1351	Ostomy Appliances - Appliances for exceptional conditions, ostomy retraction of at least 1 cm, measured in backward position - two piece appliance - Convex peristomal protective flange with minimal thickness of 3 mm at centre, attachment (eg ring), regardless of other complimentary attributes Allowance: 45 items/3 months List 1351

REPRESENTATIVE PRODUCTS FOR THE BELGIAN MARKET (CORRESPONDING TO THE OUTLINED PRODUCT SCOPE, AS REPORTED BY NATIONAL DISTRIBUTORS).

BBRAUN®

I. Eendelige systemen	Colo	Ileo	Uro
Nomenclatuur	640275	640290	niet voorzien in de scope van het project
Omschrijving	Eendelig / gesloten / colo - ileo	Eendelig / open / colo - ileo	
Code	BB02	BB09	
Categorie	B	B	
Identificatie	Crysalis Quiétude	Almays Preference Ileo (2 alternatieven in de lijst)	
Prijs verstrekker 2005	1,7407	2,5737	
2. Tweedelige systemen			
A. Zakjes			
Nomenclatuur	640393	640415	640894
Omschrijving	Gesloten zakje met bevestigingssysteem	Ledigbaar zakje met bevestigingssysteem	Ledigbaar urine opvangzakje met bevestigingssysteem
Code	BB01	BB04	BB01
Categorie	B	B	B
Identificatie	System 2 Colo zakjes	Almays Twin Ileo + filter	System 2 zakjes
Prijs verstrekker 2005	1,0347	1,0783	2,127
B. Beschermpaten			
Nomenclatuur	640371		640872
Omschrijving	Peristomale bescherschijf met bevestigingssysteem		Peristomale bescherschijf voorzien van een bevestigingssysteem
Code	BB01		BB04
Categorie	B		B
Identificatie	System 2 platen (1 alternatief) (Twin platen genomen onder cat 640872)		Almays twin platen
Prijs verstrekker 2005	4,024		4,008
C. Convexe beschermpaten			
Nomenclatuur	641351		
Omschrijving	convexe peristomale bescherschijf		
Code	BB01		
Categorie	B		
Identificatie	Systeem 2 convex		
Prijs verstrekker 2005	5,338		

COLOPLAST®

I. Eendelige systemen	Colo	Ileo	Uro
Nomenclatuur	640275	640290	niet voorzien in de scope van het project
Omschrijving	Eendelig / gesloten / colo - ileo	Eendelig / open / colo - ileo	
Code	BL 05	BL 06	
Categorie	B	B	
Identificatie	Alternia free gesloten	Alternia free ileo + hide away sluiting	
Prijs verstrekker 2005	1,82	2,59	
2. Tweedelige systemen			
A. Zakjes			
Nomenclatuur	640393	640415	640894
Omschrijving	Gesloten zakje met bevestigingssysteem	Ledigbaar zakje met bevestigingssysteem	Ledigbaar urine opvangzakje met bevestigingssysteem
Code	BL06	CL 06	BL 02
Categorie	B	B	B
Identificatie	Alternia free gesloten	Alternia free ileo + hide away sluiting	Alternia uro zakje
Prijs verstrekker 2005	1,09	1,14	2,17
B. Beschermplaten			
Nomenclatuur	640371		
Omschrijving	Peristomale beschermplaat met bevestigingssysteem		
Code	BL 03		
Categorie	B		
Identificatie	Alternia plaat		
Prijs verstrekker 2005	4,25		
C. Convexe beschermplaten			
Nomenclatuur	641351		
Omschrijving	convexe peristomale beschermplaat		
Code	BL01		
Categorie	B		
Identificatie	Alternia convexe beschermplaat		
Prijs verstrekker 2005	5,63		

CONVATEC®

I. Eendelige systemen	Colo	Ileo	Uro
Nomenclatuur	640275	640290	niet voorzien in de scope van het project
Omschrijving	Eendelig / gesloten / colo - ileo	Eendelig / open / colo - ileo	
Code	BV 01	BV03	
Categorie	B	B	
Identificatie	Colodress plus	Ileodress plus TM	
Prijs verstrekker 2005	1,7 of BV11 Esteem TM gesloten (B) 1,7€	2,366 of BV07 Esteem TM open (B) 2,463 €	
2. Tweedelige systemen			
A. Zakjes			
Nomenclatuur	640393	640415	640894
Omschrijving	Gesloten zakje met bevestigingssysteem	Ledigbaar zakje met bevestigingssysteem	Ledigbaar urine opvangzakje met bevestigingssysteem
Code	BV 04	BV 08	BV 03
Categorie	B	B	B
Identificatie	Combihesive II S Colo WF comfort	Combihesive II S zakje met afvoer - transparant	Combihesive II S Uro stomazakje
Prijs verstrekker 2005	1,025 of BV 11 Esteem + synergy gesloten - klein transparant 1,08 €	1 of BV 14 (B) Esteem + synergy invisiclose standaard open zakje transparant 1,1 €	2,057 of BV 08 Consecura TM urostomazakjes + accusealkraantje (B) 2,057
B. Beschermplaten			
Nomenclatuur	640371		640872
Omschrijving	Peristomale beschermerschijf met bevestigingssysteem		Peristomale beschermerschijf voorzien van een bevestigingssysteem
Code	BV15		BV04
Categorie	B		B
Identificatie	Esteem synergy hydroflex, flexibele plaat met hydrocolloïden		Combihesive II S
Prijs verstrekker 2005	4,102		3,942
C. Convexe beschermplaten			
Nomenclatuur	641351		
Omschrijving	convexe peristomale beschermerschijf		
Code	BV02		
Categorie	B		
Identificatie	Combihesive II S Durahesive convex		
Prijs verstrekker 2005	5,274 of BV03 Esteem + synergy TM Durahesive kneedbare convexe plaat (B) 5,824€		

HOLLISTER-DANSAC®

		Colo	Ileo	Uro
1-delig		Moderma Flex	Moderma Flex	Compact
2-delig	Zakjes	Conform 2	Conform 2	Tandem
	Platen	Conform 2	Conform 2	Tandem

ANNEXES CHAPTER III: SURVEY ON PRODUCTION OF OSTOMY APPLIANCES

This questionnaire is focused on stoma appliances

Market information

1. What is the importance of stoma appliances for your company?

..... % of turn-over

..... % of personnel involved

2. How would you classify your production type?

..... % of production is tailor-made, answering specific client needs

..... % of production is standard production

3. What is your market share in the following countries?

Belgium:%

Denmark:%

France:%

Italy:%

Netherlands:%

United Kingdom:%

4. Cost structure: Could you give us an indication on the importance of the different elements of the production cycle for stoma appliances?

- Please indicate these as an average % of the total production cost.
- Detailed information on representative products of the indicated categories can be added in the following columns.
- Please specify the name of these products.

*** Research & Development**

5. Can you give us an indication on the following R&D matters concerning stoma applications?

- Budget for R&D activities. (% of turn-over)

- Number of people directly involved in R&D activities

- Number of “patents” related to stoma appliances for your company

- What is the average development time for stoma appliances at your company (e.g. time passing before an innovative product for an existing pathology will be launched?)

- What share of research projects is successful and leads to beneficial commercialisation? (%)

**** Raw material**

6. Can you list the raw materials (plastic film, non-woven, sealing, flange, filter, adhesive,...) with the highest impact on the total material cost, and indicate their share of total material cost?
Please apply for the most representative products

One piece colostomy product: _____

Two piece colostomy product (bag): _____

One piece ileostomy product:

Two piece ileostomy product (bag): _____

Two piece colostomy / ileostomy products (plate) : _____

Two piece colostomy / ileostomy products (convex plate):

***** Manufacturing process**

7. Production sites, operated by your company, are located in following countries

8. Can you give us an indication on the following aspects?

- Number of persons directly involved in the manufacturing process
- Volume of products (e.g. pieces / year)

	Overall (stoma appliances)	Representative product colostomy One piece	Representative Product Colostomy Two piece Bag	Representative Product Ileostomy One piece	Representative Product Ileostomy Two piece Bag	Representative Product Colo / ileo Two piece Plate	Representative Product Colo / ileo Two piece Convex plate
Product name							
Number of persons directly involved in the manufacturing process							
Volume of products (e.g. pieces / year)							

9. The production process can be characterised, from a costing point of view, as

- Mainly capital intensive
 Mainly labour intensive
 Both (capital and labour intensive)

Please, specify your choice

10. Production is organised as follows:

- Specialised approach: focus on a limited number of production steps/product components at one site
 Integrated approach: production of complete products at one site (all production steps)
 Integrated approach for the complete product range: all products are manufactured at each site

11. Manufacturing equipment is:

- Mainly developed with internal engineering department
 Mainly standard equipment
 Mix of both, in a sense that standard machines are purchased, but system integration and adaptation is done internally (engineering)
 Other, please describe if relevant

12. Can you list your typical production steps, and check the relevant boxes?

- Give a short description (function addressed) of each production step.
- Indicate what manufacturing equipment (machine) is used.
- Indicate its capacity (e.g. pieces /hour).
- Check the relevant boxes (IA= In house activity; OA= Outsourced activity; LI= Labour Intensive; CI= Capital Intensive).

For standard production:

	description / function	manufacturing equipment	capacity	IA	OA	LI	CI
step 1				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 2				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 3				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 4				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 5				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

step 6			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 7			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 8			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 9			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 10			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For tailor-made production: (if applicable)

	description / function	manufacturing equipment	capacity	IA	OA	LI	CI
step 1				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 2				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 3				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 4				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 5				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 6				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 7				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 8				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 9				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
step 10				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. We received some indication on different price levels per country in which Belgium has a low ranking.

What is the minimum mark-up above net manufacturing costs (direct labour + material cost) to guarantee sustainable activity for the product & development function of the company?

ANNEXES CHAPTER IV: RESULTS FOR INTERNATIONAL PRICE COMPARISON

Table 1: Reference product list Belgium

		product name	patient price
1-piece systems			
Colostomy			
1	A-products		2,62 €
2	BBraun	Crysalis Quiétude	2,85 €
3	Coloplast	Alternia Free closed	2,98 €
4	Convatec	Colodress plus	2,79 €
5	Hollister	Moderma Flex	2,80 €
Ileostomy			
1	A-products		3,57 €
2	BBraun	Almarys Preference Ileo	4,22 €
3	Coloplast	Alternia free ileo + hide away closure	4,25 €
4	Convatec	Ileodress plus TM	3,88 €
5	Hollister	Moderma Flex Ileo	3,96 €
2-piece pouches			
Colostomy			
1	A-products		1,57 €
2	BBraun	System 2 Colo pouches	1,70 €
3	Coloplast	Alternia free closed	1,79 €
4	Convatec	Combihesive II S Colo WF comfort	1,68 €
5	Hollister	Conform 2 Colo	1,69 €
Ileostomy			
1	A-products		1,54 €
2	BBraun	Almarys Twin Ileo + filter	1,77 €
3	Coloplast	Alternia free ileo + hide away closure	1,87 €
4	Convatec	Combihesive II S zakje with drainage - transparant	1,64 €
5	Hollister	Conform 2 Ileo	1,72 €
Ureterostomy			
1	A-products		3,17 €
2	BBraun	System 2	3,49 €
3	Coloplast	Alternia uro	3,56 €
4	Convatec	Combihesive II S Uro	3,37 €

5	Hollister	Conform 2 Uro	3,38 €
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2-piece plates

1	A-products		6,05 €
2	BBraun	System 2	6,60 €
3	Coloplast	Alterna	6,97 €
4	Convatec	Esteem synergy hydroflex	6,73 €
5	Hollister	Conform 2	6,48 €

2-piece convex plates

1	A-products		8,11 €
2	BBraun	Systeem 2 convex	8,75 €
3	Coloplast	Alterna convex plate	9,23 €
4	Convatec	Combihesive II S Durahesive convex	8,65 €
5	Hollister	Conform 2 Convex	8,70 €

Source: RIZIV-INAMI limitative lists 01/01/2005

Table 2: Product selection Denmark

	reference products Belgium				selection Denmark		other products Belgium				hypothesis Belgium			
	product name	patient price	CI	C2	product name	price	product name	patient price	CI	C2	product name	patient price	CI	C2
I-piece systems														
Colostomy														
BBraun					Almays Optima	3,18 €	Almays Optima	2,81 €	-13%	14%				
Coloplast					Assura Plus	4,29 €					Alterna Free closed	2,98 €	-44%	-10%
Convatec	Colodress plus	2,79 €	-59%	-22%	Colodress plus	4,45 €								
Hollister	Moderma Flex	2,80 €	-76%	-34%	Moderma Flex	4,93 €								
Ileostomy														
BBraun					Almays Optima	3,90 €	Almays Optima	4,01 €	3%	26%				
Coloplast					Assura	6,36 €					Alterna Open	4,13 €	-54%	-17%
Convatec	Ileodress plus TM	3,88 €	-63%	-24%	Ileodress Plus	6,33 €								
Hollister	Moderma Flex Ileo	3,96 €	-76%	-35%	Moderma Flex Ileopose	6,98 €								
2-piece bags														
Colostomy														
BBraun	System 2 Colo pouches	1,70 €	10%	32%	System 2	1,52 €								
Coloplast					Assura	2,19 €					Alterna free closed	1,79 €	-23%	6%
Convatec					Combihesive II Plus	1,93 €					Combihesive II S Colo WF comfort	1,68 €	-15%	12%
Hollister	Conform 2 Colo	1,69 €	-29%	1%	Conform 2 colostomipose	2,18 €								

Table 3: Comparison based on reimbursement for France

	France	Belgium		
	reimbursement	reimbursement	C1	C2
1-piece systems				
Colostomy				
Selection of products	2,50 €	2,62 €	4%	7%
Ileostomy				
Selection of products	3,37 €	3,57 €	6%	8%
2-piece bags				
Colostomy				
Selection of products	1,52 €	1,57 €	3%	6%
Ileostomy				
Selection of products	2,39 €	1,54 €	-55%	-51%
Urostomy				
Selection of products	3,87 €	3,17 €	-22%	-19%
2-piece plates				
Selection of products	3,67 €	6,05 €	39%	41%
2-piece convex plates				
Selection of products	5,18 €	8,11 €	36%	38%

Table 4: Selected products the Netherlands

reference products Belgium				selection Netherlands			other products Belgium				hypothesis			
product name	patient price	CI	C2	product name	Z-index	product name	patient price	CI	C2	product name	patient price	CI	C2	
I-piece systems														
Colostomy														
Eurotec				Eurotec: Ostomate Colozak ID medium	3,97 €	Eurotec: Ostomate Colostomiezakjes	2,62 €	-52%	-50%					
BBraun				Preference colozak wit + filt	5,68 €	Preference	2,85 €	-99%	-97%					
				Almays Quiet colozak	5,23 €	Almays Quiet	2,85 €	-83%	-82%					
Coloplast				Assura Colozak ID	4,37 €					Alterna Free closed	2,98 €	-46%	-45%	
Convatec	Colodress plus	2,79 €	-69%	-68%	Colodress plus	4,73 €								
Hollister	Moderma Flex	2,80 €	-91%	-89%	Modermaflex Colozak Beige	5,35 €								
Welland				Welland: Liberty Colozak	5,04 €									
Ileostomy														
Eurotec				Eurotec: Ostomate Ileozak ID medium	4,70 €	Eurotec: Ostomate Ileostomiezakjes	3,57 €	-32%	-30%					
BBraun	Almays Preference Ileo	4,22 €	-33%	-31%	Almays Preference Ileozak	5,60 €								
Coloplast				Assura Ileozak ID midi	7,16 €					Alterna Open	4,13 €	-73%	-72%	
Convatec	Ileodress plus TM	3,88 €	-104%	-102%	Ileodress Plus	7,93 €								
Hollister	Moderma Flex Ileo	3,96 €	-114%	-112%	Modermaflex Ileo	8,49 €								
Welland				Welland: Liberty Ileozak	6,73 €									
2-piece bags														
Eurotec				Eurotec: Combimate Colozak medium	2,45 €					Eurotec: Ostomate Colostomiezakjes	1,57 €	-56%	-54%	
BBraun	System 2 Colo pouches	1,70 €	-52%	-50%	System 2 Colozak	2,58 €								
Coloplast				Assura Colozak 2D midi	2,25 €	Alterna Colozakje	1,79 €	-26%	-25%					
Convatec				Esteem Synergy Colozak KL + F beige	2,46 €	Esteem + Synergy gesloten klein opaak	1,77 €	-39%	-38%					
Hollister	Conform 2 Colo	1,69 €	-53%	-52%	Conform 2 Colozak Beige	2,59 €								

	reference products Belgium				selection Netherlands		other products Belgium				hypothesis			
	product name	patient price	CI	C2	product name	Z-index	product name	patient price	CI	C2	product name	patient price	CI	C2
Welland					Welland Liberty Colozak 2D Beige	2,49 €	Welland: Liberty 2	1,57 €	-58%	-57%				
Eurotec					Eurotec: Combimate Ileozaak medium	2,45 €					Eurotec Ostomate Ileozaakzakjes	1,54 €	-59%	-57%
BBraun	Almarys Twin Ileo + filter	1,77 €	-39%	-37%	Almarys Twin Ileozaak	2,45 €								
Coloplast					Assura Ileozaak 2D midi	2,25 €	Alterna Ileozaakje	1,87 €	-20%	-19%				
Convatec					Esteem Synergy invis Ileozaak ST+F T R	3,46 €	Esteem +Synergy Invisiclose standaard open zakje transparant	1,80 €	-92%	-90%				
Hollister	Conform 2 Ileo	1,72 €	-77%	-75%	Conform 2 Ileozaak Beige Filter	3,05 €								
Welland					Welland Liberty Ileozaak 2D Beige	2,48 €	Welland Liberty 2	1,54 €	-61%	-59%				
Eurotec					Eurotec: Urozaak Large Transparant Overlap	4,91 €	Eurotec: urostomiezaakjes	3,17 €	-55%	-54%				
BBraun	System 2	3,49 €	-62%	-60%	System 2 Urozaak	5,65 €								
Coloplast	Alterna uro	3,56 €	-30%	-29%	Assura Urozaak 2D	4,64 €								
Convatec					Natura Urozaak Stand Transparant	4,40 €					Combihesive II S Uro	3,37 €	-30%	-29%
Hollister	Conform 2 Uro	3,38 €	-47%	-45%	Conform 2 Urozaak Beige	4,96 €								
2-piece plates														
Eurotec					Eurotec: Combimate Flex / Hydrocolloid plak	7,89 €	Eurotec: Ostomate Flexibele plakken	6,05 €	-30%	-29%				
BBraun	System 2	6,60 €	-24%	-23%	System 2	8,21 €								
Coloplast	Alterna	6,97 €	-21%	-20%	Assura	8,41 €								
Convatec	Esteem synergy hydroflex	6,73 €	-42%	-40%	Esteem synergy hydroflex	9,53 €								
Hollister	Conform 2	6,48 €	-29%	-28%	Conform 2	8,36 €								
Welland					Welland: Liberty Huidplak	8,75 €	Welland: Liberty 2	6,05 €	-45%	-43%				

reference products Belgium				selection Netherlands		other products Belgium				hypothesis			
product name	patient price	CI	C2	product name	Z-index	product name	patient price	CI	C2	product name	patient price	CI	C2
2-piece convex plates													
BBraun				Almarys Twin convex	14,13 €	Almarys Twin Convex	8,75 €	-61%	-60%				
Coloplast	Alterna convex plate	9,23 €	-64%	-62%	Assura Convex	15,11 €							
Convatec				Esteem Synergy Hdpl Flex Conv W KN	17,23 €	Esteem + Synergy Durahesive kneedbare convexe plaat	9,55 €	-80%	-79%				
Hollister	Conform 2 Convex	8,70 €	-75%	-73%	Conform 2 Convex	15,21 €							

Table 5: Product selection United Kingdom

	reference products Belgium				selection United Kingdom			other products Belgium				hypothesis Belgium			
	product name	patient price	CI	C2	product name	price	product name	patient price	CI	C2	product name	patient price	CI	C2	
1-piece systems															
Colostomy															
Welland	Welland: Impact	2,62 €	-35%	-30%	Welland: Impact	3,54 €									
BBraun					Elite bag with filter, skin protector adhesive, fabric backing	3,48 €					Crysalis Quiétude	2,85 €	-22%	-17%	
Coloplast					Assura Closed Bag	3,65 €	Alternia gesloten	2,98 €	-22%	-17%					
Convatec	Colodress plus	2,79 €	-28%	-23%	Colodress Plus	3,56 €									
Hollister					Compact	3,62 €					Moderma Flex	2,80 €	-29%	-24%	
Ileostomy															
Welland					Welland: FreeStyle	4,14 €					Welland Freeform Ileo	3,57 €	-16%	-11%	
BBraun					Elite bag with skin protector adhesive and fabric backing (transparent)	3,55 €					Almays Preference Ileo	4,22 €	16%	19%	
Coloplast					Assura Drainable Bag	3,69 €	Alternia Open	4,13 €	11%	14%					
Convatec					Esteem Drainable Pouches with Integral Filter and Invisiclos Outlet	4,15 €	Esteem TM ééndeig invisiclose opaak en transparant	4,04 €	-3%	1%					
Hollister	Moderma Flex Ileo	3,96 €	8%	12%	Moderma Flex	3,62 €									
2-piece bags															
Colostomy															
Welland					Welland: Silhouette 2 closed pouch	1,73 €					Welland: Liberty 2 of Assist	1,57 €	-10%	-6%	
BBraun					Almays Twin Closed Bag with filter	1,80 €	Almays Twin Colo	1,70 €	-6%	-2%					
Coloplast					Assura Closed Bags	2,01 €					Alternia free closed or Alternia Colozakje	1,79 €	-12%	-8%	
Convatec					Combihesive Natura - Closed Pouch with filter - standard size	1,84 €					Combihesive II S Colo WF comfort	1,68 €	-9%	-5%	
Hollister	Conform 2 Colo	1,69 €	-3%	1%	Conform 2 Closed Pouch	1,74 €									
Ileostomy															
Welland					Welland: Silhouette 2 drainable pouch	1,76 €					Welland: Liberty 2 of Assist	1,54 €	-14%	-10%	
BBraun					Assura Drainable bag with filter	1,79 €					Almays Twin Ileo + filter	1,77 €	-1%	3%	
Coloplast					Assura Inspire with Hide-away outlet	2,17 €					Alternia free ileo + hide away closure	1,87 €	-16%	-12%	

ANNEXES CHAPTER V: SURVEY FORMS (ENGLISH AND FRENCH VERSION)

INSTITUTIONAL SETTING OF THE STOMA APPLIANCE MARKET:

Questionnaire

Instructions: Please respond to questions electronically. You can move forward through the main body of the questionnaire by pressing "Tab" and backwards by pressing "Shift + Tab", or you can use the scroll feature and the mouse. Boxes can be ticked and ticks can be removed by double-clicking the mouse.

IDENTIFICATION

COUNTRY NAME:	
----------------------	--

CONTACT DETAILS FOR THE PERSON COMPLETING THE FORM

Name:	
Title:	
Institution:	
Address:	
Country:	
Telephone:	
Fax:	
Email:	

CORRESPONDENCE ADDRESS:

Steven Simoens
 Centre for Drug and Patient Information
 Faculty of Pharmaceutical Sciences
 Katholieke Universiteit Leuven

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 3000 Leuven
 Belgium

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 Fax: +32-(0)16/32.34.68.
 E-mail: steven.simoens@pharm.kuleuven.ac.be

SECTION 1. PRICING OF STOMA APPLIANCES

1.1	Describe the mechanism by which prices of stoma appliances are set:	
.a	Public procurement at national level:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
	If "Yes", describe system of tendering:	
.b	Public procurement at regional/local level:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
	If "Yes", describe system of tendering:	
.c	National list of stoma appliance tariffs:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
	If "Yes", specify name of national list:	
.d	Regional list of stoma appliance tariffs:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
	If "Yes", specify name of regional list:	
.e	Other (please specify):	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
1.2	Describe the principal bodies or agencies that are involved in price setting of stoma appliances:	
1.3	Is there a procedure for revising prices of stoma appliances on national/regional lists? <i>If "No", go to question 1.4</i>	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.a	If "Yes", describe which factors are taken into account when revising prices (e.g. change in production costs, evolution of price index):	
.b	Indicate how often prices are revised:	
1.4	Any additional comments on pricing system of stoma appliances:	

SECTION 2. REIMBURSEMENT OF STOMA APPLIANCES

2.1	Which third-party payer reimburses stoma appliances? <i>(tick appropriate box)</i>	National Health Service <input type="checkbox"/> Social insurance <input type="checkbox"/>
.b	Describe the process and decision criteria that are used for admitting a new stoma appliance to the system of third-party payer reimbursement:	
.c	Are there any restrictions on the number of stoma appliances per month that is reimbursed?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
	If "Yes", describe restrictions:	
.d	Specify the level of patient co-payments for stoma appliances in ambulatory setting:	
.e	Specify the level of patient co-payments for stoma appliances in hospital setting:	
2.2	Any additional comments on reimbursement system of stoma appliances:	

SECTION 3. DELIVERY CHANNELS

3.1	Describe principal bodies or agencies that distribute stoma appliances to patients:	
.a	Community pharmacies:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.b	Medical equipment shops:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.c	Domiciliary distributors:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.d	Health authorities:	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.e	Other (please specify):	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
3.2	Describe remuneration system for each type of distributor:	
.a	Community pharmacies:	
.b	Bandagers:	
.c	Domiciliary distributors:	
.d	Health authorities:	
.e	Other (please specify):	

3.3	Specify market share of each type of distributor:	
.a	Community pharmacies:	
.b	Bandagers:	
.c	Domiciliary distributors:	
.d	Health authorities:	
.e	Other (please specify):	
3.4	Any additional comments on delivery channels:	
SECTION 4. PRESCRIBING PROCESS		
4.1	Which party issues the first prescription? (<i>tick appropriate box</i>)	Specialist physician <input type="checkbox"/>
.a		Hospital stoma nurse <input type="checkbox"/>
		General practitioner <input type="checkbox"/>
.b	Prescriptions generally refer to stoma appliances by: (<i>tick appropriate box</i>)	Generic name (type of device) <input type="checkbox"/>
		Specific brand name <input type="checkbox"/>
.c	Does the general practitioner need to certify the needs of stoma patients after discharge from hospital?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
.d	Does the general practitioner need to renew prescriptions for stoma appliances?	Yes: <input type="checkbox"/> No: <input type="checkbox"/>
4.2	Any additional comments on prescribing process:	

PLEASE RETURN QUESTIONNAIRE BY E-MAIL
TO: STEVEN.SIMOENS@PHARM.KULEUVEN.AC.BE

CADRE INSTITUTIONNEL DU MARCHÉ POUR LE MATÉRIEL DE STOMIE:**Questionnaire**

Instructions: Veuillez répondre aux questions dans un format électronique. Vous pouvez parcourir le document en tapant « Tab » et revenir en arrière en tapant « Shift + Tab », ou vous pouvez utiliser la roulette de votre souris. Les cases peuvent être cochées et décochées par un double-clic gauche de la souris.

IDENTIFICATION

NOM DU PAYS:	
-------------------------	--

**COORDONNEES DE LA PERSONNE COMPLETANT LE
DOCUMENT**

Nom:	
Fonction:	
Organisation:	
Adresse:	
Pays:	
Numéro de Tel:	
Fax:	
Email:	

ADRESSE DE RETOUR:

Steven Simoens
Centre for Drug and Patient Information
Faculty of Pharmaceutical Sciences
Katholieke Universiteit Leuven

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Belgium

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E-mail: steven.simoens@pharm.kuleuven.ac.be

SECTION 1. PRIX DU MATERIEL DE STOMIE

1.1	Décrivez la façon dont le prix du matériel de stomie est établi:	
.a	Offre publique au niveau national:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
	Si "Oui", décrivez le système d'offre:	
.b	Offre publique au niveau régional/local:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
	Si "Oui", décrivez le système d'offre:	
.c	Liste nationale des tarifs relative au matériel de stomie:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
	Si "Oui", spécifiez la dénomination de la liste:	
.d	Liste régionale des tarifs relative au matériel de stomie :	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
	Si "Oui", spécifiez la dénomination de la liste régionale:	
.e	Autres (veuillez spécifier):	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
1.2	Décrivez les organismes principaux ou les agences impliqués dans l'établissement des prix du matériel de stomie :	
1.3	Existe-t-il une procédure pour revoir des prix de matériel de stomie repris dans des listes régionales/nationales? <i>Si "Non", continuez par 1.4</i>	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
.a	Si "Oui", décrivez les facteurs pris en compte lors des révisions des prix (p.e. changements dans les coûts de production, évolution des indices de prix,...) :	
.b	Indiquez la fréquence de changements de prix:	
1.4	Commentaires supplémentaires sur le système de prix du matériel de stomie:	

SECTION 2. REMBOURSEMENT DU MATERIEL DE STOMIE

2.1	Quel organisme tiers-payant rembourse le matériel de stomie? (cochez la case qui convient)	Service National de Santé <input type="checkbox"/> Sécurité Sociale <input type="checkbox"/>
.b	Décrivez le processus et les critères de décision d'application pour l'introduction d'un matériel de stomie nouveau dans le système de remboursement par un tiers-payant :	
.c	Y-a-t-il des limites aux quantités mensuelles de matériel de stomie remboursées?	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
	Si "Oui", décrivez ces restrictions:	
.d	Spécifiez le niveau de participation personnelle dans la facture pour le matériel de stomie pour un patient ambulatoire :	
.e	Spécifiez le niveau de participation personnelle dans la facture pour le matériel de stomie pour un patient hospitalisé :	
2.2	Commentaires supplémentaires sur le système de remboursement du matériel de stomie:	

SECTION 3. CIRCUITS DE DISTRIBUTION

3.1	Décrivez les organismes principaux ou des agences qui distribuent le matériel de stomie aux patients:	
.a	Pharmacies locales:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
.b	Magasins de matériel médical:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
.c	Fournisseurs à domicile:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
.d	Organismes publics de santé:	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>
.e	Autres (veuillez spécifiez):	Oui: <input type="checkbox"/> Non: <input type="checkbox"/>

3.2	Décrivez le système de rémunération pour chaque type de distributeur:	
.a	Pharmacies locales:	
.b	Bandagistes:	
.c	Distributeurs à domicile:	
.d	Organismes publics de santé:	
.e	Autres (veuillez spécifier):	
3.3	Spécifiez les parts de marché de chaque type de distributeur:	
.a	Pharmacies locales:	
.b	Bandagistes:	
.c	Distributeurs à domicile:	
.d	Organismes publics de santé:	
.e	Autres (veuillez spécifier):	
3.4	Commentaires supplémentaires sur les circuits de distribution:	

SECTION 4. PROCÉDURES DE PRESCRIPTION

4.1	Quelle personne ordonne la première prescription? (cochez la case qui convient)	Médecin spécialiste	<input type="checkbox"/>
.a		Infirmière clinique	<input type="checkbox"/>
		Médecin généraliste	<input type="checkbox"/>
.b	Des références au matériel de stomie dans la prescription en général concernent: (cochez las case qui convient)	Dénomination générique (type de matériel)	<input type="checkbox"/>
		Dénomination (de produit) spécifique	<input type="checkbox"/>
.c	Le médecin généraliste a-t-il l'obligation vérifier les besoins du patient stomisé après sa décharge de l'hôpital?	Oui: <input type="checkbox"/>	Non: <input type="checkbox"/>
.d	Le médecin généraliste a-t-il l'obligation de renouveler la prescription pour le matériel de stomie ?	Oui: <input type="checkbox"/>	Non: <input type="checkbox"/>
4.2	Commentaires supplémentaires sur les procédures de prescription:		

VEUILLEZ RENVoyer CE DOCUMENT PAR EMAIL A:
STEVEN.SIMOENS@PHARM.KULEUVEN.AC.BE

CONTACTS AND BACKGROUND WEBSITES

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Ministère des solidarités, de la santé et de la famille

Comité économique des produits de santé
Url : <http://www.sante.gouv.fr/ceps/>

French Agency for the Safety of Health Products
Url: <http://agmed.sante.gouv.fr/index.htm>

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Z-index
Url: <http://www.z-index.nl/frameset.htm>

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ANNEXES CHAPTER VI

Survey sent to bandagers: forms and data

ANNEX I: SURVEY FORM FOR BANDAGING COMPANIES

Alle gegevens worden vertrouwelijk en anoniem verwerkt en alleen aangewend voor deze studie.

Retouradres van deze enquête: Tav Dirk Van den Steen
Résidence Palace (10^{de} verdieping-10ième étage),
Wetstraat 155 Rue de la Loi,
B-1040 Brussel-Bruxelles

Bijkomende **inlichtingen**: e-mail: Dirk.VandenSteen@Kenniscentrum.fgov.be
tel: +32 (0)2 287 33 23
fax: +32 (0)2 287 33 85

1. Welke is de regio waar uw bedrijf gevestigd is (Vlaanderen of Brussel), wat is het aantal personeelsleden, hoeveel van deze personeelsleden hebben een erkenningsnummer als bandagist.

Regio: VL BL

	Aantal Personen	Aantal Erkenningsnummers
Zelfstandige zaakvoerder		
Zelfstandige vennoten		
Personeelsleden		

2. Verstrekking naar type materiaal. Gelieve aan te kruisen welk type materiaal u verstrekt/verstrekte voor de jaren 1995, 2000, 2005. Bedoeling is na te gaan of er een wijziging in uw productengamma opgetreden is het afgelopen decennium. Indien u een bepaald type materiaal niet verstrekt(e), vult u het cijfer "0" in. Indien uw zaak niet bestond op het bevroegde moment, kan u de kolom doorschrijven.

Type Materiaal	1995	2000	2005
Breukbanden			
Buikgordels			
Lumbostaten			
Materiaal na mammectomie			
Orthopedische zolen			
Materiaal voor mucoviscidose			
Tracheacanule			
Incontinentiemateriaal			
Stomamateriaal			
Invalidenwagentjes en toestellen voor hulp bij het lopen			

Indien u geen stomamateriaal verstrekt of verstrekt hebt voor de betrokken periode, eindigt de enquête bij deze vraag.

Indien u niet langer stomamateriaal verstrekt, maar wel verstrekt heeft in het afgelopen decennium, dient u enkel de toelichting bij vraag 5 verder te beantwoorden.

3. Stomamateriaal: aandeel type stomamateriaal. Gelieve bij benadering het type stomapatiënten (in functie van hun pathologie) weer te geven in percentage.

	Aandeel Patiënten (%)
Colostomie	
Ileostomie	
Ureterostomie	

4. Fabrikanten. Gelieve bij benadering het belang van de vernoemde fabrikanten in uw totale omzet van stomamateriaal (ééndelige en tweedelige systemen) weer te geven in percentage.

Verzorgingssystemen voor colostomie, ileostomie en ureterostomie: aandeel in verkoop (%)	
BBraun	
Coloplast	
ConvaTec	
Eurotec	
Hollister-Dansac (samengevoegd marktaandeel)	
Welland	
Overige fabrikanten	

5. Evolutie van de markt voor stomamateriaal. Gelieve aan te duiden hoe het aantal stomapatiënten dat u als klant heeft, geëvolueerd is het laatste decennium. U kan het corresponderende vak (toename/afname) aankruisen. Indien u de wijziging in aantal patiënten bij benadering percentueel kan inschatten, mag u het percentage in kwestie invullen.

Indien mogelijk, gelieve deze evolutie toelichten.

Aantal Stomapatiënten	Situatie in 2005 ten opzichte van	
	1995	2000
Toename (%)		
Afname (%)		

Eventuele Toelichting:

.....

.....

.....

.....

.....

Toutes les données seront traitées de manière confidentielle et anonyme et leur usage sera purement limité à cette étude.

Adresse de renvoi : A l'attention de Dirk Van den Steen
 Résidence Palace (10^{de} verdieping-10ième étage),
 Wetstraat 155 Rue de la Loi,
 B-1040 Brussel-Bruxelles

Informations supplémentaires : e-mail: Dirk.VandenSteen@Kenniscentrum.fgov.be
 tel: +32 (0)2 287 33 23
 fax: +32 (0)2 287 33 85

1. Quelle est la région où se situe votre entreprise (la Wallonie ou Bruxelles), quel est le nombre de membres du personnel, combien d'entre eux disposent d'un numéro d'agrément comme bandagiste ?

Région: WA BXL

	Nombre de Personnes	Nombre de numéros d'agrément
Gérant indépendant		
Associés indépendants		
Membres du personnel		

6. Type de matériel. Veuillez cocher la case / les cases qui conviennent concernant le type de matériel que vous avez distribué pour les années 1995, 2000, 2005 (situation 1^{er} janvier). De cette façon nous pourrions vérifier si votre gamme de produits a changé durant la dernière décennie. Si certains type de matériel ne font/faisaient pas partie de votre gamme, vous pouvez remplir les cases avec un chiffre «0». Si votre société n'était pas encore opérationnelle au moment en question, vous pouvez barrer la colonne correspondante.

Type de Matériel	1995	2000	2005
Bandages pour hernie			
Ceintures abdominales			
Lombostats			
Appareillages après mammectomie			
Semelles orthopédiques			
Matériels en cas de mucoviscidose			
Canules Trachéales			
Matériels pour incontinence			
Matériels pour stomie			
Voitures d'invalides et appareils d'aide à la marche			

.....
.....
.....
.....

Survey Addressees: region, response rate, sales rate for ostomy products

QUESTIONNAIRE	VL	WA	BXL	TOTAL
SENT	55	17	9	81
RESPONSE	22	7	3	32
OSTOMY PRODUCTS	15	4	2	21
RESPONSE RATE	40%	41%	33%	40%
SALES RATE	68%	57%	67%	66%

Data for 32 bandaging shops: indication of region, indication of size by number of staff/staff entitled to prescribe ostomy products, indication of type of material sold in 1995-2000-2005.

	REGION			SIZE		MAT 1995										MAT 2000										MAT 2005											
	VL	WA	BL	PERS	NUM	BB	BG	LS	MM	OZ	MC	TC	IM	SM	INV	BB	BG	LS	MM	OZ	MC	TC	IM	SM	INV	BB	BG	LS	MM	OZ	MC	TC	IM	SM	INV		
1	1	0	0	12	4	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	1	0	0	3	1	1	0	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	
3	1	0	0	5	NA	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	
4	1	0	0	28	11	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	
5	1	0	0	5	2	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	
6	1	0	0	2	2	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
7	1	0	0	3	1	0	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	
8	1	0	0	3	NA	1	0	0	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	
9	1	0	0	2	2	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
10	1	0	0	4	4	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
11	1	0	0	2	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	
12	1	0	0	4	1	0	0	0	1	0	1	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	
13	0	1	0	6	4	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	
14	0	1	0	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	1	1	1	1	1	1	1	
15	0	1	0	5	2	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
16	0	1	0	6	4	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
17	0	1	0	1	NA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
18	0	1	0	NA	NA	1	1	1	1	0	0	0	0	0	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	
19	0	0	1	8	3	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
20	0	0	1	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	
21	0	0	1	10	7	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
22	1	0	0	7	2	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
23	0	1	0	4	3	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
24-31 ²³	8	0	0	23	7	8	8	8	8	8	0	0	8	8	8	8	8	8	8	8	0	0	8	1	8	8	8	8	8	8	8	8	8	8	8	8	
32	1	0	0	3	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	22	7	3	152	64	27	25	25	28	24	4	2	21	20	24	29	27	27	30	27	4	1	22	14	25	30	27	28	31	28	4	1	22	21	26		

²³ Eight survey forms were sent (following separate entries in the BBOB affiliates database) to eight bandaging shops owned by one particular bandager. One survey form was returned to KCE, emphasizing that data concerned mean overall figures for 8 separate bandaging shops (with the exception of mentioned number of staff; which concerned the aggregate overall number for all 8 shops). Data for 24-31 are therefore given a 8/32 weight in all calculations.

Break-up of number of patients according to type of ostomy

	REGION			SIZE		COLO	ILEO	URETERO
	VL	WA	BL	PERS	NUM			
1	1	0	0	12	4	60%	10%	30%
6	1	0	0	2	2	50%	35%	15%
9	1	0	0	2	2	95%	0%	5%
10	1	0	0	4	4	56%	37%	7%
16	0	1	0	6	4	70%	20%	10%
17	0	1	0	1	NA	80%	10%	10%
19	0	0	1	8	3	60%	20%	20%
21	0	0	1	10	7	75%	10%	15%
22	1	0	0	7	2	34%	33%	33%
24-31	8	0	0	23	7	40%	10%	50%
32	1	0	0	3	1	90%	5%	5%
AVERAGE ^x						55%	14%	31%

^x Value for observations 24-31 calculated with 8/32, ie 8/21 weight.

Break-up of turnover (€) for ostomy products according to make

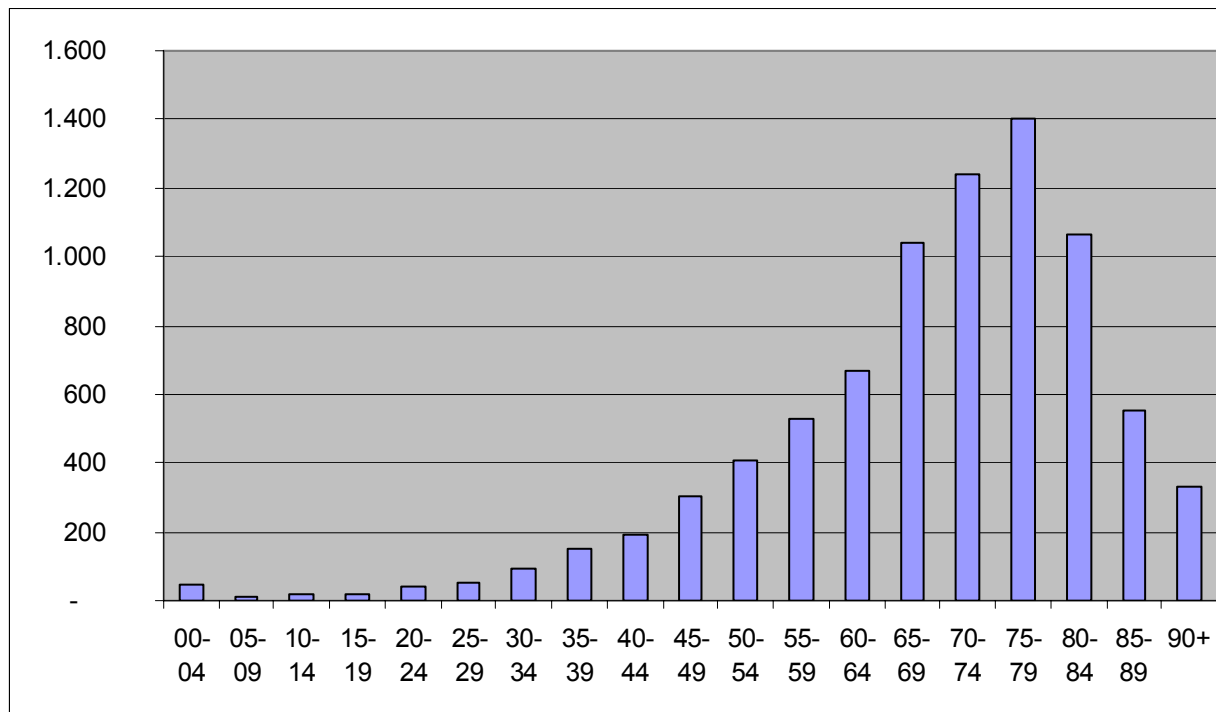
	V L	W A	B L	PE RS	NU M	BBRA UN	COLOPL AST	CONVA TEC	EURO TEC	H-D	WELA ND	OTH ER
6	1	0	0	2	2	2,00%	35,00%	45,00%	1,00%	15,00%	0,00%	2,00%
9	1	0	0	2	2	0,00%	5,00%	95,00%	0,00%	0,00%	0,00%	0,00%
10	1	0	0	4	4	26,00%	12,00%	42,00%	0,00%	20,00%	0,00%	0,00%
16	0	1	0	6	4	5,00%	85,00%	5,00%	0,00%	5,00%	0,00%	0,00%
17	0	1	0	1	NA	10,00%	50,00%	10,00%	0,00%	30,00%	0,00%	0,00%
19	0	0	1	8	3	9,25%	55,52%	18,51%	0,04%	16,66%	0,02%	0,00%
21	0	0	1	10	7	2,00%	60,00%	15,00%	0,00%	22,00%	0,00%	1,00%
22	1	0	0	7	2	6,00%	63,00%	31,00%	0,00%	0,00%	0,00%	0,00%
24-31	8	0	0	23	7	10,00%	40,00%	30,00%	0,00%	20,00%	0,00%	0,00%
32	1	0	0	3	1	1,00%	70,00%	29,00%	0,00%	0,00%	0,00%	0,00%
AVERAGE ^y						7,13%	47,55%	32,05%	0,10%	12,87%	0,00%	0,30%
CUMULATIVE							54,68%	86,73%	86,83%	99,70%	99,70%	100,00%

^y Value for observations 24-31 calculated with 8/32, ie 8/21 weight.

Epidemiologic data from LCM 2002 (calculations by KCE)

Patients (distinctly counted) LCM - 2002 ostomy products: allowances + hospital lump sums

NUMBER OF PATIENTS AND DEATHS AMONG PATIENTS BY AGE CATEGORY (AFFILIATES LCM 2002)																			
AGE	00-04	05-09	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90+
PATIENTS	47	9	16	18	39	55	92	153	191	305	409	531	668	1.044	1.238	1.405	1.065	555	331
CUM		56	72	90	129	184	276	429	620	925	1.334	1.865	2.533	3.577	4.815	6.220	7.285	7.840	8.171
DEMISES	2	0	0	1	0	2	4	3	5	15	29	49	65	114	138	216	179	135	96
CUM		2	2	3	3	5	9	12	17	32	61	110	175	289	427	643	822	957	1.053



Category containing median patient: 70-74

$8.778 - 8.171 = 607$
Patients with Multiple Ostomies?

Number of Patients according to Sex and Stomy		
	Colostomy OR Ileostomy	Urostomy
M	3.308	1.545
F	3.093	832
TOTALS	6.401	2.377
TOTAL	8.778	

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Dépôt légal : D/2005/10.273/28

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2. Etude relative aux coûts potentiels liés à une éventuelle modification des règles du droit de la responsabilité médicale (Phase I). D/2004/10.273/4.
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6. Validation du rapport de la Commission d'examen du sous financement des hôpitaux. D/2004/10.273/12.
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10. Le coût des prothèses dentaires. D/2005/10.273/04.
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13. Traitement endovasculaire de la sténose carotidienne. D/2005/10.273/10.
14. Variations des pratiques médicales hospitalières en cas d'infarctus aigu du myocarde en Belgique. D/2005/10.273/12
15. Evolution des dépenses de santé. D/2005/10.273/14.
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17. Evaluation des montants de référence. D/2005/10.273/18.
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Renseignements

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