

DAGORDE VAN DE VERGADERING VAN DE BELGISCHE FARMACOPEECOMMISSIE – SUBCOMMISSIE BIOLOGIE – VAN 16/05/2023

1. GOEDKEURING VAN DE DAGORDE

2. MELDING VAN BELANGENCONFLICTEN

3. GOEDKEURING VAN DE NOTULEN VAN DE VERGADERING VAN DE BELGISCHE FARMACOPEECOMMISSIE – SUBCOMMISSIE BIOLOGIE – VAN 10/11/2022

4. BEOORDELING VAN EUROPESE MONOGRAFIEPROJECTEN

PHARMEUROPA 35.1

Volgende monografieën worden opgenomen in de dagorde:

- Pyrogenicity (5.1.13), doc. PA/PH/Exp. BET/T (21) 13 ANP
- Guidelines for using the test for bacterial endotoxins (5.1.10), doc. PA/PH/Exp. BET/T (22) 2 ANP
- Substances for pharmaceutical use, doc. PA/PH/Exp. BET/T (21) 6 ANP
- Fibrinogenum humanum, doc. PA/PH/Exp. 6B/T (22) 7 ANP
- Solutiones anticoagulantes et sanguinem humanum conservantes, doc. PA/PH/Exp. 6B/T (22) 8 ANP
- Albumini humani solutio, doc. PA/PH/Exp. 6B/T (22) 9 ANP
- Factor VIII coagulationis humanus, doc. PA/PH/Exp. 6B/T (22) 10 ANP
- Immunoglobulinum humanum normale ad usum intramusculum, doc. PA/PH/Exp. 6B/T (22) 11 ANP
- Prothrombinum multiplex humanum, doc. PA/PH/Exp. 6B/T (22) 12 ANP
- Antithrombinum III humanum densatum, doc. PA/PH/Exp. 6B/T (22) 13 ANP
- Immunoglobulinum humanum normale ad usum intravenosum, doc. PA/PH/Exp. 6B/T (22) 14 ANP
- Factor IX coagulationis humanus, doc. PA/PH/Exp. 6B/T (22) 15 ANP
- Factor VII coagulationis humanus, doc. PA/PH/Exp. 6B/T (22) 16 ANP
- Factor XI coagulationis humanus, doc. PA/PH/Exp. 6B/T (22) 17 ANP
- Plasma humanum coagmentatum conditumque ad extinguendum virum, doc. PA/PH/Exp. 6B/T (22) 18 ANP
- Immunoglobulinum anti-T lymphocytorum ex animali ad usum humanum, doc. PA/PH/Exp. 6B/T (22) 19 ANP
- Factor humanus von Willebrandi, doc. PA/PH/Exp. 6B/T (22) 20 ANP
- α-1-Proteinasi inhibitor humanum, doc. PA/PH/Exp. 6B/T (22) 21 ANP
- Immunoglobulinum humanum normale ad usum subdermicum, doc. PA/PH/Exp. 6B/T (22) 22 ANP
- C1-esterasi inhibitor humanus, doc. PA/PH/Exp. 6B/T (22) 23 ANP
- Vaccina ad usum humanum, doc. PA/PH/Exp. 15/T (22) 7 ANP
- Immunosera ex animale ad usum humanum, doc. PA/PH/Exp. 15/T (22) 8 ANP
- Adeps A 3-O-desacyl-4'-monophosphorylatus, doc. PA/PH/Exp. 15/T (22) 9 ANP
- Carrier proteins for the production of conjugated polysaccharide vaccines for human use (5.2.11), doc. PA/PH/Exp. 15/T (22) 10 ANP
- Vaccinum hepatitis B (ADNr), doc. PA/PH/Exp. 15/T (22) 11 ANP
- Vaccinum haemophilii stirpis b coniugatum, doc. PA/PH/Exp. 15/T (22) 12 ANP
- Vaccinum encephalitis ixodibus advectae inactivatum, doc. PA/PH/Exp. 15/T (22) 13 ANP

- Vaccinum rabiei ex cellulis ad usum humanum, doc. PA/PH/Exp. 15/T (22) 14 ANP
- Vaccinum diphtheriae, tetani, pertussis sine cellulis ex elementis praeparatum,hepatitidis B (ADNr), poliomyelitis inactivatum et haemophili stirpis b coniugatum adsorbatum, doc. PA/PH/Exp. 15/T (22) 15 ANP
- Vaccinum pneumococcale polysaccharidicum coniugatum adsorbatum, doc. PA/PH/Exp. 15/T (22) 16 ANP
- Vaccinum meningococcale polysaccharidicum, doc. PA/PH/Exp. 15/T (22) 17 ANP
- Vaccinum pneumococcale polysaccharidicum, doc. PA/PH/Exp. 15/T (22) 18 ANP
- Vaccinum diphtheriae, tetani, pertussis sine cellulis ex elementis praeparatum ethaemophili stirpis b coniugatum adsorbatum, doc. PA/PH/Exp. 15/T (22) 19 ANP
- Vaccinum diphtheriae, tetani, pertussis sine cellulis ex elementis praeparatum, poliomyelitis inactivatum et haemophili stirpis b coniugatum adsorbatum, doc. PA/PH/Exp. 15/T (22) 20 ANP
- Vaccinum meningococcale classis C coniugatum, doc. PA/PH/Exp. 15/T (22) 21 ANP
- Vaccinum haemophili stirpi b et meningococcale classis C coniugatum, doc. PA/PH/Exp. 15/T (22) 22 ANP
- Vaccinum meningococcale classium A, C, W135 et Y coniugatum, doc. PA/PH/Exp. 15/T (22) 23 ANP
- Vaccinum Salmonellae Typhimurium vivum perorale ad pullum, doc. PA/PH/Exp. 15V/T (22) 24 ANP
- Vaccinum Salmonellae Enteritidis vivum perorale ad pullum, doc. PA/PH/Exp. 15V/T (22) 25 ANP
- Producta allergenica, doc. PA/PH/Exp. ALG/T (22) 5 ANP

PHARMEUROPA 35.2

Volgende monografieën worden opgenomen in de dagorde:

- Evaluation of safety of veterinary vaccines and immunosera (5.2.6), doc. PA/PH/Exp. 15V/T (21) 35 ANP
- Evaluation of efficacy of veterinary vaccines and immunosera (5.2.7), doc. PA/PH/Exp. 15V/T (21) 36 ANP
- Phage therapy active substances and medicinal products for human and veterinary use (5.31), doc. PA/PH/Exp. BACT/T (22) 1 ANP
- Additional information on gene therapy medicinal products for human use (5.34), doc. PA/PH/Exp. GTP/T (22) 7 ANP
- Enoxaparinum natricum iniectabile, doc. PA/PH/Exp. 6/T (21) 61 ANP
- Aprotinini solutio concentrata ,doc. PA/PH/Exp. 6/T (23) 1 ANP
- Vaccina ad usum veterinarium, doc. PA/PH/Exp. 15V/T (21) 34 ANP

5. ANDERE PUNTEN

- Voorstelling van het werkprogramma van de expert- en werkgroepen van de Europese Farmacopeecommissie.