EC consults on equivalence test for imported APIs

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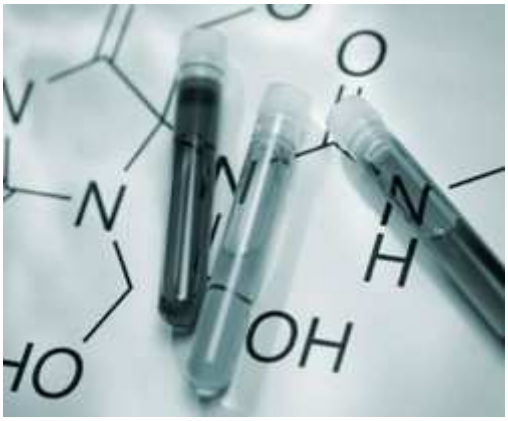
19-Dec-2011



The European Commission has released a concept paper explaining future procedures for assessing whether active substances imported from third countries have been manufactured under the same strict standards as those of the EU, as required by the Falsified Medicines Directive (2011/62/EU).

The paper – a precursor to an implementing act – describes how the Commission will carry out so-called 'equivalence assessments', i.e. evaluations that will permit third countries to export APIs to the EU without having to submit with shipments a written statement verifying GMP equivalence.

Directive 2011/62/EU stipulates that APIs may only be imported from third countries if they are accompanied by a written statement from the exporting country's competent authority. That statement must confirm that the country's GMP standards for manufacturing sites, as well as related controls (i.e., the regularity of unannounced inspections) and enforcement activities (i.e., how effectively GMP violations are handled and how fast other authorities are informed of violations) , are equivalent to those in the EU.

However, countries that request and pass an equivalence assessment verifying the above can be put on a list that waives this requirement. The assessment will involve a review of the exporting country's relevant documentation as well as an on-site review of its regulatory system – unless a mutual recognition agreement is in place that covers the manufacturing of APIs.

If necessary, the assessment will also include an observed inspection of one or more of the country's manufacturing sites for APIs. The Commission will carry out assessments in co-operation with the European Medicines Agency and EU Member States.

The concept paper contains an audit checklist with "critical","very important" and "important" items that may be reviewed as part of assessments. Among other items, these include reviews, inspections and/or observations of:

- relevant legislative and regulatory requirements (critical)
- GMP standards (critical)
- inspection resources such as staffing and training (very important)
- inspection standard operating procedures (critical)
- post-inspection activities (very important)
- storage of inspection data (important)
- quality management systems (critical)
- alert mechanisms (critical)

Stakeholders have until 23 March 2012 to submit comments on the paper. Assuming the implementing act is adopted in 2013 as planned, the importation rules will apply from 2 July 2013.

This is the second concept paper published by the EC as the FMD moves towards the implementation stage via the delegated acts process. In November, the Commission published a paper on the unique identifier for medicinal products laid out in the directive (see EC seeks comment on unique medicine identifiers).