European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Follow-up to 132nd Session of the Commission

REVISION OF MONOGRAPHS	REASON
Human antithrombin III concentrate / Antithrombine III humaine (concentré d') (878)	Inclusion of a provision for use of an *in vivo* 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

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 *in vivo* 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 *in vivo* 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 *in vivo* 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 *in vivo* 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 *in vivo* 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 *in vivo* 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 *in vivo* method as an alternative to the pyrogen test and acceptance criteria for the bacterial endotoxin test

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