

CMDv SUB-GROUP ON HARMONISATION OF SPCs - II
--

BACKGROUND

Pursuant to Article 34(2) of Directive 2001/82, as amended, the CMDv received 4 proposals for SPC harmonisation, comprising 82 veterinary medicinal products, from the Member States by 30 April 2005. CMDv considered the proposals and concluded on 22 June 2006 that none of them would help achieve the objectives of the Directive, and agreed not to forward a list to the European Commission. It was also feared that SPC harmonisation could lead to an undesirable loss of indications or products.

In the mean time considerable experience has been gained with the mutual recognition procedure, the decentralised procedure and referrals under article 33(1), 33(4), 34(1) and 35 of the Directive.

Article 34(1) and article 35 referrals have been coming in at unpredictable times for the CMVP and marketing authorisation holders alike, putting a serious strain on resources. The choice of products was determined by ongoing generic applications, as they brought SPC disharmony of the reference product to the light, rather than by deliberate prioritisation in the context of public health objectives.

Furthermore, some Member States have expressed the wish to explore the possibilities of harmonising SPCs of nationally authorised products by other mechanisms than referrals, for example through national variations under the co-ordination of a “Reference Member State”.

Last but not least, potential benefits of SPC harmonisation have been recognised, including strengthening public confidence and reduction of administration and packaging costs. These benefits need to be balanced against the cost of harmonising a SPC.

Therefore CMDv decided to install “Subgroup on Harmonisation of SPCs – II” and give it the following mandate.

MANDATE

1. To establish selection criteria and to propose to CMDv a prioritised list of products:
 - a. that may be used as reference product up to 2012 inclusive, with differences in the nationally authorised SPCs that could lead to a referral under article 34 or 35 of the Directive.
 - b. for which SPC harmonisation is important in relation to the protection of public health, even though they may not be necessarily referred as a result of generic application.
2. To develop and propose to CMDv alternative mechanisms for SPC harmonisation outside the scope of article 34(1) and 35 referrals.
3. To propose to CMDv a plan, including a time schedule, regarding the harmonisation of SPCs.
4. To have contact with CVMP, CMDh and interested parties, in an appropriate way and time, to ensure their views will be considered.