



STRASBOURG, 15/05/08

Note for the Editors: The mission of the European Pharmacopoeia and the European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe responsible for the Secretariat of the European Pharmacopoeia, is to protect and promote public and animal health through the elaboration of quality standards for medicines for human and veterinary use. Medicines need to be safe, effective and of good quality in order to produce the expected therapeutic effect. The EDQM works closely with its international and European partners to ensure that sub-standard or counterfeit medicines do not reach the marketplace. Its networks collaborate on a daily basis with all authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. For more information, please go to: www.edqm.eu.

EDQM INTERNATIONAL SYMPOSIUM: ALTERNATIVES TO ANIMAL TESTING - NEW APPROACHES IN THE DEVELOPMENT AND CONTROL OF BIOLOGICALS **23-24 April 2008, Dubrovnik, Croatia**

This international symposium, organised by the European Directorate for the Quality of Medicines and HealthCare (EDQM, Council of Europe), was essentially aimed at the application of 3Rs* in routine quality control of therapeutic biologicals. It was recognised that for the development and characterisation of these products, different approaches and priorities may be necessary.

As experience is gained in product characterisation and production processes and as analytical tools are improved, an exploration of new approaches for lot-to-lot consistency monitoring becomes possible. This should be addressed on a case-by-case basis.

Participants acknowledged that considerable progress has been made in setting requirements, especially in Europe, but that implementation and regulatory acceptance were still key elements that needed further work, in particular for routine application in the control of biologicals. Better transparency and dissemination of existing and future scientific work and achievements should be promoted by publication in appropriate journals and using other platforms.

The obligation to address 3Rs is just as important for the veterinary industry as it is for the human industry. Manufacturers, in general, should consider better co-operation in method elaboration and voiced exploring the possibility to waive intellectual property rights for alternative techniques, which could bring large benefits to all the scientific and regulatory communities concerned. Participants from industry also highlighted that running *in-vitro* assays routinely was less expensive than *in-vivo* approaches and that this could be considered as an incentive to switch but it had to be balanced against the cost of development, validation and regulatory implementation. In this context, the need for international harmonisation was strongly expressed and supported. Representatives from all the European and International Institutions present indicated their willingness to investigate means to improve the situation.

As this work is resource demanding, all possible funding opportunities should be considered, for example interaction with ECVAM, the Seventh Framework Programme (FP7, DG Research) and with other relevant national and international organisations.

It was highlighted that in exploring all these developments, public perceptions have to be taken into account, not only with respect to the desire to apply 3Rs but also in terms of the final quality, safety and ultimate confidence in products used in critical public health programmes, such as infant vaccinations.

It was recognised that Europe has taken a leading role in addressing the challenges and was encouraged to continue to promote new ideas and their application. Representatives from the EU Commission, the EDQM and the World Health Organisation (WHO) stated their commitment to refer the ideas expressed during the symposium to their decision-making bodies and groups of experts so as to facilitate their incorporation into appropriate work programmes.

The presentations and proceedings of this symposium will be published later on the EDQM's internet site (www.edqm.eu). This symposium was attended by almost 150 participants from 26 different countries, including representatives from industry and key regulatory stakeholders.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

Contact: Caroline Larsen Le-Tarnec

Public Relations Division, EDQM; Tel: + 33 3 88 41 30 30 (Dial 4); E-mail: Via the Helpdesk on the EDQM website

*3R = Reduction, refinement and replacement of animal use