

BIOLOGICAL STANDARDISATION

Corrigendum of the annual report of activities - 2001 - of EDQM

Unfortunately in Pharmeuropa 14.2, page 206-207, the activity report of the Biological Standardisation Programme for 2000 was published. The activity report for 2001 is published below.

The Biological Standardisation Programme (BSP, Division IV) continued to pursue the following goals in the area of standardisation of biologicals.

- The establishment of European working standards
- The development and validation of new analytical methods
- The validation of alternative methods in the framework of the 3R concept (i.e. the **R**efinement, **R**eduction and **R**eplacement of animal experiments)

To this end, projects are organised and collaborative studies are performed involving all interested partners (e.g. OMCLs and manufacturers). The results of these studies are published in Pharmeuropa-Bio (2 issues per year). In 2001, the National Library of Medicines (USA) agreed to reference Pharmeuropa-Bio in MEDLINE and Index Medicus and thus to make the titles and summaries of all publications in this journal globally available on the Internet.

In 2001, the following projects were pursued.

- Establishment of inactivated poliomyelitis vaccine (IPV) BRP batch 2
- Establishment of oral poliomyelitis vaccine (OPV) BRP batch 3
- Establishment of hepatitis A vaccine BRP (type B) batch 2
- Establishment of rDNA hepatitis B vaccine BRP (methods A and B) batch 2
- Establishment of tetanus vaccine (human use) BRP batch 2 and WHO 3rd International Standard
- Reporting phase for tetanus vaccine (human use) BRP batch 2 and WHO 3rd International Standard
- Validation of a serological method for potency assay of diphtheria vaccine (Prevalidation phase)
- Establishment of diphtheria toxin BRP for the test for absence of residual toxin in diphtheria vaccine
- Reporting phase for acellular pertussis vaccine, mouse anti-serum BRP

- Establishment of pertussis toxin BRP for the test for absence of residual toxin in acellular pertussis vaccine (Phase II)
- Validation of an HPLC method as an alternative to the bio-assay for pertussis toxin (Phase III)
- Establishment of ELISA coating antigen BRP for the serological potency assay of swine erysipelas vaccine
- Reporting phase for antisera BRPs for potency assays of equine influenza vaccine
- Validation of the *in vitro* potency assay for Newcastle disease vaccine (Prevalidation phase)
- Establishment of BRPs for Newcastle disease vaccine
- Establishment of mycoplasma reference strains BRPs (Feasibility phase)
- Establishment of human coagulation factor VIII concentrate BRP batch 3
- Establishment of human immunoglobulin BRP batch 2
- Establishment of anti-D immunoglobulin BRP
- Establishment of BRP for prekallikrein activator (PKA)
- Establishment of BRP for normal human plasma for the assay of SD-plasma and fibrin sealant kits
- Establishment of BRP for human coagulation factor VII concentrate
- Establishment of BRP for parvovirus B19 spiked plasma for NAT
- Establishment of an HPLC potency assay for interferon alfa2

The studies led to the adoption of the following reference preparations in 2001.

- Tetanus vaccine (adsorbed) for human use batch 2
- Pertussis toxin
- Erysipelas ELISA coating antigen
- Human coagulation factor VIII batch 3
- Human immunoglobulin batch 2

The project concerning the validation of a serological potency assay for tetanus vaccine for human use (to replace the direct challenge assay) was concluded and the method was presented to Group of Experts No. 15 for incorporation into the monograph.