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23 July

UPDATE - Contact Points

29 July

- NEW - Report from the meeting held on 21-22 July 2026
- UPDATE - Template of letter of intent for the submission of a worksharing procedure
- UPDATE - EMA/CMDh Explanatory notes on Variation Application Form - Human medicinal products only
- UPDATE - Chapter 7 - CMDh BPG on Variation Worksharing
- UPDATE - Type II variation Preliminary-Final Variation Assessment Report
- NEW - 2026 (Jan-Jun) - Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures

28 July

- NEW - 23-25 June CMDh Minutes
- NEW - Minutes of the 25 June 2026 meeting with Interested Parties

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
31/07/2026	**Medicine**: Iclusig ponatinib	Updated
31/07/2026	**Document**: Member states guidance: New CTIS safety module on the annual safety report	New
31/07/2026	**Document**: Sponsor guidance: New safety module on the annual safety report	New

Date	Content	Status
31/07/2026	**Medicine**: Qoyvolma ustekinumab	Updated
31/07/2026	**Event**: Fifth European Medicines Agency and Nuclear Medicines Europe bilateral meeting	Updated
31/07/2026	**Event**: 18th Industry Standing Group (ISG) meeting	New
31/07/2026	**Event**: First European Medicines Agency (EMA) and Active Pharmaceutical Ingredients Committee (APIC) bilateral meeting	New
31/07/2026	**Medicine**: Kaftrio ivacaftor; tezacaftor; elexacaftor	Updated
31/07/2026	**Medicine**: Multaq dronedarone	Updated
31/07/2026	**Medicine**: Aspaveli pegcetacoplan	Updated
31/07/2026	**Page**: Medicines for human use under evaluation	Updated
31/07/2026	**Document**: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (26 June 2026 - 23 July 2026)	New
31/07/2026	**Document**: Start of procedure: Extension of marketing authorisation (26 June 2026 - 23 July 2026)	New
30/07/2026	**Event**: Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) new safety module	Updated
30/07/2026	**News**: New leadership team appointments	New
30/07/2026	**Document**: Dates of 2027 SAWP meetings and submission deadlines Scientific advice, protocol assistance, qualification of biomarkers and parallel HTACG/EMA Joint Scientific Consultation requests	Updated
30/07/2026	**Document**: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 6-8 July 2026	New
30/07/2026	**Document**: Annex to letter of intent	Updated
30/07/2026	**Document**: Template - Request for accelerated assessment pursuant to Article 14(9) of Regulation (EC) No 726/2004' to be replaced by 'Briefing Note and Recommendations on a Request for Accelerated Assessment Pursuant to Article 14 (9) of Regulation (EC) No 726/2004	Updated
30/07/2026	**Medicine**: Sylvant siltuximab	Updated
30/07/2026	**Medicine**: Privigen human normal immunoglobulin (IVIg)	Updated
30/07/2026	**Medicine**: Gilenya fingolimod	Updated

Date	Content	Status
30/07/2026	**Page**: Non-clinical requirements for severely debilitating or life-threatening diseases	New
30/07/2026	**Document**: Concept paper on the development of a reflection paper on the non-clinical requirements for severely debilitating or life-threatening diseases	New
30/07/2026	**Medicine**: Xofigo radium Ra223 dichloride	Updated
30/07/2026	**Medicine**: Mayzent siponimod	Updated
30/07/2026	**Medicine**: Jascayd nerandomilast	Updated
30/07/2026	**Medicine**: Boey trenibotulinumtoxinE	Updated
30/07/2026	**Document**: List of centrally authorised products with safety-related changes to the product information	Updated
30/07/2026	**Medicine**: Leflunomide ratiopharm leflunomide	Updated
30/07/2026	**Medicine**: Hulio adalimumab	Updated
29/07/2026	**Medicine**: PecFent fentanyl	Updated
29/07/2026	**Medicine**: Xtandi enzalutamide	Updated
29/07/2026	**Medicine**: Padcev enfortumab vedotin	Updated
29/07/2026	**Document**: Template - Application for transfer of marketing authorisation from transferor to transferee, attachment 1 (veterinary)	New
29/07/2026	**Medicine**: Rxulti brexpiprazole	Updated
29/07/2026	**Document**: Regulatory Perspectives on Herbal Medicinal Botanical Drug Product Development - Joint FDA-EMA Workshop: Event agenda	Updated
29/07/2026	**Document**: List of medicinal products under additional monitoring	Updated
29/07/2026	**Page**: List of medicines under additional monitoring	Updated
29/07/2026	**Document**: List of medicinal products under additional monitoring	Updated
29/07/2026	**Document**: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
28/07/2026	**Medicine**: Itvisma onasemnogene abeparvovec	New

Date	Content	Status
28/07/2026	**Medicine**: Trodelvy sacituzumab govitecan	Updated
28/07/2026	**Medicine**: Inflectra infliximab	Updated
27/07/2026	**Medicine**: Macitentan AccordPharma macitentan	Updated
27/07/2026	**Medicine**: Macitentan Accord macitentan	Updated
27/07/2026	**Medicine**: Irbesartan Zentiva (previously Irbesartan Winthrop) irbesartan	Updated
27/07/2026	**PIP**: EMEA-002883-PIP02-22 - paediatric investigation plan trimodulin	Updated
27/07/2026	**Document**: Draft guideline on veterinary good pharmacovigilance practices (VGVP) - Module: Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files - Revision 1	New
27/07/2026	**Page**: Podcast: Inside EMA	Updated
27/07/2026	**Medicine**: Cerdelga eliglustat	Updated
27/07/2026	**Medicine**: Apixaban Accord apixaban	Updated

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
31.07.2026	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
	No updates since July 27th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
30.07.2026	**Informationsschreiben von Regeneron GmbH: Libtayo (Cemiplimab)**

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.