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 PUBLIC CONSULTATION PAPER ON THE REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS.
SUBMITTED BY THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS), SPAIN

The Spanish Agency of Medicines and Medical Devices only will make comments on the point about the Hospital Exemption. All other issues are oriented more to other stakeholders and are regularly discussed at the CAT and CHMP by the national competent authorities.

2.3. Hospital exemption.

We fully support the regulation at the national level of this clause. As occurs with other medicines like radiopharmaceuticals, it has been considered that advanced therapy medicinal products (ATMP) with a non-industrial manufacture should have a specific procedure tailored to their specific characteristics of production and dispensing as well as providing the adequate guarantees of quality, safety and efficacy. It should not be forgiving that it is expected that the hospital exemption should only cover a few number of ATMP.

Regulation (CE) nº 1394/2007 established the Hospital exemption clause indicating that their use is under the authorization of the national competent authorities that should provide national trazability, pharmacovigilance (PhV) requirements, as well as specific quality rules equivalent to those applying to ATMP authorised under the Regulation n. 726/2004 of the Parliament and the Council.

Thus, from a given date it is anticipated that ATMP could be either under a clinical trial, centrally authorized or under the Hospital exemption clause (provided it fulfils the definition and is authorised by the NCA). This authorisation must guarantee that the ATMP satisfy the requirements of quality, safety, efficacy, identification and correct information. Also the authorisation must indicate that the ATMP could not be used outside de centre and that the responsible (holder) of the authorization of use is the Hospital itself. The dossier for the authorisation must include the documentation about manufacturing that should accomplish with the requirements of GMP tailored to the product itself. Authorisation of use should be renewable after a period of time (three years, for example). Requirements of trazability, PhV, identification, correct information and conditioning are under the responsibility of the holder of the authorization of use.

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