Lonza

PUBLIC CONSULTATION PAPER
IMPLEMENTING ACT ON THE REQUIREMENTS FOR THE ASSESSMENT OF THE REGULATORY FRAMEWORK APPLICABLE TO THE MANUFACTUIFNG OF ACTIVE SUBSATNCES OF MEDICINAL PRODUCTS FOR HUMAN USE
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Input from Lonza:

General comment:

Lonza is one of the world's leading suppliers to the pharmaceutical, healthcare and life science industries. It is the global leader in the production and support of active pharmaceutical ingredients (API) both chemically as well as biotechnologically.

Lonza has API manufacturing sites globally positioned that supply medicinal product manufacturers around the world.

Therefore, Lonza would like to comment on the proposed Implementing Act.

Consultation item no. 1:
EQUIVALENCE ASSESSMENT OF THE RULES FOR GMP

Considering the global nature of the supply chain of APIs it may be more appropriate to reference the adaption of the principles and guidelines of good manufacturing practice of active substances as contained in ICH Q7 rather than Eudralex Volume 4, Part II. That is ICH Q7 is adapted in the 3 major regions i.e. EU, USA and Japan and forms the basis of an agreed GMP standard for the manufacturing and supply of APIs.

Consultation item no. 2:
EQUIVALENCE ASSESSMENT OF THE REGULARITY OF INSPECTIONS TO VERIFY COMPLIANCE WITH GMP AND THE EFFECTIVENESS OF ENFORCEMENT OF GMP

Considering the request for equivalence assessments by countries wanting to be added to the equivalency list, how would the assessments be performed by the EU to maintain continuity of human medicinal product?
Will sufficient resource be available to perform these assessments within a timely fashion in relation to the time scale for the adoption of this Act?
Further clarification is required regarding interim arrangements.

There is concern that some counties may be unwilling to accept the arrangements set out in the Directive and associated Implementing Act. If such circumstances prevail, i.e. where the site concerned has received a satisfactory GMP inspection including one from an EU member State, consideration should be given to permitting continued supply from that site.

Consultation item no. 3:
REGULARITY AND RAPIDITY OF INFORMATION PROVIDED BY THE THIRD COUNTRY RELATING TO NON-COMPLIANT PRODUCERS OF ACTIVE SUBSTANCES

No comment

Consultation item no. 4:
OTHER ISSUES

4.1 Form of Assessment

Further clarification on the “Review of relevant documentation” needs to be provided i.e. what documentation?

“On site review”: see comment on consultation item no. 2 with regard to resources and timing.

4.2 Interface with existing mechanisms

MRA
In cases where a MRA or other joint inspection arrangements regarding GMP exists that includes manufacturing of APIs it should be accepted as a demonstration of equivalence.

Existing assessment programs
If the API manufacturer in a country not on the equivalence list has already been successfully inspected by a MRA partner, the competent authority of a listed country or other recognized authorities e.g. US-FDA or the EU; will this allow that specific manufacturer to continue to supply into the EU?

4.3 Regular verification

What is the format and basis for the “regular verification” whether the conditions of the conditions of the GMP equivalence are fulfilled?

4.4 Date of application

See comment on consultation item no. 2 with regard to resources and timing.

Consultation item no. 5:
Any OTHER ISSUE or COMMENT

The Implementing Act should include an obligation by the Commission to proactively raise awareness to impacted countries about this directive 2011/62/EU and the Implementing Act. Concern is that imposing this Directive/Implementing Act may adversely affect the continuity of supply and cost of medicinal products to patients in the EU.

If a multinational company operates a manufacturing site according to ICH Q7 (which has been verified through regulatory inspection i.e. EU /US-FDA) in a country that decides not to join the equivalency list and refuses to provide the written GMP statement as defined in Article 46b(2.) of Directive 2011/62/EU how can such a manufacturing operation obtain acceptability to continue to supply APIs into the EU?