European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

EUROPEAN PHARMACOPOEIA
BIOLOGICAL STANDARDISATION PROGRAMME
ACHIEVEMENTS IN 2006

The following projects were pursued:

Vaccines for human use

- Validation of alternatives to Auszyme ELISA kits for the *in vitro* potency assay of the rDNA hepatitis B vaccine
- Validation of a serological method for potency assay of acellular pertussis vaccine
- Standardisation of the assay for residual pertussis toxin
- Standardisation of human influenza vaccine serology
- Validation of NMR methods for quality control of polysaccharide vaccines
- Establishment of (non-adsorbed) hepatitis A vaccine BRP
- Establishment of varicella vaccine BRP
- Establishment of diphtheria vaccine BRP replacement batch

Biotechnology products

- Establishment of somatropin CRS batch 2 and somatropin / desamidosomatropin resolution mixture CRS batch 1
- Establishment of heparin sodium BRP batch 3
- Establishment of an HPLC assay for interferon alfa-2
- Establishment of low molecular mass heparin for calibration BRP batch 2
- Establishment of erythropoietin BRP batch 3
- Establishment of BRPs and ELISA assays for two major recombinant allergens (Bet v 1, Phl p 5a)
- Establishment of C-GSF (filgrastim) BRP

Vaccines for veterinary use

- Establishment of mycoplasma reference strains BRPs
- Establishment of a new type of equine influenza antiserum BRP

Blood and plasma products

- Establishment of BRP for assay of SD-plasma and fibrin sealant kits
- Establishment of human coagulation factor VII concentrate BRP
- Validation of an in vitro assay method for tetanus immunoglobulin
- Establishment of von Willebrand factor BRP for ristocetin cofactor assay
- Establishment of BRPs for determination of anti-A, anti-B haemagglutinin titres in human normal immunoglobulin for intravenous administration
- Establishment of BRP replacement batch for determination of pre-kallikrein titres in human albumin

New BRPs and replacement batched adopted in 2006

The studies led to the adoption of the following reference preparations by the Ph. Eur. Commission in 2006:

- 5 low-passage mycoplasma reference strains:
  - Acholeplasma laidlawii BRP batch 1
  - Mycoplasma fermentans BRP batch 1
  - Mycoplasma hyorhinis BRP batch 1
  - Mycoplasma orale BRP batch 1
  - Mycoplasma synoviae BRP batch 1

- Equine influenza subtype 2 American-like strain A/eq/South Africa/4/03 horse antiserum BRP batch 1
- Heparin sodium BRP batch 3
- Somatropin CRS batch 2
- Somatropin/desamidosomatropin resolution mixture CRS batch 1
- Human coagulation factor VII concentrate BRP batch 1