

**RECOMMENDATION FOR IMPLEMENTATION OF
COMPLIANCE STATEMENT
FOR THE AGREED COMPLETED PAEDIATRIC INVESTIGATION PLAN
(PIP)**

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Background

Article 28(3) of the Paediatric Regulation (1901/2006/EC as amended) states that the competent authority shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan provided that the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan.

It is furthermore stated in Article 28(3) that for the purpose of the application of Article 45(3) the possibility for obtaining the reward as stated in Article 36 (for MR approved products) the compliance statement also shall indicate whether significant studies contained in the agreed paediatric investigation plan have been completed after the entry into force of this Regulation.

Further guidance on the subject is given in the Commission Communication (2008/C 243/01) “Guideline on the format and content of application for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies”(Commission website, EudraLex, Volume 1, Miscellaneous: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol1_en.htm or Official Journal of the European Union C243/1 of 24 September 2008). The specific guidance on compliance statement is to be found in 3. Section 2: Operation of the compliance check of the guideline.

Reasoning behind this Recommendation

As the reward as stated in Article 36(3) shall be granted only if the product is authorised in all Member States the CMD(h) has decided to make a recommendation to MS on how to implement the compliance statement within the marketing authorisation to smooth this procedure for the benefit of the applicant.

The Annexed Template is though only a recommendation and may therefore be used by the NCA in full or partly or as a basis of a MS’s wording of the official decision. Many MS will also issue the

decision in their national language due to their administrative practice. However, the wording of the compliance statement as set out in the Commission Guideline referred to above should be used.

The responsibility of the RMS

The RMS for the procedure will in their finalisation letter make it clear that a statement indicating compliance has to be issued by the MS involved and the RMS will also state which of the two possible compliance statements MS's have to use in their national implementation (depending on whether or not the PIP contains studies completed before the entry into force of the Paediatric Regulation). The RMS will in addition also kindly remind the MS of the importance of implementing the compliance statement within 30days in all MS after receipt of high quality national translation as the applicant may wish to submit a request for reward according to the legislation.

Publication of a given Compliance Statement for a Medicinal Product

The CMD(h) has agreed upon that information regarding issued compliance statements under the Paediatric Regulation should come into public domain by the RMS updating the Public Assessment Report (PAR, Module 6). The PAR is to be found on the Heads of Medicines Agencies website, Human Medicines, MRI product Index, <http://www.hma.eu/mri.html>, see the specific medicinal product.