REVISED/CORRECTED TEXTS PUBLISHED IN SUPPLEMENT 4.1

A summary of the technical modifications to the revised texts (adopted at the March 2001 Session) and corrected texts is indicated below.

METHODS OF ANALYSIS

2.7.2. Microbiological assay of antibiotics
Revision of Tables 2.7.2-1 and 2.7.2-2 following the adoption of the monographs *Josamycin (1983)* and *Josamycin propionate (1982).*

DOSAGE FORMS

Premixes for medicated feeding stuffs for veterinary use (1037)
Definition: introduction of liquid forms.
Production: introduction of requirements for active ingredients of Ph. Eur. quality.
Tests: introduction of a test for loss on drying for solid forms.
Labelling: section completed.

Tablets (0478)
Production: introduction of a test for uniformity of mass/content for divided tablets.
Modification of the tests for uniformity of content and uniformity of mass.
Coated tablets: addition of a test for uniformity of mass/content of the cores.
Orodispersible tablets: new section.
Modified-release tablets: modification of the definition.
Tablets for use in the mouth: reference to the monograph *Oromucosal preparations (1807).*

MONOGRAPHS

Aceclofenac (1281)
Identification B: use of a Ph. Eur. reference spectrum.
Related substances: replacement of the HPLC method with a gradient HPLC method that allows the quantification of some additional impurities.
Impurities: addition of impurities G, H and I.

Caffeine (0267)
Caffeine monohydrate (0268)
Addition of an impurities section.

Calcium hydrogen phosphate, anhydrous (0981)
Deletion of the test for monocalcium phosphate and tricalcium phosphate (and therefore deletion of identification test A).
Modification of identification test B (becomes identification test A).

Calcium hydrogen phosphate dihydrate (0116)
Deletion of the test for monocalcium phosphate and tricalcium phosphate.

D-Camphor (1400)
Revision of the related substances test.
Addition of an impurities section.

Clomipramine hydrochloride (0889)
Identification: revision of identification test B by infrared absorption spectrophotometry.
Related substances: replacement of the TLC method with an HPLC method.
Revision of the storage section.

Dextropropoxyphene hydrochloride (0713)
Assay: determination of the end-point by potentiometry as the indicator used in the assay was no longer commercially available.

Docusate sodium (1418)
Chlorides: indication of the colour change of the indicator since by further addition of 0.1 M silver nitrate a second colour change can be seen.

Glycerol dibehenate (1427)
Assay: modification of the preparation and injection of the test solution.

Gonadorelin acetate (0827)
Water: modification of the quantity of the substance to be examined.

Guanethidine monosulphate (0027)
Assay: determination of the end-point by potentiometry as the indicator used in the assay was no longer commercially available.

Insulin preparations, injectable (0854)
Definition: replacement of the reference to the monograph on *Insulin (0276)* with references to the monographs on *Insulin, bovine (1637)* and *Insulin, porcine (1638).*

Insulin zinc injectable suspension (0837)
Revision of the definition.

Isopropyl alcohol (0970)
Addition of a test for absorbance since isopropyl alcohol can often be deteriorated by atypical impurities (from storage barrels), which can be detected by a UV test.

Lactic acid (0458)
Methanol: correction of the reference to the general method (English text only).

Lavender oil (1338)
Revision of the chromatographic profile test and modification of contents.

Lemon oil (0620)
Refractive index: modification of the lower limit.

Deletion of the test for adulterants and the assay of citral following the addition of a chromatographic profile test.
Deletion of the test for foreign essential oils.

Levodropropizine (1535)
Impurity B and related substances: modification of the preparation of the reference solutions.
Impurity C: modification of the GC method.

Macrogol lauryl ether (1124)
Identification: deletion of the identification by TLC.
Ethylene oxide and dioxan: replacement of the 2 methods with general method 2.4.25 (Ethylene oxide and dioxan).

Macrogol oleyl ether (1125)
Identification: deletion of the identification by TLC.
Iodine value: introduction of a maximum variation around the nominal value.
Peroxide value: addition of a test.
Ethylene oxide and dioxan: replacement of the 2 methods with general method 2.4.25 (Ethylene oxide and dioxan).

Metronidazole benzoate (0934)
Identification:
—deletion of identification test A from the first identification series;
—deletion of identification test D (identification test E becomes identification test D).
Related substances test: TLC method replaced with an HPLC method and modification of the limits.
Impurities : addition of impurity C.

Nifedipine (0627)
Assay: replacement of 0.1 M ammonium and cerium sulphate solution with 0.1 M cerium sulphate in order to eliminate the use of arsenious trioxide and osmium tetroxide for standardisation.

Pancreas powder (0350)
Identification test A: indication of the quantity of fibrin congo red R to be added.

Pancuronium bromide (0681)
Related substances test: revision of the TLC method.
Addition of an impurities section.

Phenoxymethylpenicillin (0148)
Assay: modification of the sentence for the calculation of the percentage content of 4-hydroxyphenoxymethylpenicillin to take into account the base/salt form of the CRS (correction factor).

Phenoxymethylpenicillin potassium (0149)
Assay: modification of the sentence for the calculation of the percentage content of 4-hydroxyphenoxymethylpenicillin potassium to take into account the base/salt form of the CRS (correction factor).

Prazosin hydrochloride (0856)
Identification: deletion of the recrystallisation in the IR identification as the substance does not show polymorphism.
Related substances test: replacement of the TLC method by an HPLC method and addition of a 0.5 per cent limit for the total of impurities.
Assay: indication that the titration should be performed quickly.

Progesterone (0429)
Characters: addition of a statement concerning polymorphism.
Identification: deletion of the melting point; replacement of chloroform with methylene chloride in the TLC identification.
Related substances test: replacement of the TLC method with a gradient HPLC method.
Addition of a transparency section.

Propyphenazone (0636)
Addition of a transparency section.

Pyridoxine hydrochloride (0245)
Addition of a transparency section.

Sage leaf (salvia officinalis) (1370)
Identification: revision of identification test C by TLC.

Sodium (*S*)-lactate solution (2033)
Methanol: correction of the reference to the general method (English text only).

Sorbitan oleate (1041)
Sorbitan trioleate (1044)
Definition: revision in order to differentiate between sorbitan oleate, sesquioleate and trioleate.
Identification C: addition of a statement on margarinic acid.
Addition of a labelling section.

Starch, pregelatinised (1267)
Revision of the definition.
Tests for pH, for iron and for oxidising substances: the preparation of the solutions has been adapted to take account of the high viscosity of solutions of the substance.
Modification of the test for foreign matter.

Stearic acid (1474)
Solubility: modification of the solubility in water.
Assay: correction of the preparation of the test solution and use of reagents instead of CRS for palmitic acid and stearic acid.

Sumatriptan succinate (1573)
Related substances test A. Revision of the LC procedure to limit impurities A and H and not to take account of other impurities. Modification of the title of the test to read “Impurity A and impurity H”.
Related substances test B. Modification of the test to identify all impurities unambiguously by the addition of impurity D CRS and removal of the relative retentions.

Terfenadine (0955)
Related substances: modification of reference solution (d).

Thyme (0865)
Definition: content expressed in thymol and carvacrol as minimum 40 per cent of essential oil.
Addition of identification test D.
Modification of the test for foreign matter.
Assay of phenols: replacement of the photometric method with a GC method for the determination of thymol and carvacrol.

Thyme oil (1374)
Identification by TLC: replacement of terpinen-4-ol with α-terpineol.
Chromatographic profile: modification of column parameters.

Wool fat, hydrogenated (0969)
Tests: deletion of the test for butylhydroxytoluene.

VACCINES FOR HUMAN USE

Pertussis vaccine (acellular, component, adsorbed) (1356)
Tests: combination of the tests for Residual pertussis toxin and Irreversibility of pertussis toxoid. A validity requirement concerning the control group has been added and provision has been made for repetition of the test to take account of the possibility of non-specific death in the test animals.

HOMOEOPATHIC PREPARATIONS

Homoeopathic preparations (1038)
Introduction of references to the general monographs *Herbal drugs for homoeopathic preparations (2045)* and *Mother tinctures for homoeopathic preparations (2029)*.

COMMUNIQUÉ

ADVANCING SCIENCE AND ELIMINATION OF THE USE OF LABORATORY ANIMALS FOR DEVELOPMENT AND CONTROL OF VACCINES AND HORMONES:

REALISTIC GOAL OR MISSION IMPOSSIBLE?

12-14 November 2001
Jaarbeurs Congress Centre, Utrecht, The Netherlands

Symposium organized by the
International Association for Biologicals (IABS)

Programme Chairman
Coenraad Hendriksen (RIVM, NL)
Dorothea Sesardic (NIBSD, UK)
Klaus Cussler (PEI, D)

A number of physico-chemical, immuno-chemical, biochemical and cell biological methods have been proposed for the replacement, reduction and refinement of animal tests in the development and control of vaccines and hormones. However, the validation, standardization, implementation and ultimately regulatory acceptance of these procedures are still at a very early stage. The purpose of this meeting is to bring together research scientists, manufacturers and regulators to promote the rational development and acceptance of alternative methods.

The scope of the Conference falls broadly into four main session categories:

- **Replacement, reduction and refinement alternatives,**
- **Emerging technologies in production and control,**
- **Test validation and regulatory acceptance,**
- **Test implementation.**