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HEADS OF AGENCIES – CMDh

23 September

NEW - Template for Applicants to Prepare Similarity Report

UPDATE - Applicant's response document in Mutual Recognition and Decentralised Procedures for Marketing Authorisation Applications

UPDATE - RMS validation checklist for human medicinal products in DCP

UPDATE - Request for MRP/RUP / Update assessment report

UPDATE - CMDh Best Practice Guide on the compilation of the dossier for New Applications submitted in Mutual Recognition and Decentralised Procedures

UPDATE - CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) 1234/2008

NEW - Overview of timetables 2023 - CMDh 60-day procedures for MRP/DCP applications

NEW - HaRP Assessment Report on Amorolfin

NEW - HaRP Assessment Report on Azithromycin (systemic formulations)

NEW - HaRP Assessment Report on Betahistine

NEW - HaRP Assessment Report on Cefepime

NEW - HaRP Assessment Report on Celecoxib

NEW - HaRP Assessment Report on Clarithromycin

NEW - HaRP Assessment Report on Cyclophosphamide

NEW - HaRP Assessment Report on Fluticasone propionate

NEW - HaRP Assessment Report on Hydrochlorothiazide

NEW - HaRP Assessment Report on Ibuprofen

NEW - HaRP Assessment Report on Levonorgestrel (for emergency contraception)

NEW - HaRP Assessment Report on Nitrofurantoin

NEW - HaRP Assessment Report on Paracetamol and Ibuprofen

NEW - HaRP Assessment Report on Paracetamol

UPDATE - HaRP Assessment Report on Olmesartan hydrochlorothiazide

22 September

NEW - Report from the meeting held on 13-14 September 2022

20 September

NEW - 19-20 July CMDh Minutes

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

26/09/2022	Union Pharmacovigilance Database: refresher webinar on signal management overview , Online, 10:00-12:00 Amsterdam time (CET), from 27/10/2022 to 27/10/2022
26/09/2022	Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)
26/09/2022	EPAR - Product Information: Soliris : EPAR - Product Information (updated)
26/09/2022	Human medicines European public assessment report (EPAR): Evusheld, tixagevimab, cilgavimab, COVID-19 virus infection, 25/03/2022, 1, Authorised (updated)
26/09/2022	Work programme: Work programme of the HMA/EMA task force on availability of authorised medicines for human and veterinary use (updated)
26/09/2022	Availability of medicines (updated)
26/09/2022	Opinions and letters of support on the qualification of novel methodologies for medicine development (updated)
26/09/2022	Other: Terms of reference of the HMA/EMA task force on availability of authorised medicines for human and veterinary use
23/09/2022	Human medicines European public assessment report (EPAR): Tagrisso, osimertinib mesilate, Carcinoma, Non-Small-Cell Lung, 01/02/2016, 16, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Evkeeza, Evinacumab, Hypercholesterolemia, 17/06/2021, 1, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Kadcyla, trastuzumab emtansine, Breast Neoplasms, 15/11/2013, 14, Authorised (updated)
23/09/2022	Other: FAQs: How to create, submit and withdraw a Clinical Trial Application - CTIS Training Programme - Module 10 (updated)
23/09/2022	Regulatory and procedural guideline: IRIS guide to registration and RPIs (updated)

23/09/2022	Other: IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants (updated)
23/09/2022	News and press releases: New co-chairs elected for working parties for healthcare professionals and for patients and consumers
23/09/2022	Clinical Trials Information System: training and support (updated)
23/09/2022	Other: Clinical Trial Information System (CTIS) evaluation timelines
23/09/2022	Committee for Herbal Medicinal Products (HMPC): 18-20 July 2022 , from 18/07/2022 to 20/07/2022 (updated)
23/09/2022	Minutes: Minutes of the HMPC 18-20 July 2022 meeting
23/09/2022	Work programme: 2022-2025 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP) (updated)
23/09/2022	Second Veterinary Big Data stakeholder forum , Online, 09:30 - 17:00 Amsterdam time (CET), from 23/11/2022 to 23/11/2022 (updated)
23/09/2022	Risk management information day 2022 , Virtual meeting, from 09/12/2022 to 09/12/2022
23/09/2022	Human medicines European public assessment report (EPAR): Lyxumia , lixisenatide, Diabetes Mellitus, Type 2, 31/01/2013, 16, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Spikevax (previously COVID-19 Vaccine Moderna), CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2), COVID-19 virus infection, 06/01/2021, 29, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Rydapt, Midostaurin, Leukemia, Myeloid, Acute; Mastocytosis, 18/09/2017, 9, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Elzonris, tagraxofusp, Lymphoma, 07/01/2021, 5, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Nexpovio, Selinexor, Multiple Myeloma, 26/03/2021, 5, Authorised (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 29, Authorised (updated)
23/09/2022	Direct healthcare professional communication (DHPC): Metalyse (tenecteplase) 8000 units (40 mg) and 10000 units (50 mg) powder and solvent for solution for injection: temporary supply shortage, Active substance: tenecteplase, DHPC type: Medicine shortage, Last updated: 23/09/2022
23/09/2022	Supply shortage: Shortage of Actilyse (alteplase) and Actilyse Cathflo (alteplase)
23/09/2022	Supply shortage: Shortage of Metalyse (tenecteplase)
23/09/2022	Human medicines European public assessment report (EPAR): Metalyse, tenecteplase, Myocardial Infarction, 23/02/2001, 21, Authorised (updated)
23/09/2022	Scientific and technical recommendations: Veterinary Medicines Regulation (updated)
23/09/2022	Regulatory and procedural guideline: Implementing measures under Article 93(2) of Regulation (EU) 2019/6 as regards the good manufacturing practice for veterinary medicinal products and active substances used as starting materials
23/09/2022	EudraVigilance training and support (updated)
23/09/2022	Human medicines European public assessment report (EPAR): Veklury, remdesivir, Coronavirus Infections, 03/07/2020, 13, Authorised (updated)

23/09/2022	Human medicines European public assessment report (EPAR): Posaconazole Accord, posaconazole, Mycoses, 25/07/2019, 6, Authorised (updated)
22/09/2022	Other: Article 57 product data (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Libtayo, Cemiplimab, Carcinoma, Squamous Cell, 28/06/2019, 12, Authorised (updated)
22/09/2022	Minutes: Minutes of the COMP meeting on 15-17 March 2022 (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Hulio, adalimumab, Hidradenitis Suppurativa; Psoriasis; Uveitis; Arthritis, Rheumatoid; Spondylitis, Ankylosing; Crohn Disease; Colitis, Ulcerative; Arthritis, Psoriatic, 17/09/2018, 12, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Blincyto, blinatumomab, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 23/11/2015, 15, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Ruxience, rituximab, Leukemia, Lymphocytic, Chronic, B-Cell; Arthritis, Rheumatoid; Microscopic Polyangiitis; Pemphigus, 01/04/2020, 9, Authorised (updated)
22/09/2022	Orphan designation: Govorestat for the: Treatment of galactosaemia, 21/06/2022, Positive
22/09/2022	Orphan designation: Eltanexor for the: Treatment of myelodysplastic syndromes, 21/06/2022, Positive
22/09/2022	Orphan designation: Diflunisal for the: Treatment of ATTR amyloidosis, 21/06/2022, Positive
22/09/2022	Orphan designation: Modified mRNA encoding human methylmalonyl-coenzyme A mutase containing a polymorphism at position 671 for the: Treatment of methylmalonic acidaemia, 21/06/2022, Positive
22/09/2022	Orphan designation: 2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl -(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioadenylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiocytidylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-P-thioguanylyl-(3'-O->5'-O)-2'-O-(2-methoxyethyl)-5-methyl-P-thiouridylyl for the: Treatment of cystic fibrosis, 21/06/2022, Positive
22/09/2022	Orphan designation: Human allogeneic keratinocytes for the: Treatment of partial deep dermal and full thickness burns, 21/06/2022, Positive
22/09/2022	Orphan designation: 2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting UBE3A antisense transcript RNA for the: Treatment of Angelman syndrome, 21/06/2022, Positive
22/09/2022	Orphan designation: Tamoxifen citrate for the: Treatment of neuronal ceroid lipofuscinosis, Positive
22/09/2022	Orphan designation: Sirolimus for the: Treatment of follicular lymphoma, 21/06/2022, Positive
22/09/2022	Orphan designation: Sirolimus for the: Treatment of lymphatic malformations, 21/06/2022, Positive
22/09/2022	Orphan designation: Lithium carbonate for the: treatment of TBR1-related disorder, 21/06/2022, Positive

22/09/2022	Human medicines European public assessment report (EPAR): Komboglyze, metformin hydrochloride, saxagliptin hydrochloride, Diabetes Mellitus, Type 2, 24/11/2011, 18, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Onglyza, Saxagliptin, Diabetes Mellitus, Type 2, 30/09/2009, 20, Authorised (updated)
22/09/2022	Other: List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs) (updated)
22/09/2022	Orphan designation: Humanised IgG4 monoclonal antibody against A proliferation-inducing ligand for the: Treatment of primary IgA nephropathy, 21/06/2022, Positive
22/09/2022	Human medicines European public assessment report (EPAR): Nyxoid, Naloxone hydrochloride dihydrate, Opioid-Related Disorders, 09/11/2017, 7, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Imbruvica, Ibrutinib, Lymphoma, Mantle-Cell; Leukemia, Lymphocytic, Chronic, B-Cell, 21/10/2014, 27, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Rinvoq, upadacitinib, Arthritis, Rheumatoid, 16/12/2019, 12, Authorised (updated)
22/09/2022	Human medicines European public assessment report (EPAR): Polivy, polatuzumab vedotin, Lymphoma, B-Cell, 16/01/2020, 4, Authorised (updated)
21/09/2022	Human medicines European public assessment report (EPAR): Vitrakvi, larotrectinib sulfate, Abdominal Neoplasms, 19/09/2019, 7, Authorised (updated)
21/09/2022	Human medicines European public assessment report (EPAR): Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron), dinutuximab beta, Neuroblastoma, 08/05/2017, 11, Authorised (updated)
21/09/2022	Human medicines European public assessment report (EPAR): Tezspire, tezepelumab, Asthma, 19/09/2022, Authorised
21/09/2022	Human medicines European public assessment report (EPAR): Illuzyce, lutetium (177Lu) chloride, Radionuclide Imaging, 15/09/2022, Authorised (updated)
21/09/2022	Human medicines European public assessment report (EPAR): Tabrecta, capmatinib dihydrochloride monohydrate, Carcinoma, Non-Small-Cell Lung, 20/06/2022, Authorised (updated)
21/09/2022	Organisation Management System (OMS) Trouble Shooting Session for CTIS users - July 2022 , Online, 14:00 - 15:00 Amsterdam time (CEST), from 21/07/2022 to 21/07/2022 (updated)
21/09/2022	IRIS for Good Pharmacovigilance practice (GVP) inspections training session for industry users , Online, 10:00 - 11:30 Amsterdam time (CEST), from 07/09/2022 to 07/09/2022 (updated)
21/09/2022	PRIME: priority medicines (updated)
21/09/2022	Report: List of products granted eligibility to PRIME (updated)
21/09/2022	Annex to CHMP highlights: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 12-15 September 2022
21/09/2022	Human medicines European public assessment report (EPAR): Pemetrexed Pfizer (previously Pemetrexed Hospira), pemetrexed disodium, pemetrexed disodium hemipentahydrate, Carcinoma, Non-Small-Cell Lung; Mesothelioma, 19/11/2015, 14, Authorised (updated)
20/09/2022	Human medicines European public assessment report (EPAR): Lupkynis, Voclosporin, Lupus Nephritis, 15/09/2022, Authorised (updated)
20/09/2022	Human medicines European public assessment report (EPAR): Opdualag, nivolumab, Relatlimab, Melanoma, 15/09/2022, Authorised (updated)

20/09/2022	Human medicines European public assessment report (EPAR): Carmustine Obvius, carmustine, Hodgkin Disease; Lymphoma, Non-Hodgkin, 18/07/2018, 7, Authorised (updated)
20/09/2022	Human medicines European public assessment report (EPAR): Ontruzant, trastuzumab, Stomach Neoplasms; Breast Neoplasms, 15/11/2017, 14, Authorised (updated)
20/09/2022	Human medicines European public assessment report (EPAR): Replagal, agalsidase alfa, Fabry Disease, 03/08/2001, 28, Authorised (updated)
20/09/2022	Second Industry Standing Group (ISG) meeting , Online, from 26/09/2022 to 26/09/2022
20/09/2022	Extended EudraVigilance medicinal product dictionary (XEVMPD) training course for clinical trial sponsors - September 2022 , Online, 14:00 - 18:00 Amsterdam time (CEST) , from 29/09/2022 to 30/09/2022 (updated)
20/09/2022	Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making , European Medicines Agency, Amsterdam, the Netherlands, from 21/09/2022 to 21/09/2022 (updated)
20/09/2022	Human medicines European public assessment report (EPAR): Fortacin, lidocaine, prilocaine, Sexual Dysfunction, Physiological, 15/11/2013, 11, Authorised (updated)
20/09/2022	Other: Records of data processing activity of personal data in the context of public procurement procedures (public) (updated)
20/09/2022	Other: European Medicines Agency's Data Protection Notice for the processing of personal data in the context of public procurement procedures (updated)
20/09/2022	Agenda: Draft agenda - PCWP and HCPWP meeting - 22 September 2022 (updated)
20/09/2022	European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting , European Medicines Agency, Amsterdam, the Netherlands, from 22/09/2022 to 22/09/2022 (updated)
20/09/2022	Scientific guideline: Concept paper on the establishment of a guideline on the development and manufacture of synthetic peptides
20/09/2022	Establishment of a guideline on the development and manufacture of synthetic peptides
20/09/2022	Scientific guideline: Concept paper on the establishment of a guideline on the development and manufacture of synthetic oligonucleotides
20/09/2022	Establishment of a guideline on the development and manufacture of synthetic oligonucleotides
20/09/2022	Human medicines European public assessment report (EPAR): Tenofovir disoproxil Mylan, tenofovir disoproxil, HIV Infections, 08/12/2016, 16, Authorised (updated)
19/09/2022	Human medicines European public assessment report (EPAR): Palforzia, defatted powder of Arachis hypogaea L., semen (peanuts), Peanut Hypersensitivity, 17/12/2020, 5, Authorised (updated)
19/09/2022	News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 September 2022 (updated)
19/09/2022	Summary of opinion: Zynlonta , loncastuximab tesirine, 15/09/2022, Positive (updated)
19/09/2022	DADI PDF electronic application forms (eAF) training webinar , Online, 11:00 - 12:30 Amsterdam time (CEST), from 02/09/2022 to 02/09/2022 (updated)
19/09/2022	Human medicines European public assessment report (EPAR): Envarsus, tacrolimus, Graft Rejection, 18/07/2014, 11, Authorised (updated)
19/09/2022	News and press releases: Biosimilar medicines can be interchanged

NOTICE TO APPLICANTS

No updates since February 20th 2022.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

23.09.2022	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/155022/2022 vom 24.03.2022 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Leuprorelin (Depotformulierungen) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Leuprorelin (Depotformulierungen) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

19.09.2022	19.09.2022: Klinische Prüfung gemäß MDR/MPDG

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 3rd 2022.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.