

UPDATED WORK PROGRAMME OF THE EUROPEAN PHARMACOPOEIA

(November 2006)

The following items have recently been added to the work programme of the European Pharmacopoeia. Interested parties are invited to contact the EDQM (lynn.kelso-eleuterio@edqm.eu) with a view to participating in the work on items of interest.

TEXTS TO BE REVISED

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|---|---|
| 2.2.29. Liquid chromatography: <i>detectors</i> | Human normal immunoglobulin (0338): <i>pH, total protein</i> |
| 2.7.9. Test for Fc function of immunoglobulin: <i>addition of a micro-plate method</i> | Hydroxypropylbetadex (1804): <i>related substances</i> |
| 5.1.2. Biological indicators of sterilisation: <i>general revision, notably to take account of recent work by ISO and CEN</i> | Isotretinoin (1019): <i>publication in Pharmeuropa</i> |
| 5.2.3. Cell substrates for the production of vaccines for human use: <i>retroviruses</i> | Lymecycline (1654): <i>light-absorbing impurities; related substances</i> |
| Allergen products (1063): <i>general revision</i> | Mannitol (0559): <i>limit for unspecified impurities in Related substances</i> |
| Calcium folinate (0978): <i>chlorides</i> | Methylethylergometine maleate (1788): <i>limits for impurities in Related substances</i> |
| Calcium gluconate (0172): <i>water content</i> | Nadolol (1789): <i>related substances</i> |
| Cefoxitin sodium (0990): <i>addition of a test for heavy metals</i> | Phloroglucinol, anhydrous (2301): <i>heavy metals; related substances</i> |
| Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065): <i>revision to cover liquid vaccines</i> | Phloroglucinol dihydrate (2302): <i>heavy metals; related substances</i> |
| Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521): <i>development of the safety test under Production</i> | Tetracosactide (0644): <i>water determination</i> |
| Glutathione (1670): <i>related substances</i> | Vaccines for human use (0153): <i>appearance</i> |
| Haemophilus type b conjugate vaccine (1219): <i>determination of volatile matter</i> | Vibriosis (cold-water) vaccine (inactivated) for salmonids (1580): <i>development of the safety test under Production</i> |
| | Vibriosis vaccine (inactivated) for salmonids (1581): <i>development of the safety test under Production</i> |

NEW MONOGRAPHS

- | | |
|--|---|
| D-Glucosamine hydrochloride (2446) | Oxygen (93 per cent) (2455) |
| D-Glucosamine sulphate (2447) | Polyethylene oxide (2444) |
| Human papillomavirus vaccine (2441) | Porcine enzootic pneumonia vaccine (inactivated) (2448) |
| Measles, mumps, rubella and varicella vaccine (2442) | |

COUNTERFEIT MEDICINES - SURVEY REPORT (2006)

Counterfeit medicines pose an ever-greater threat to public health in Europe today. In an effort to adequately measure the scope of the phenomenon and reduce the inherent risks, the Council of Europe has commissioned a survey on issues related to this particularly disquieting form of fraud. This report covers, among others: the current and estimated market and trade matters; the status of pharmaceutical regulation; national and international co-operation between authorities, the industry and wholesalers; detection systems and procedures; the adequacy of legal, judicial and administrative systems; and professional training in the matter. It also sets out to define counterfeit medicine and pharmaceutical crime.

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Ms Sophie Lobey, F-67075 Strasbourg Cedex, France.

Tel: +33 (0)3 88 41 25 81 - Fax: +33 (0)3 88 41 39 10

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