MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

COMMENTS TO THE CONCEPT PAPER ON 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.

FROM: AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS.

The comments of the Spanish Agency of Medicines and Medical devices to the Concept paper SANCO/D3/(2011)ddg1.d3. 1438409 are included below.

Comments to consultation Item nº 2

Article 52a(4) establishes that competent authorities may, based on a risk assessment, decide to carry out an inspection and Article 111(1b) makes a reference to a "system of supervision including by inspections at an appropriate frequency based on risk". The regulatory framework set out in Article 52a(4) and Article 111(1b) is too vague as to serve as a basis for equivalence assessment.

The other supporting document (Guidance on the Occasions When It Is Appropriate for Competent Authorities to Conduct Inspections at the Premises of Manufacturers of Active Substances Used As Starting Materials) was adopted in September 2005, and is not in line with current regulatory expectations. This document is not useful to assess the risk based approach in the third country, based on the following:

- Almost all the examples listed under section 5.1 are not applicable to third countries.

- Many of the examples provided in point 5.2 (e.g. 5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.2.8, 5.2.11...) are applicable if the active substance is manufactured for the third country market, but would not be applicable if the active substance is manufactured for export only.

Therefore, the guidance document should be revised if it is going to be used as a tool to assess the risk-based approach.

Comments to consultation Item nº 3

Concerning the participation of third country authorities to the 'Community information and rapid alert system', it is to be noted that:

- This system is primarily intended for the transmission of information when urgent action is needed relating to a recall of medicinal products. Although it can also be used to transmit information about quality defects, counterfeit or fraud in active substances, it seem wiser to use "Procedure for Dealing with Serious GMP Non-compliance or Voiding/Suspension of CEPS Thus Requiring Coordinated Administrative Action" for the notification of a non-compliance by the third country (as MRA partners would do under point 7.1.10 of that document).

CORREO ELECTRÓNICO
sdaem@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 28
FAX: 91 822 50 10

- The procedure envisaged in the 'Community information and rapid alert system' is limited to the exchange of information between Competent Authorities in the EEA, in EU acceding countries, MRA countries, PIC/S participating authorities among others, but it is not open to all third countries. Thus the evaluation of the participation and contributions to the system would not be feasible for all third countries.

Comments to consultation Item nº 4

Concerning the applicability of other evaluation mechanisms, it should be born in mind that themanufacture of active substances has not been included in the scope of the audits for all these mechanisms. A case by case evaluation is needed.

When the manufacture of active substances is already covered by an MRA, an additional paper-based evaluation will have little added-value to the formalized assessment on which the MRA is based.

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