EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2012
EMA/CHMP/CVMP/JEG-3Rs/252137/2012
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia

Applicable to all medicinal products regardless of type

In accordance with the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, tests performed in animals must be carried out in such a way as to use the minimum number of animals and to cause the least pain, suffering, distress or lasting harm.

To comply with the European Convention the European Pharmacopeia (Ph. Eur.) has, over the years, aimed at implementing alternative tests and assays where the 3Rs principles of reduction, refinement and replacement are applied. It is however noted that voluntarily uptake of such methods has been slow, particularly in the field of globally marketed vaccines. A number of initiatives, undertaken separately and jointly by regulators and industry, are therefore taking place to promote the uptake of 3Rs methods.

After 1 January 2013, the date for the full implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes[1], the use of animals in testing of medicinal products will clearly be more regulated.

Article 13 of the above-mentioned directive states that “Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union”.

Article 13 also requires that, if it is necessary to use animal tests, the method which to the greatest extent reduces the number of animals, causes the least pain, suffering, distress or lasting harm and is most likely to provide satisfactory results, shall be selected.

Within the framework of pharmaceutical legislation, monographs including general monographs and general chapters of the Ph. Eur. have legal force with regard to the quality part of the dossier[2]. As a consequence, if the Ph. Eur. includes a method more compliant with the objectives of the 3Rs than that

[1] Available at http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm
[2] Status of EMEA scientific guidelines and European Pharmacopoeia monographs and chapters in the regulatory framework applicable to medicinal products (EMEA/42371/2008)

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used by Marketing Authorisation Holders (MAHs), the competent authorities responsible for granting approval of animal testing will request the more animal friendly Ph. Eur. method to be used.

Therefore, in order to comply with the provisions of Directive 2010/63/EU and to secure an undisrupted supply of medicinal products to the European Market, MAHs should take all necessary actions to introduce 3Rs Ph. Eur. methods including submission of variations to marketing authorisations as appropriate.