COUNCIL OF EUROPE CONSEIL DE L'EUROPE

EUROPEAN PHARMACOPOEIA
BIOLOGICAL STANDARDISATION PROGRAMME

ACHIEVEMENTS IN 2002

The following projects were started or pursued:

- Establishment of inactivated poliomyelitis vaccine (IPV) BRP;
- Establishment of oral poliomyelitis vaccine (OPV) BRP;
- Establishment of hepatitis A vaccine BRP (type B);
- Establishment of rDNA hepatitis B vaccine BRP (methods A and B);
- Reporting phase for tetanus vaccine (human use) BRP and WHO 3rd International Standard;
- Validation of serological method for potency assay of diphtheria vaccine;
- Establishment of diphtheria toxin BRP for test for absence of residual toxin in diphtheria vaccine;
- Reporting phase for acellular pertussis vaccine, mouse anti-serum BRP;
- Validation of HPLC method as alternative to bio-assay for pertussis toxin;
- Standardisation of test on "Molecular Size Distribution" of *haemophilus influenzae* type B conjugate vaccine;
- Reporting phase for antisera BRPs for potency assays of equine influenza vaccine;
- Validation of *in vitro* potency assay for Newcastle Disease Vaccine;
- Establishment of BRPs for Newcastle Disease Vaccine;
- Establishment of Mycoplasma reference strains BRPs;
- Validation of *in vitro* potency assay for *Clostridium perfringens* vaccine;
- Establishment of BRPs for *in vitro* potency assay of *Clostridium perfringens* vaccine;
- Establishment of rabies vaccine for veterinary use;
- Establishment of anti-D immunoglobulin BRP;
- Establishment of prekallikrein activator (PKA);
- Establishment of BRP for normal human plasma for assay of SD-plasma and fibrin sealant kits;
- Establishment of human coagulation factor VII concentrate;
- Establishment of B19 virus spiked plasma for NAT testing;
- Establishment of low molecular mass heparin;
- Establishment of an HPLC potency assay for interferon alfa2;
- Establishment of BRP for rDNA erythropoietin

Ten new projects were started. As in previous years, co-operation with international partners continued. Projects to establish common standards were set up whenever possible with the WHO Expert Committee on Biological Standardisation (ECBS); examples include the establishment of standards for PKA and low molecular mass heparin. The project for the establishment of the anti-D immunoglobulin reference material was a tripartite project, conducted together with WHO and FDA/CBER. As a result, a common global reference preparation was made available in 2003.