

REPORT FOR RELEASE

Meeting of 22-23 June 2006

CMD(v) agreed there would be no products on the SPC harmonisation list. The group took note of the guideline on the definition of a potential serious risk, discussed 12 MRP applications and answered questions regarding generics and diagnostic kits.

No products on SPC harmonisation list

CMD(v) agreed that no products would appear on the list of medicinal products requiring harmonisation of the summary of product characteristics (SPC). Pursuant to Article 34(2) of Directive 2001/82/EC, as amended, 4 proposals comprising 82 products for SPC harmonisation were received from Member States. CMD(v) scrutinised each of the products, as to whether SPC harmonisation would be necessary for safety reasons or would enhance the availability of the product in the European Economic Area. It considered that for none of the products SPC harmonisation could be justified.

Definition of a potential serious risk

It was noted that the "Guideline¹ on the definition of a potential serious risk to human or animal health or for the environment" had been adopted by the European Commission and published in the Official Journal C 132. In addition, all official language versions have been published on the website of DG Enterprise and Industry:

<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev5.htm> (Miscellaneous).

Member States should take the guideline into account during the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP).

Diagnostic kits

From time to time questions are received about the regulatory path of veterinary diagnostic kits. Companies concerned with diagnostic kits are requested to take note of the following.

Where veterinary diagnostics are used in, or administered to animals, to make a medical diagnosis, they may be subject to Directive 2001/82/EC (as amended by Directive 2004/28/EC) and require authorisation as a veterinary medicinal product.

For veterinary *in vitro*-diagnostics there is no horizontal legislation of the European Community (EC) in place. Such legislation is only available for human *in vitro*-diagnostics. They have to comply with Directive 98/79/EC. Specific veterinary EC legislation may, however, be applicable for certain diagnostics, for example for the approval of rapid tests for TSE monitoring².

In some countries there is national legislation in force for veterinary diagnostic kits. Companies are advised to contact the Competent Authority of the Member State concerned, to inquire about the national requirements.

¹ in the context of Article 33(1) and (2) of Directive 2001/82/EC

² Regulation (EC) No 999/2001, as amended

Generics

CMD(v) addressed the following question regarding applications for generic veterinary medicinal products.

- *Can the SPC for the generic have more up-to-date warnings/contra-indications than the reference product?*

As a general principle the SPC for a generic should follow the SPC of the reference product. However, it is the responsibility of the applicant to check whether there is new scientific knowledge, which in that case will be part of the application. The evaluation of the new information could in turn lead to an amended SPC text. Based on the evaluation of the current scientific knowledge the competent authority will decide whether the SPCs of the reference product and comparable products need to be amended.

Product discussion

12 applications were discussed out of 14 that reached day 78 of the MRP. It was noted that following the May meeting 5 MRP applications were approved, of which 4 had been discussed at the meeting and 1 was agreed bilaterally between the reference member state and concerned member state.

Adopted documents

The following document has been adopted:

- Meetings with representative organisations (published for consultation on [http://www.hevra.org/documents/organisational_issues/CMD\(v\)_BPG_013.doc](http://www.hevra.org/documents/organisational_issues/CMD(v)_BPG_013.doc))

Information

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