Heads of Medicines Agencies
Management Group

8 April 2014

Andrzej Rys
DG SANCO
European Commission
Sent by e-mail to: Andrzej.RYS@ec.europa.eu
Cc: Sabine.Juelicher@ec.europa.eu

**Subject: Availability of Human Medicinal Products**

Dear Mr Rys,

The Heads of Medicines Agencies (HMA) appreciate the initiative of DG SANCO on the availability of medicinal products for human use within the EU and EFTA being high on the agenda and Matrix Insight reflecting on different case studies related to medicinal product availability in the Member States.

The potential regulatory consequences of the Matrix Insight study to support broader availability of authorised pharmaceuticals in Europe is of major importance for the HMA. In 2007, the issue of availability of medicinal products was taken up by the HMA Taskforce on the Availability of Pharmaceuticals for Human Use. The conclusions and recommendations of this taskforce were sent to DG Enterprise at that time. The outcome was that unavailability is mostly, however not only, associated with economically less attractive markets, as all the Member States had experienced availability problems. This issue is still relevant as all heads had discussed this during the HMA meeting in Vilnius, September 2013. The European Union faces a problem of significant risks for public health since patients might not be treated due to a lack of certain pharmaceuticals or are treated via off-label use. The lack of authorised medicines concerns patients, health care professionals and governments. Therefore it has been identified as an issue with high priority, particularly for Member States with small and medium-sized markets.

The HMA welcomes the study report of Matrix Insight. However, as the **Common Baltic Package Procedure** is incorrectly quoted from the HMA report dated from 2007, this part should be revised before publication of this draft on the Commission website. We wish to clarify that this procedure may be used for all medicinal products authorised either via the national, the mutual recognition or the decentralised procedure and does not depend on the time of the issue of Marketing Authorisation (the study report of Matrix Insight is incorrect on page 85: *According to the stakeholder consultation, the procedure applies to medicinal products authorised via National Procedure before 1 May 2004*. It is also used in the conclusion on page 88 - *Although the applicability of the Common Baltic Package procedure is somewhat narrow (it only applies to products authorised nationally prior to 2004)).*
For products in the centralised procedures, the applicant should consider the possible combination of languages already during the MA procedure. In addition, the alternative of re-labelling in order to comply with the language requirements has to be taken into account before granting of the Marketing Authorisation because the later addition of the re-labeling site through the variation procedure could delay the availability.

The current legal framework is considered insufficient to solve the problem of unavailability of medicines even if all given possibilities are optimally used. Too broad interpretations of some provisions (e.g. **Article 126a of the Directive 2001/83/EC**) still have a limited impact on addressing the problem of availability of medicines. Also some National Competent Authorities attempt to solve the problems of availability at a national level whereas they may find themselves under criticism. We acknowledge that building of double-standards for European patients depending on their country of treatment should be avoided by any means.

Matrix Insight recommends a revision of the **sunset clause** to potentially avoid reducing the number of authorisations in place in the individual Member States. As indicated by some Member States, the sunset clause is useful for their national market and reimbursement system, whereas in other Member States the sunset clause causes problems to keep the registration of Marketing Authorisations for pharmaceuticals with a medical need in place. More discussion with the HMA is needed on the sunset clause in the near future.

As it is made clear from the Matrix Insight study report, it is essential to find a solution in which public health needs can be met and at the same time the spirit of the pharmaceutical *acquis* be maintained. Several regulatory aspects and recommendations should be discussed by the HMA to provide input to DG SANCO.

The HMA MG would like to have feedback from DG SANCO on the planned next steps regarding the results of the Matrix Insight study report after publication on the Commission website (in conjunction with the comments made on the study report). Furthermore,we kindly ask you to correct the above-mentioned mistakes in the report **before** publishing it.

Best regards,

Klaus Cichutek
Chair of HMA Management Group

Attachments:

- (Also for publication on the website of DG SANCO) Report on the Availability of Human Medicinal Products (adopted by the HMA in Madeira in November 2007)