



Practical aspects on how to submit an application for paediatric investigation plan and requests for waiver and deferral

Letter of Intent

For applications to be submitted from July 2007 on, the EMEA Secretariat should be formally notified of the intent to submit an application for paediatric investigation plan and requests for waiver and deferral using the template of Letter of Intent published.

The deadline for the Letter of Intent is normally 2 months before the start of the procedure. The Letter of Intent should be sent to the following address: paediatrics@emea.europa.eu using EMEA secure email system, Eudralink.

Should you not yet have a Eudralink account please contact eudralink@emea.europa.eu in order to open an account.

When to submit the application

Applicants should submit their application for PIP and/or waiver according to the published deadlines for submission to the EMEA 2007, which have been set according to the Paediatric Committee (PDCO) meetings. Dates for 2008 will be available shortly.

Template of the application

For the submission of applications, please use the EMEA templates available on the EMEA website.

Where to submit the application

Applications for PIPs, waivers and deferrals should be sent to the European Medicines Agency to the attention of Dr. Agnès Saint Raymond, Head of Sector Scientific Advice, Paediatric Medicines and Orphan Drugs.

For the initial period of acceptance of applications (end of June 2007), upon receipt of the validation letter by the EMEA, the company should send identical sets of the final application (1 to the appointed rapporteur and 1 to each of the PDCO members, all in electronic format). Companies will receive the name of the rapporteur in the validation correspondence. Prompt delivery of the dossier will give sufficient time to the rapporteur to review the information and contribute to the summary report.

The EMEA paediatric coordinator will be appointed to be the contact person for the company during the procedure.

Number of copies

Application should be submitted to the as one **original paper copy** (unbound, signed and dated) and **one electronic copy on CD-Rom** accompanied by a cover letter.

Applicant should clearly identify in the cover letter and on the paper copy itself that it is an application for paediatric investigation plan and/or requests for waiver and deferral, in the context of the Paediatric Regulation. The applicant should also declare that the electronic version is identical to the original paper copy.

Applicants shall submit to the EMEA the original paper copy signed and dated, including full printed copies of the bibliographical references submitted as part of the application.

Applicants are requested to submit the copy of the application in electronic form (CD-Rom). The files in the electronic application can be in MS Word format or PDF:

1. The PDF file must be created in PDF Reference 1.4 or later.
2. The PDF file must be created directly from the Office applications using a PDF converter tool.
3. Please use the EMEA templates in order to generate a table of content of the electronic application which can be browsed.
4. The PDF file must not have a password or other security settings, so it is possible to print it, select text and images and copy them into another office application.
5. Ensure that the fonts used in the original documents are embedded into the PDF document, so the text appears as intended.
6. Ensure that the PDF file created is compliant with full text search engines.
7. Scanning of physical documents or generation of PDF image file must be avoided. When a document is only available in paper, ensure that the scanned version is readable both on screen and print-out. The scan resolution should be 300 dots per inch (dpi) in black and white as it is good compromise between legibility and file size.
8. The PDF files should be titled for ease retrieval and for publications they should named as first author and year, such as in "Smith PH et al 2004.PDF". In the text of the application, references to the literature should be made with the same format of the file name between parentheses, i.e. (Smith PH et al., 2004), and not as a footnote or numbered item. The reference list at the end of the application should be set in alphabetical order (first Author's name). Please avoid the use of hyperlinks in the references and in the application. All documents enclosed in the printed application should be in electronic format, including the Investigator's Brochure(s) if any.