

Follow-up to 132nd Session of the Commission

| REVISION OF MONOGRAPHS | REASON |
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| Human antithrombin III concentrate / Antithrombine III humaine (concentré d') (878) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Pertussis vaccine (acellular, component, adsorbed) / Vaccin coquelucheux (adsorbé, multicomposé, acellulaire) (1356) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Alternative methods for control of microbiological quality / Méthodes alternatives pour le contrôle de la qualité microbiologique (5.1.6.) (MMM WP): Liaise with MYC, 15V, 15 (viruses) | General revision to take account of recent technological developments |
| Amidotrizoic acid dihydrate / Amidotrizoïque (acide) dihydraté (873) | Related substances |
| Ascorbic acid / Ascorbique (acide) (253) | Related substances |
| Atomic emission spectrometry / Spectrométrie d'émission atomique (2.2.22.) | Improvement of direct calibration method |
| BCG vaccine, freeze-dried / Vaccin BCG cryodesséché (163) | Deletion of the test for temperature stability |
| Biological indicators of sterilisation / Indicateurs biologiques de stérilisation (5.1.2.) | General revision to take into account technological and scientific developments |
| Calcium dobesilate monohydrate / Calcium (dobésilate de) monohydraté (1183) | Related substances |
| Camphor, racemic / Camphre racémique (655) | Related substances |
| Chymotrypsin / Chymotrypsine (476) | Test for trypsin |
| Cladribine / Cladribine (2174) | Test for pH |
| Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed) / Vaccin diphtérique, tétanique et coquelucheux (acellulaire, multicomposé), adsorbé (1931) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Diphtheria, tetanus, pertussis (acellular, component) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et conjugué de l'haemophilus type b adsorbé (1932) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Diphtheria, tetanus, pertussis (acellular, component) and hepatitis B (rDNA) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et de l'hépatite B (ADNr), adsorbé (1933) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé) et poliomyélitique (inactivé), adsorbé(1934) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |

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| Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), de l'hépatite B (ADNr), poliomyélitique (inactivé) et conjugué de l'haemophilus type b adsorbé (2067) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) / Vaccin diphtérique, tétanique, coquelucheux (acellulaire, multicomposé), poliomyélitique (inactivé) et conjugué de l'haemophilus type b adsorbé (2065) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Ear preparations / Préparations auriculaires (652) | Definition |
| Etamsylate (1204) | Related substances |
| Fluphenazine dihydrochloride / Fluphénazine (dichlorhydrate de) (904) | Related substances |
| Gemfibrozil (1694) (Group 10A) | Related substances |
| Glucagon, human / Glucagon humain (1635) | Tests for deamidated glucagon and related proteins, assay |
| Hepatitis B vaccine (rDNA) / Vaccin de l'hépatite B (ADNr) (1056) | Addition of tests concerning the biological adjuvant MPL |
| Human coagulation factor IX (1223) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human coagulation factor VII (1224) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human coagulation factor XI (1644) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human fibrinogen (24) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human normal immunoglobulin / Immunoglobuline humaine normale (338) | Test for IgA and maximum Iga content to be stated on the label |
| Human papillomavirus vaccine (rDNA) / Vaccin du papillomavirus humain (ADNr) (2441) | Addition of tests concerning the biological adjuvant MPL |
| Human plasma pooled and treated for virus inactivation (1646) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human prothrombin complex (554) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |
| Human von willebrand factor (2298) | Inclusion of a provision for use of an <i>in vivo</i> method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test |

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| Imipenem / Imipénem (1226) | Impurities |
| Measles, mumps and rubella vaccine (live) / Vaccin rougeoleux, des oreillons et rubéoleux, vivant (1057) | Pregnancy statement in the labelling section |
| Measles, mumps, rubella and varicella vaccine (live) / Vaccin rougeoleux, des oreillons, rubéoleux et varicelleux, vivant (2442) | Pregnancy statement in the labelling section |
| Metamizole sodium / Métamizole sodique (1346) | Related substances test |
| Methylphenidate hydrochloride / Méthylphénidate (chlorhydrate de) (2235) | Related substances test |
| Oleyl alcohol / Oléique (alcool) (2073) | Limits for refractive index |
| Opium tincture, standardised / Opium (teinture titrée d') (1841) | Assay method: update and harmonisation with the monograph on standardised Opium tincture |
| Opium, raw / Opium brut (777) | Assay method: update and harmonisation with the monograph on standardised Opium tincture |
| Pertussis vaccine (acellular, co-purified, adsorbed) / Vaccin coquelucheux (adsorbé, copurifié, acellulaire) (1595) | Addition of an alternative method to the absence of residual pertussis toxin and irreversibility of pertussis toxoid test |
| Rabies vaccine (inactivated) for veterinary use / Vaccin rabique inactivé pour usage vétérinaire (451) | Potency test |
| Rubella vaccine (live) / Vaccin rubéoleux vivant (0162) | Pregnancy statement in the labelling section |
| Sodium ascorbate (1791) | Related substances |
| Sodium bromide / Sodium (bromure de) (190) | Test for chlorides |
| Sodium lactate solution / Sodium (lactate de), solution de (1151) | - Definition - Test for aluminium |
| Triglycerides, medium-chain / Triglycérides à chaîne moyenne (868) | Definition |
| Tri-n-butyl phosphate / Tri-n-butyle (phosphate de) (1682) | Related substances |
| Varicella vaccine (live) / Vaccin varicelleux vivant (0648) | Pregnancy statement in the labelling section |
| Zinc sulphate monohydrate / Zinc (sulfate de) monohydraté (2159) | Test for pH |

Additions to the work programme following the 132nd Session of the Commission

Abacavir sulphate
Amprenavir
Cypermethrin
Docetaxel anhydrous
Fondaparinux sodium
Fosamprenavir
Hepatitis A (Inactivated) and Typhoid vaccine
Levofloxacin
Nicotine (Bi)tartrate dihydrate
Olmesartan medoxomil
Polyoxypropylene-15-stearyl ether
Pullulan
Ropinirole HCl
Rosiglitazone maleate
Theobroma oil (cocoa butter)
Topotecan HCl
Triclabendazole
Yttrium (90Y) Dota-(TYR3)-octreotide injection
Zanamivir