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From: Hansen, Vera -112 BMG [mailto:Vera.Hansen@bmg.bund.de]
Sent: Friday, May 16, 2014 3:04 PM
To: SANCO PHARMACEUTICALS D5
Cc: 112 BMG; 114 BMG; PG-BAM
Subject: 72nd Pharmaceutical Committee - Action points

Dear colleagues

Please find attached the answers of Germany on the following agenda points:

(…)

- 6.b) AOB 2. Update on external study on availability

With regard to the recommendation on page 64: "Ensure more effective transposition and implementation of Article 81":
Germany has transposed the so-called "public service obligation" into national law, by which pharmaceutical entrepreneurs and wholesalers shall be obliged to provide medicinal products in amounts tailored to the market needs, if these medicinal products have obtained licensure and are placed on the market. The experience gained is predominantly positive. In this way, the full-line wholesale in Germany has been strengthened and was not squeezed out of the market by exclusive contracts of direct supply between pharmaceutical entrepreneurs and pharmacies.
However, the public service obligation will be useless if the pharmaceutical entrepreneur completely withdraws a medicinal product which has obtained licensure from the market. The same shall apply to supply shortages or other disturbances of the supply chain which are related to the active substances.
The Laender which implement the medicinal products legislation in Germany had criticized in the past that the public service obligation was too vague for the implementation. An attempt to render the provision more efficient by an amendment of the law and to facilitate the implementation on the part of the Laender failed in the parliamentary procedure. When meeting vague requirements set forth in a Directive by national legislation, the opponents of more stringent rules frequently reproach the legislator for going beyond the actual requirements under Community law.
As a rule, it has to be noted that from our point of view the course of action taken by the European Commission is critically assessed. An in-depth examination of the report would have been preferable before its completion. The statements set forth in the report are standing on their own. It is not possible to ascertain whether the conclusions reached have been sufficiently examined and thus are reliable. An addendum which has been planned to be provided afterwards cannot completely correct or replace a statement that is possibly not complete or incorrect. In case of doubt, the report is perceived as a document on its own, in particular concerning the statements from relevant stakeholder organisations. It is pointed out that Germany takes note of this report

as one possible view. At the most, the report may serve as a so-called trigger of the subsequent consultations. Recommendations from the report have to be critically scrutinized and reasonably discussed with the Member States.

Regarding pharmaceutical pricing and reimbursement issues: According to Art. 168 (7) TFEU, Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. Therefore, the aspects of pharmaceutical pricing and reimbursement should not be included in the report, in particular as Member States have not been involved.

Kind regards,

Vera Hansen