PHARMIG
Verband der pharmazeutischen Industrie Österreichs

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PHARMIG response to the European Commission Concept Paper: Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medicinal Products for Human Use

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the Concept paper for the Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medicinal Products for Human Use.

Please find following our comments.

1. Equivalence Assessment of the Rules for GMP

Consultation item n°1: Please comment.

PHARMIG comment:

Since the adoption of the delegated act on the principles and guidelines of good manufacturing practice for active substances is still pending, respectively a concept paper for this document is under consultation at the moment, we strongly recommend waiting the publication of the finished delegated act before releasing the implementing act which is subject of this consultation. A publication of the implementing act first might cause a subsequent revision of itself after the release of the delegated act.

It is important to ensure that the requirements laid down by this Implementing Act are clear to all parties and consistently implemented. Successful implementation of these provisions requires a clear mutual understanding between industry and regulators as to the practical requirements of the provisions and the means to achieve them. Failure to do so may result in unnecessary supply chain issues for active substances and consequently medicinal products.

2. Equivalence Assessment of the Regularity of Inspections to Verify Compliance with GMP and the Effectiveness of Enforcement of GMP

Consultation item n°2: Please comment.

PHARMIG comment:

PHARMIG supports the need for adequate oversight and control of the importation of active substances into the European Union. We therefore welcome the installation of a list of third countries whose GMP requirements and enforcements procedures for active substances have been judged by the Commission to be equivalent to EU GMP standards for APIs. It would be worthwhile if this list would consist of a high number of third countries.

Apart from the list of equivalent third countries an alternative is addressed in Directive 2011/62/EU for importations of active substances into the European Union, namely a written confirmation from the competent authority of the exporting third country that the standards of GMP are at least equivalent to those laid down by the Union.

Regarding these two possibilities of importing APIs into the European Union clarification has to be ensured regarding the following issues:

It is not made clear what incentive is there for a third country to seek listing as an "EU-GMP-equivalent country" when effectively it can confirm its equivalency by itself. In our understanding there is no necessity for those countries to seek listing, so they might prefer the way of self-conforming (most likely with costs for the importer at each delivery). Furthermore it is not clear if or how the self-conformation will be evaluated and against which criteria the self-confirmation will be performed.

Regarding the list of equivalent third countries it has to be addressed what happens if a country fails to be accepted on that list. Is this country then banned for exportation of active substances or can the competent authority go back to self-confirming its equivalency? In this context it has to be specified in which way the list of approved countries and especially corrections to this list will be communicated to the industry.

3. Regularity and Rapidity of Information Provided by the Third Country Relating of Non-compliant Producers of Active Substances

Consultation item n°3: Please comment.

PHARMIG comment:

Generally our comments to consultation item n°2 would also apply to this item. It is not made clear either in Directive 2011/62/EU or in the present concept paper how the third country will be committed to provide information relating to non-compliant producers of active substances. Also it should be clearly indicated what are the consequences if a third country does not meet the obligations imposed on it by Directive 2011/62/EU.

4. Other Issues

Consultation item n° 4: Please comment on the issues raised in point 4 ('other issues').

PHARMIG comment:

regarding 4.3. Regular verification:

In Directive 2011/62/EU Art.111b(3) it is addressed that the Commission shall verify no later than 3 years after the country has been included in the list whether the conditions for GMP-equivalency are still fulfilled. It has to be clarified what are the consequences if a country does not meet those conditions anymore and is therefore removed from the list.

regarding 4.4. Date of application:

Directive 2011/62/EU specifies that the provisions relating to the new Article 46(b) must be implemented by Member States by 2 July 2013 latest. Consequently, it will be necessary to have mechanisms and approvals in place for third countries complying with the requirements of the criteria by that time. Failure to do so may result in disruption of the supply chain for APIs and cause problems of medicinal product supply to the European and global markets.