EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

PHARM 670

PHARMACEUTICAL COMMITTEE
22 October 2014

Subject: **Summary of comments to study on availability of medicines for human use**

Agenda item 2d

The Pharmaceutical Committee was asked[1] to provide feedback on the study report, in terms of appreciation of the correctness of the analysis and applicability of the findings to national situations. Responses from 20 Member States and Norway, as well as a letter from the HMA (Heads of Medicines Agencies) Management Group were received by the Commission services.

This document serves as a summary of the comments which were issued by the Pharmaceutical Committee on the external study report on the availability of medicinal products for human use prepared by Matrix Insight to the European Commission. The individual comments received are published separately.

Some comments include specific requests to reword or remove some specific paragraphs of the report. It is hereby reminded that whilst the report is being published as it has been provided by the contractor, the information and views set out in this external study report are those of the author(s) and do not necessarily reflect the official opinion of the European Commission. Responsibility for the information and views expressed in the study report lies entirely with the author(s).

On the general approach

In the majority of the responses received there are no comments or no major comments within the defined scope of the study. However, four Member States expressed critical comments, notably on the scope of the study and the methodology used by the contractor. These comments point out for instance that even though the study explicitly excludes the subject of affordability and prices from its scope, considerations on affordability may have an impact on availability in some cases. Other comments point out, on the contrary, that aspects of pharmaceutical pricing and reimbursement should not be included in the report, as responsibilities of the Member States include the management of health

[1] Meetings on 23 October 2013 and 26 March 2014

services and medical care and the allocation of the resources assigned to them (Art. 168 (7) TFEU is quoted in that respect).

Some comments tend to qualify the approach to availability adopted by the study as insufficiently refined, pointing for instance to the possibility to include in the analysis alternative products or to focus the analysis on predefined 'essential products', while criticising the emphasis of one of the conclusions on products such as herbals or homeopathics. Other possible definitions of 'availability' are also discussed.

Another critical remark states that it is not possible to ascertain whether the conclusions reached have been sufficiently examined and calls for critical scrutiny of the recommendations of the study and reasonable discussion with the Member States.

On the substance

There is seemingly no agreement on the conclusion regarding the 'sunset clause' owing to the fact that different Member States apply that clause in different contexts. One of the comments seems to establish a link between exemptions granted from that clause and the possibility to fill in gaps of availability through parallel imports. Another comment underlines on the contrary that the 'sunset clause' is very useful on their market, while recognising that the appreciation may vary depending on the situation on each particular market.

Opinions on the application and the effect of Article 126a ('Cyprus clause') vary from indifferent to positive, with some critical remarks regarding the conclusion on the need to clarify individual responsibilities, expressed by a Member State who does not seem to experience such difficulties in the application of that clause. It is underlined at the same time that the MRP/DCP procedure is the preferred option and efforts should be made by all stakeholders towards a more systematic use of that procedure versus the 'Cyprus clause' procedure.

Conclusions regarding the application of Article 81 ('public service obligation') tend to receive general support. One remark points to possible negative effects of a very stringent interpretation in the specific context of small markets.

Other critical comments relate to the fundamental principle in the EU legislation that there is no obligation for a product that has been authorised to be actually placed on the market. Three Member States discuss directly or indirectly possible new obligations for marketing authorisation holders aimed at improving availability, in the context of possible new incentives. Another comment, however, suggests that the current legislation may be close to achieving the best possible balance between a variety of objectives.

Finally, several replies underline the importance of a good collaboration between marketing authorisation holders and national competent authorities in terms of transparency on foreseeable availability issues, mutual information and information of the public, including through collaboration between Member States and coordination at EU level.

Action to be taken:
For information