EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 624

PHARMACEUTICAL COMMITTEE
27 March 2013

Subject: **Classification of medicinal products for human use-Prescription status**

Agenda item 4c)

The issue

The Commission services have been informed of a case where the national competent authorities intend to classify a generic product as not subject to prescription even if the reference medicinal product, which is authorised under the centralised procedure, is classified as subject to prescription.

The case raises questions about the application of the rules on classification status, which DG SANCO would like to bring to the attention of the Pharmaceutical Committee for discussion.

Background

1.1 Rules on classification status

The classification status for medicines is governed by Directive 2001/83. Specifically, Article 71 of the Directive provides for the classification criteria. However, according to Article 71(4) Member States may depart from the criteria on the basis of "other circumstances of use".

For centrally authorised medicinal products, the classification status is part of the Commission decision. For nationally authorised products, the legislation does not specifically provide that Member States have to agree on the classification status but, in practice, classification is part of the discussion during the mutual recognition/decentralised procedure due to its impact on the wording of the SmPC and on the package leaflet.

Under the rules governing the mutual recognition/decentralised procedure, Member States are not allowed to disagree with the assessment of the reference Member State for issues related to the prescription status.

1.2 Commission's note on classification status

In 2009 the COM addressed a note to the Pharmaceutical Committee in which it noted that the Commission would consider triggering a referral in cases where Member States did not follow the classification status of a centrally authorised product (for their national similar products).

The note aimed at preserving consistency in the application of the classification criteria of the Directive.

Discussion

DG SANCO would like to discuss with the Member States the application of the rules on classification status and in particular the following issues:

(i) How to reconcile the competence of the Member States to decide on the prescription status with the rules on the mutual recognition/decentralised procedure?

(ii) How to reconcile the fact that there are common classification criteria with the fact that there may be divergent classification for the same medicinal product?

(iii) How to address a possible divergent position on classification status for a centrally authorised product and similar medicinal products authorised nationally?