



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
United Kingdom
email: paediatrics@ema.europa.eu

Version 1.0.2

Date: 22/02/2012

Please select type of application which is intended to be submitted:

Letter of intent to submit an application

Please fill all the predefined fields as accurately as possible

Applicant / Company	Name: <input type="text"/>
	Address: <input type="text"/>
	State / County: <input type="text"/>
	Postcode: <input type="text"/>
	City: <input type="text"/>
	Country: <input type="text"/>
Contact Person's Details	Name: <input type="text"/>
	Telephone: <input type="text"/> Fax: <input type="text"/>
	Email: <input type="text"/>
Name of the active substance(s) <i>(including salt, hydrate, ester or prodrug form, mixture of isomer, isomer if relevant; do NOT use a proposed INN, only a recommended INN is acceptable)</i>	
Active substance:	<input type="text"/>
Product invented name (if available)	
Therapeutic field	<input type="checkbox"/> Neurology <input type="checkbox"/> Psychiatry <input type="checkbox"/> Haematology-Hemostaseology <input type="checkbox"/> Uro-nephrology <input type="checkbox"/> Pain <input type="checkbox"/> Oto-rhino-laryngology <input type="checkbox"/> Gastroenterology-Hepatology <input type="checkbox"/> Oncology <input type="checkbox"/> Pneumology - Allergology <input type="checkbox"/> Dermatology <input type="checkbox"/> Infectious Diseases <input type="checkbox"/> Vaccines <input type="checkbox"/> Cardiovascular Diseases <input type="checkbox"/> Ophthalmology <input type="checkbox"/> Diagnostic <input type="checkbox"/> Anaesthesiology <input type="checkbox"/> Endocrinology-Gynaecology-Fertility-Metabolism <input type="checkbox"/> Neonatology - Paediatric Intensive Care <input type="checkbox"/> Immunology -Rheumatology-Transplantation <input type="checkbox"/> Other, please specify: <input type="text"/>

Condition(s) (in adults and children) <i>(if referred to, e.g. ICD9 or ICD10: code and in full)</i>	
Condition: <input type="text"/>	
Proposed pharmaceutical form(s) <i>(as far as known)</i>	
Proposed form: <input type="text"/>	
Proposed Paediatric Investigation Plan Indication(s)	
Proposed indication: <input type="text"/>	
Planned PIP submission date <i>(day/month/year)</i>	<input type="text"/>
This application will concern <i>(not binding / for information only)</i>	<input type="checkbox"/> A waiver request for all subsets of paediatric population, in all conditions. <input type="checkbox"/> A PIP for one or more conditions: <input type="checkbox"/> number of conditions for which a PIP (with or without deferral) will be included, in at least some subsets <input type="checkbox"/> number of conditions for which a waiver will be requested for <u>all</u> paediatric subsets <hr/> <input type="text" value="0"/> total conditions in the application
A confirmation of applicability of a class waiver will also be requested, for one or more conditions	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are there or will there be duplicate marketing authorisations (or informed consent MA) for this PIP/ waiver application?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If a new application for an existing PIP, please specify the PIP number	<input type="text"/>
Modification of an agreed PIP?	<input type="checkbox"/> Yes <input type="checkbox"/> No
In case of a modification of an agreed PIP, please specify the PIP number	<input type="text"/>

Important: please send this form via Eudralink in PDF format as it is to: paediatrics@ema.europa.eu