COM(2014) 558	**1st Reading EP started in October 2014**
Lead committee: ENVI	**Opinion committee: AGRI**

REGULATION ON VETERINARY MEDICINES

TOPIC: SINGLE MARKET FOR EXISTING NATIONAL PRODUCTS

Background to the issue

A veterinary medicinal product is defined by the summary of product characteristics (SmPC) and the product's quality/manufacturing dossier. The vast majority of veterinary medicinal products (VMP) have national marketing authorisations following an assessment by a national competent authority.

Differences in the conclusions of the national assessments can lead to differences in the national SmPCs of the same product. As the SmPC is part of the product authorisation, a different SmPC means it is seen as a different product requiring a different label from a legal perspective. To facilitate a single market and reduce administrative burden, the SmPCs in different member states for the same product of a company could be harmonised.

What is needed?

A legal procedure to voluntarily harmonise SmPCs of the same product of the same company in different member states. The procedure should be 'administrative' and should be distinguished from products that require a scientific re-evaluation to address a scientific question (a potential serious risk) - these products should be subject to a referral procedure.

What needs to be done?

Support: COM(2014) 558 includes a section on "Harmonisation of SmPCs for nationally authorised products" (articles 68 to 71). It also includes an 'administrative' procedure (art. 69) and a majority voting system to reach agreement amoung the member states.

Reject: The requirement that 'groups of similar products' (art. 69.2) containing the same active ingredient are harmonised in a process which would potentially involve many companies and different products, is not scientifically sound and would be unworkable. Forced harmonisation of groups of similar products should only be triggered by a safety issue handled through a class referral procedure at the European Medicines Agency(see art. 84).

Reject: The criteria to qualify for an administrative procedure (art. 70) are too restrictive and not science-based. They effectively exclude the majority of products and should be rejected.

Reject: Any mandatory SmPC-harmonisation (art. 69.2) in the absence of an identified serious risk. It should be voluntary for MAHs.

Amend the text to add:

- An appeal procedure for the marketing authorisation holder (MAH).
- Allowance for dialogue and collaboration of authorities with the MAH in elaborating the text of the harmonised SmPC to ensure that "minor" issues are not taken to referral.
- An option to allow the harmonised set of national marketing authorisations to be turned into a single European marketing authorisation.
- If new data are requested by authorities, a period of protection is needed to preserve fair competition (a company should not profit from the investments of another company).

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