Development of alternative methods is a key step toward implementing the 3Rs (replacement, reduction and refinement) in animal testing. The aims of the symposium were to share information and experiences on the recent advances that have been made in this field with regard to the EDQM’s Biological Standardisation Programme (BSP) and the European Pharmacopoeia (Ph. Eur.). Particular attention was given to the successful completion of a number of EDQM collaborative studies for the validation of 3R methods in the fields of human and veterinary vaccines, as well as human blood-derived products and to the European Pharmacopoeia’s efforts for replacing the pyrogen test. Aiming at the facilitation of the practical implementation of the new methods, the symposium provided the opportunity for an in-depth discussion of the new methods.

In her opening speech, Dr Susanne Keitel, Director of the EDQM, highlighted the EDQM’s achievements in the 3R area through the progresses being made by the BSP and the Ph. Eur. She reiterated the EDQM’s commitment to the 3R principles and thanked stakeholders, regulators, OMCLs and industry for their support and collaboration.

The scientific programme was composed of four, topic-specific sessions and discussions on: acellular pertussis vaccine, tetanus immunoglobulin, rabies vaccine for veterinary and human use, and pyrogens replacement. Participants heard from leading experts in each area and they shared key information on implementation achievements, new in vitro tests, presented study results and engaged in discussions on the issues. A poster session took place providing the participants with the opportunity to present their work.

The presentations and proceedings will be published later on the EDQM’s internet site: www.edqm.eu.

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Note for the editor: The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia¹ is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards and participates in the areas of blood transfusion, organ transplantations and consumer health issues

¹There are currently thirty-seven members of the European Pharmacopoeia Commission: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union and twenty-three observers The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 16 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America.
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.