



DIRECCIÓN DE LA
AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y
PRODUCTOS SANITARIOS

Detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors, pursuant to Article 78(7) of Regulation (EU) No 536/2014

Comments from the Spanish Agency and Medical Devices (AEMPS).

4.2. Right of access of inspectors to premises and documents

159 Member States shall set up a legal and administrative framework with regards to the
160 powers of inspectors, **including inspectors from other MS**, for entry into sites and
161 access to data, as set out in the above paragraph.

For which our proposal (*in bold italics*) is:

159 Member States shall set up a legal and administrative framework with regards to the
160 powers of inspectors, including inspectors from other MS that **may observe these**
161 **inspections**, for entry into sites and access to data, as set out in the above
162 paragraph.

Justification:

Member States' regulatory authorities are competent for carrying out inspection in their territories. National regulations don't recognise as inspectors those from other MS.

Moreover, any inspectors representing other EU competent authority should act as observers and should be accompanied by the respective MS competent authority's inspectors unless an agreement between them has been reached.

The proposed solution is in line with Article 44 of the COMMISSION DELEGATED REGULATION (EU) No .../.. of XXX supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use:

3. Where a repository not physically located in the territory of a Member State is used for the purpose of verifying the authenticity of medicinal products placed on the market in that Member State, the competent authority of that Member State **may observe an inspection** of the repository or perform an independent inspection, subject to the agreement of the Member State in which the repository is physically located.

Spain, 23 November 2015

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