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HEADS OF AGENCIES – CMDh

3 April

[UPDATE - Q&A on Pharmacovigilance Legislation](#)

[NEW - Procedural advice on Zero Day MR Procedures](#)

[NEW - Minutes of the Meeting of a subgroup of CMDh with Interested Parties dedicated to LoSC and publication of PI updates](#)

[NEW - Art. 46 PAR on Verorab \(Rabies virus, inactivated\)](#)

[NEW - Art. 46 PAR on Triptorelin \(Decapeptyl, Diphereline, Arvekap\)](#)

[UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

05/04/2024	PIP: EMEA-000334-PIP01-08-M11 - paediatric investigation plan	Updated
05/04/2024	PIP: EMEA-000576-PIP01-09-M14 - paediatric investigation plan	Updated
05/04/2024	PIP: EMEA-000997-PIP01-10-M06 - paediatric investigation plan	Updated
05/04/2024	PIP: EMEA-001220-PIP01-11-M07 - paediatric investigation plan	Updated
05/04/2024	PIP: EMEA-003238-PIP01-22 - paediatric investigation plan	New
05/04/2024	PIP: EMEA-003241-PIP01-22 - paediatric investigation plan	New
05/04/2024	PIP: EMEA-003245-PIP01-22 - paediatric investigation plan	New
05/04/2024	Medicine: Imfinzi	Updated
05/04/2024	PIP: EMEA-003317-PIP02-22 - paediatric investigation plan	New
08/04/2024	Medicine: Cibinqo	Updated
05/04/2024	Medicine: Aspaveli	Updated
05/04/2024	Medicine: Strimvelis	Updated
05/04/2024	PIP: EMEA-003032-PIP01-21-M01 - paediatric investigation plan	Updated

05/04/2024	Medicine: Lonsurf	Updated
05/04/2024	Medicine: Perjeta	Updated
05/04/2024	PIP: EMA-001809-PIP01-15-M03 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-001744-PIP01-14-M02 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-001734-PIP01-14-M06 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-001332-PIP01-12-M06 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-001429-PIP01-13-M07 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-003237-PIP01-22 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-003218-PIP01-22 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-003171-PIP01-21 - paediatric investigation plan	Updated
05/04/2024	PIP: EMA-001371-PIP03-22 - paediatric investigation plan	New
05/04/2024	PIP: P/0096/2023 : EMA decision of 10 March 2023 on the granting of a product specific waiver for pembrolizumab (Keytruda), (EMA-001474-PIP03-22) - paediatric investigation plan	New
05/04/2024	Event: Third European Medicines Agency and Affordable Medicines Europe bilateral meeting	New
05/04/2024	Document: Traineeship - Frequently asked questions (FAQs)	Updated
05/04/2024	PIP: EMA-002690-PIP02-22 - paediatric investigation plan	New
05/04/2024	PIP: EMA-003166-PIP01-21 - paediatric investigation plan	New
05/04/2024	PIP: EMA-003215-PIP01-22 - paediatric investigation plan	New
05/04/2024	Event: Cancer Medicines Forum workshop: April 2024	Updated
05/04/2024	Medicine: Instanyl	Updated
04/04/2024	Page: Transfer of marketing authorisation: questions and answers	Updated
04/04/2024	Document: List of industry subject matter experts and list of planned calls for industry subject matter experts	Updated
04/04/2024	PSUSA: PSUSA/00002307/202306 - periodic safety update report single assessment	New
04/04/2024	PSUSA: PSUSA/00001711/202307 - periodic safety update report single assessment	New
04/04/2024	Referral: Pseudoephedrine-containing medicinal products - referral	Updated
04/04/2024	Medicine: Niapelf	New
04/04/2024	Medicine: Opdivo	Updated
04/04/2024	Medicine: Prevenar 13	Updated
04/04/2024	Medicine: Abiraterone Mylan	Updated
04/04/2024	Event: Paediatric Committee (PDCO): 20-23 February 2024	Updated
04/04/2024	PSUSA: PSUSA/00002655/202306 - periodic safety update report single assessment	New
04/04/2024	Medicine: GoResp Digihaler (previously Budesonide/Formoterol Teva Pharma B.V.)	Updated
04/04/2024	PSUSA: PSUSA/00001713/202212 - periodic safety update report single assessment	New
04/04/2024	PSUSA: PSUSA/00001356/202212 - periodic safety update report single assessment	New
04/04/2024	PSUSA: PSUSA/00002664/202211 - periodic safety update report single assessment	New
04/04/2024	Medicine: Keytruda	Updated
04/04/2024	Medicine: PecFent	Updated
04/04/2024	Document: Day 80 assessment report - Clinical template with guidance - Rev.04.24 Revamp	Updated
04/04/2024	Medicine: Effentora	Updated
04/04/2024	Medicine: Dovato	Updated
04/04/2024	Medicine: Vfend	Updated
04/04/2024	Page: Assessment templates and guidance	Updated

04/04/2024	PSUSA: PSUSA/00003002/202306 - periodic safety update report single assessment	New
04/04/2024	Page: Reflection papers on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH) - Scientific guideline	Updated
03/04/2024	Document: List of medicines currently in PRIME scheme	Updated
03/04/2024	Medicine: Rubraca	Updated
03/04/2024	Medicine: Sixmo	Updated
03/04/2024	Medicine: Ertapenem SUN	Updated
03/04/2024	Medicine: Bovilis Nasalgen-C	Updated
03/04/2024	Medicine: Sorafenib Accord	Updated
03/04/2024	Medicine: Levodopa/Carbidopa/Entacapone Orion	Updated
03/04/2024	Medicine: Revestive	Updated
03/04/2024	Medicine: Yuflyma	Updated
03/04/2024	Event: Committee for Orphan Medicinal Products (COMP): 13-15 February 2024	Updated
03/04/2024	Event: Product Management Service (PMS) Info-Day	Updated
03/04/2024	PSUSA: PSUSA/00002256/202307 - periodic safety update report single assessment	New
03/04/2024	Medicine: Abecma	Updated
03/04/2024	Page: Marketing authorisation templates	Updated
03/04/2024	Document: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Updated
02/04/2024	Medicine: Celdoxome pegylated liposomal	Updated
02/04/2024	Medicine: Sutent	Updated
02/04/2024	Medicine: Pedmarqsi	Updated
02/04/2024	Medicine: Pylclari	Updated
02/04/2024	Page: Data protection and privacy	Updated
02/04/2024	Page: Medical devices	Updated
02/04/2024	Medicine: Locametz	Updated
02/04/2024	Medicine: Teriparatide Sun	Updated
02/04/2024	PSUSA: PSUSA/00002165/202306 - periodic safety update report single assessment	New
02/04/2024	Medicine: Cometriq	Updated
02/04/2024	Orphan: EU/3/08/610 - orphan designation for treatment of medullary thyroid carcinoma	Updated
02/04/2024	Herbal: Verbasci flos - herbal medicinal product	Updated
02/04/2024	Herbal: Vitis viniferae folium - herbal medicinal product	Updated
02/04/2024	Page: Procedures for monograph and list entry establishment	Updated
02/04/2024	Herbal: Oenotherae oleum - herbal medicinal product	Updated
02/04/2024	Herbal: Uvae ursi folium - herbal medicinal product	Updated
02/04/2024	Herbal: Melissae folium - herbal medicinal product	Updated
02/04/2024	Herbal: Myrrha - herbal medicinal product	Updated
02/04/2024	Herbal: Meliloti herba - herbal medicinal product	Updated
02/04/2024	Herbal: Cynarae folium - herbal medicinal product	Updated
02/04/2024	Herbal: Curcumae longae rhizoma - herbal medicinal product	Updated
02/04/2024	Medicine: Metalyse	Updated
02/04/2024	Document: List of signals discussed at PRAC since September 2012	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

04.04.2024	Pseudoephedrin: Risiko für posteriores reversibles Enzephalopathiesyndrom und reversibles zerebrales Vasokonstriktionssyndrom Wirkstoff: Pseudoephedrin Mit Veröffentlichung der Entscheidung der Europäischen Kommission wurde das Risikobewertungsverfahren gemäß Artikel 31 der Richtlinie 2001/83/EG zu pseudoephedrinhaltigen Arzneimitteln abgeschlossen.
04.04.2024	Rote-Hand-Brief zu Atropinsulfat 100 mg Injektionslösung: Risiko von sichtbaren Partikeln in der Lösung, Verwendung eines Filters Wirkstoff: Atropinsulfat Die Firma Dr. Franz Köhler Chemie GmbH informiert über im Rahmen des fortlaufenden Stabilitätsprogramms gefundenen sichtbaren Partikeln in dem Arzneimittel Atropinsulfat 100 mg Injektionslösung 5 x 10 ml und 25 x 10 ml.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

03.04.2024	Abgrenzung und Klassifizierung Medizinprodukte werden Risikoklassen zugeordnet. Die Klassifizierung von Medizinprodukten mit Ausnahme der <i>In-vitro</i>-Diagnostika, erfolgt nach den Klassifizierungsregeln des Anhangs VIII MDR. Die Produkte werden dabei in die vier Klassen I, IIa, IIb und III unterteilt, wobei Klasse III die höchste Risikoklasse darstellt.
02.04.2024	Meldewege nach MDR, IVDR und MPDG Übersicht über die Meldewege nach MDR, IVDR und MPDG

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Text	Group	Issue	Deadline
2.5.25. Carbon monoxide in gases Reference number:PA/PH/Exp. 9G/T (23) 12 ANP Text number:20525	9G	36.2	30-06-2024
2.6.41. High-throughput sequencing for the detection of viralextraneous agents Reference number:PA/PH/Exp. 15/T (21) 27 ANP Text number:20641	HTS	36.2	30-06-2024
2.9.17. Test for extractable volume of parenteral preparations Reference number:PA/PH/Exp. 12/T (20) 47 ANP Text number:20917	12	36.2	30-06-2024
2.9.54. Uniformity of delivered dose of inhalation and nasalpreparations	INH	36.2	30-06-2024

Text	Group	Issue	Deadline
Reference number:PA/PH/Exp. INH/T (18) 3 ANP Text number:20954			
5.32. Cell-based preparations for human use Reference number:PA/PH/Exp. CTP/T (21) 10 ANP Text number:53200	CTP	36.2	30-06-2024
5.36. mRNA vaccines for human use Reference number:PA/PH/Exp. mRNACVAC/T (23) 9 ANP Text number:53600	mRN ACVAC	36.2	30-06-2024
5.37. Recombinant viral vectored vaccines for human use Reference number:PA/PH/Exp. 15/T (23) 56 ANP Text number:53700	15V	36.2	30-06-2024
5.39. mRNA substances for the production of mRNA vaccines for human use Reference number:PA/PH/Exp. mRNACVAC/T (23) 8 ANP Text number:53900	mRN ACVAC	36.2	30-06-2024
5.40. DNA template for the preparation of mRNA substances Reference number:PA/PH/Exp. mRNACVAC/T (23) 7 ANP Text number:54000	mRN ACVAC	36.2	30-06-2024
Amlodipine besilate Reference number:PA/PH/Exp. 11/T (24) 3 ANP Text number:1491	11	36.2	30-06-2024
Aprotinin Reference number:PA/PH/Exp. 6/T (23) 41 ANP Text number:0580	6	36.2	30-06-2024
Aprotinin concentrated solution Reference number:PA/PH/Exp. 6/T (23) 39 ANP Text number:0579	6	36.2	30-06-2024
Bromperidol decanoate Reference number: PA/PH/Exp. 10B/T (21) 88 ANP R1 Text number: 1397	10B	36.2	30-06-2024
Calendula for homeopathic preparations Reference number: PA/PH/Exp. HOM/T (08) 30 ANP Text number: 2492	HOM	36.2	30-06-2024
Cefixime trihydrate Reference number: PA/PH/Exp. 7/T (13) 138 ANP Text number: 1188	7	36.2	30-06-2024
Cellulose acetate butyrate Reference number: PA/PH/Exp. EXP/T (24) 8 ANP Text number: 1406	CEL	36.2	30-06-2024
Chamomilla for homeopathic preparations Reference number: PA/PH/Exp. HOM/T (08) 29 ANP Text number: 2493	HOM	36.2	30-06-2024
Cholesterol Reference number: PA/PH/Exp. SIT/T (23) 37 ANP Text number: 0993	VIT	36.2	30-06-2024
Chymotrypsin Reference number: PA/PH/Exp. 6/T (23) 38 ANP Text number: 0476	6	36.2	30-06-2024
Clonazepam Reference number: PA/PH/Exp. 10B/T (24) 6 ANP Text number: 0890	10B	36.2	30-06-2024
Clopidogrel besilate	10c	36.2	30-06-2024

Text	Group	Issue	Deadline
Reference number: PA/PH/Exp. 10C/T (23) 43 ANP Text number: 2790			
Codergocrine mesylate Reference number: PA/PH/Exp. 11/T (23) 97 ANP Text number: 2060	11	36.2	30-06-2024
Danaparoid sodium Reference number: PA/PH/Exp. 6/T (23) 40 ANP Text number: 2090	6	36.2	30-06-2024
Daunorubicin hydrochloride Reference number: PA/PH/Exp. 12/T (23) 37 ANP Text number: 0652	7	36.2	30-06-2024
Ear preparations Reference number: PA/PH/Exp. 12/T (23) 37 ANP Text number: 0652	12	36.2	30-06-2024
Felodipine Reference number: PA/PH/Exp. SIT/T (23) 36 ANP Text number: 1013	11	36.2	30-06-2024
Fleeceflower root Reference number: PA/PH/Exp. TCM/T (23) 93 ANP Text number: 2433	TCM	36.2	30-06-2024
Foot-and-mouth disease (ruminants) vaccine (inactivated) Reference number: PA/PH/Exp. 15V/T (23) 38 ANP Text number: 0063	15V	36.2	30-06-2024
Fourstamen stephania root Reference number: PA/PH/Exp. TCM/T (24) 9 ANP Text number: 2478	13A	36.2	30-06-2024
Glycerol monostearate 40-55 Reference number: PA/PH/Exp. EXP/T (24) 4 ANP Text number: 0495	13H	36.2	30-06-2024
Heparin calcium Reference number: PA/PH/Exp. 6/T (23) 36 ANP Text number: 0332	6	36.2	30-06-2024
Heparin sodium Reference number: PA/PH/Exp. 6/T (23) 37 ANP Text number: 0333	6	36.2	30-06-2024
Hydroxyzine hydrochloride Reference number: PA/PH/Exp. 10B/T (23) 62 ANP Text number: 0916	10B	36.2	30-06-2024
Kanamycin acid sulfate Reference number: PA/PH/Exp. 7/T (23) 67 ANP Text number: 0033	7	36.2	30-06-2024
Kanamycin monosulfate monohydrate Reference number: PA/PH/Exp. 7/T (23) 68 ANP Text number: 0032	7	36.2	30-06-2024
L-Malic acid Reference number: PA/PH/Exp. 10D/T (22) 23 ANP R1 Text number: 3143	10D	36.2	30-06-2024
Linagliptin Reference number: PA/PH/Exp. P4/T (21) 41 ANP Text number: 3173	P4	36.2	30-06-2024
Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted Copolymer	P4	36.2	30-06-2024

Text	Group	Issue	Deadline
Reference number: PA/PH/Exp. P4/T (19) 94 ANP Text number: 3156			
Macrogolglycerol hydroxystearate Reference number: PA/PH/Exp. EXP/T (24) 7 ANP Text number: 1083	13H	36.2	30-06-2024
Macrogolglycerol ricinoleate Reference number: PA/PH/Exp. EXP/T (24) 6 ANP Text number: 1082	13H	36.2	30-06-2024
Metronidazole benzoate Reference number: PA/PH/Exp. 10A/T (24) 8 ANP Text number: 0934	10A	36.2	30-06-2024
Myrtle oil Reference number: PA/PH/Exp. 13A/T (13) 16 ANP Text number: 2823	13H	36.2	30-06-2024
Nasal preparations Reference number: PA/PH/Exp. 12/T (23) 6 ANP Text number: 0676	12	36.2	30-06-2024
Octenidine dihydrochloride Reference number: PA/PH/Exp. 10A/T (18) 186 ANP Text number: 3075	10A	36.2	30-06-2024
Preparations for inhalation Reference number: PA/PH/Exp. INH/T (23) 7 ANP Text number: 0671	INH	36.2	30-06-2024
Pressurised pharmaceutical preparations Reference number: PA/PH/Exp. 12/T (23) 27 ANP Text number: 0523	12	36.2	30-06-2024
Procaine hydrochloride Reference number: PA/PH/Exp. 10A/T (23) 87 ANP Text number: 0050	10A	36.2	30-06-2024
Rifamycin sodium Reference number: PA/PH/Exp. 7/T (23) 69 ANP Text number: 0432	7	36.2	30-06-2024
Sevelamer carbonate Reference number: PA/PH/Exp. 10A/T (18) 190 ANP Text number: 2747	10A	36.2	30-06-2024
Sevelamer hydrochloride Reference number: PA/PH/Exp. 10A/T (18) 191 ANP Text number: 2748	10A	36.2	30-06-2024

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