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HEADS OF AGENCIES – CMDh

11 March

[PSUR Summary Assessment Report for Yimmugo](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here](#)

EUROPEAN MEDICINES AGENCY (EMA)

15/03/2024	Medicine: Bosulif	Updated
15/03/2024	Medicine: Phelinun	Updated
15/03/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - March 2024	Updated
15/03/2024	Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting	Updated
15/03/2024	Medicine: Accofil	Updated
15/03/2024	Medicine: Skyrizi	Updated
15/03/2024	Page: Scientific publications	Updated
15/03/2024	PSUSA: PSUSA/00002060/202305 - periodic safety update report single assessment	New
15/03/2024	Medicine: VidPrevtyn Beta	Updated
14/03/2024	Page: Industry annual bilateral meetings	Updated
14/03/2024	Event: Third European Medicines Agency (EMA) and MedTech Europe bilateral meeting	Updated
14/03/2024	Page: Union Product Database	Updated
14/03/2024	Document: Record of data processing activity relating to Security Access Control System (public)	Updated
14/03/2024	Medicine: Lacosamide Adroiq	Updated
14/03/2024	Document: New Organization First User QPPV/RP or Change of EU QPPV/RP	Updated
14/03/2024	Medicine: Methylthioninium chloride Proveblue	Updated
14/03/2024	Document: EudraVigilance registration documents	Updated
14/03/2024	Document: EudraVigilance registration manual	Updated

14/03/2024	Page: Data protection and privacy	Updated
14/03/2024	Medicine: Paxlovid	Updated
14/03/2024	Medicine: Talvey	Updated
14/03/2024	Document: Record of data processing activity relating to personal files (public)	Updated
14/03/2024	Document: European Medicines Agency's privacy statement for the operation of the Security Access Control System	Updated
14/03/2024	Event: EMA Veterinary Medicines Info Day 2024	Updated
14/03/2024	Medicine: Vioice	Updated
14/03/2024	PSUSA: PSUSA/00010271/202307 - periodic safety update report single assessment	New
14/03/2024	Medicine: Retsevmo	Updated
14/03/2024	Medicine: Sustiva	Updated
13/03/2024	PIP: EMEA-001214-PIP07-21 - paediatric investigation plan	New
13/03/2024	Document: Member states contact points for translations review	Updated
13/03/2024	PIP: EMEA-001214-PIP04-19 - paediatric investigation plan	New
13/03/2024	PIP: EMEA-002229-PIP02-21 - paediatric investigation plan	New
13/03/2024	Page: Eligible patients and consumers organisations	Updated
13/03/2024	PIP: EMEA-002239-PIP02-21 - paediatric investigation plan	New
13/03/2024	PIP: EMEA-001196-PIP03-21 - paediatric investigation plan	New
13/03/2024	Medicine: Imjudo	Updated
13/03/2024	PIP: EMEA-002431-PIP02-21 - paediatric investigation plan	New
13/03/2024	Page: Proline - Scientific guideline	Updated
13/03/2024	Page: Supporting innovation	Updated
13/03/2024	PIP: EMEA-002839-PIP01-20-M01 - paediatric investigation plan	Updated
13/03/2024	Event: Quarterly System Demo Q1 2024	Updated
13/03/2024	PIP: EMEA-002700-PIP01-19-M01 - paediatric investigation plan	Updated
13/03/2024	Event: EMA and European Organisation for Research and Treatment of Cancer (EORTC) workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data inform regulatory decisions?	Updated
13/03/2024	Medicine: Xevudy	Updated
13/03/2024	Medicine: Vaxzevria (previously COVID-19 Vaccine AstraZeneca)	Updated
13/03/2024	Medicine: Blenrep	Updated
13/03/2024	Medicine: Ilaris	Updated
13/03/2024	Document: Blenrep : EPAR - Public assessment report	Updated
13/03/2024	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
13/03/2024	PSUSA: EMEA/H/N/PSR/J/0042 - periodic safety update report single assessment	New
13/03/2024	Medicine: Krazati	Updated
13/03/2024	Document: Innovation Task Force (ITF) briefing meeting request form	Updated
13/03/2024	Event: Paediatric Committee (PDCO): 16-19 January 2024	Updated
13/03/2024	Event: Committee for Advanced Therapies (CAT): 13-15 March 2024	Updated
13/03/2024	Orphan: EU/3/05/314 - orphan designation for treatment of tuberculosis	Updated
13/03/2024	Medicine: Sirturo	Updated
12/03/2024	Event: Multi-stakeholder workshop on Data Quality Framework for Adverse Drug Reaction reporting	Updated
12/03/2024	Event: CTIS Bitesize Talk: How to submit a transitional trial in CTIS	Updated
12/03/2024	Medicine: Pomalidomide Viatrix	Updated
12/03/2024	Medicine: Prevenar 20 (previously Apexxnar)	Updated
12/03/2024	PSUSA: PSUSA/00000906/202305 - periodic safety update report single assessment	New

12/03/2024	PSUSA: PSUSA/00010913/202306 - periodic safety update report single assessment	New
12/03/2024	Medicine: Striascan	Updated
12/03/2024	Page: Coordination of pharmacovigilance inspections	Updated
12/03/2024	Document: Applications for new human medicines under evaluation: March 2024	New
12/03/2024	Document: DARWIN EU Advisory Board: Membership	Updated
12/03/2024	Medicine: Ibuprofen Gen.Orph	Updated
12/03/2024	Medicine: Evkeeza	Updated
12/03/2024	Medicine: Daxas	Updated
12/03/2024	Medicine: Verzenios	Updated
12/03/2024	Medicine: Kaftrio	Updated
12/03/2024	Medicine: Idelirix	Updated
11/03/2024	Medicine: Pramipexole Accord	Updated
11/03/2024	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 12-14 March 2024	Updated
11/03/2024	Medicine: Upstaza	Updated
11/03/2024	Medicine: Innovax-ILT-IBD	New
11/03/2024	Medicine: Prevexxion RN+HVT	New
11/03/2024	Medicine: Eurican L4	New
11/03/2024	Medicine: Xultophy	Updated
11/03/2024	Medicine: Nexviadyne	Updated
11/03/2024	Medicine: Comirnaty	Updated
11/03/2024	Herbal: Symphyti radix - herbal medicinal product	Updated
11/03/2024	Document: Agenda of the COMP meeting 12-14 March 2024	New
11/03/2024	Event: Committee for Medicinal Products for Human Use (CHMP): 22-25 January 2024	Updated
11/03/2024	Page: Product-specific bioequivalence guidance	Updated
11/03/2024	Document: Minutes of the CHMP meeting 22-25 January 2024	New
11/03/2024	Document: Procedural advice for orphan medicinal product designation: Guidance for sponsors	Updated
11/03/2024	Document: Fludarabine supply shortage	New

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

11.03.2024	Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien Die Abteilung Pharmakovigilanz informiert heute über die Überarbeitung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
11.03.2024	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since February 28th 2024.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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