05. - 19.
September 2025

MEGRA

NEWSLETTER

Humanarzneimittel - EMA

Allgemeines – General

Supporting innovation
Published on: *09 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation

Medicinal products for human use: monthly figures - July 2025
Published on: *09 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-july-2025_en.pdf

Medicinal products for human use: monthly figures - August 2025
Published on: *09 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/medicinal-products-human-use-monthly-figures-august-2025_en.pdf

Human Medicines
Published on: *16 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/about-us/who-we-are/human-medicines

Quick guide to competing interests for EMA experts
Published on: *17 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/leaflet/quick-guide-competing-interests-ema-experts_en.pdf

Pharmakovigilanz – PRAC

Article 57 product data
Published on: *17 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/article-57-product-data_en.xlsx

Questions and answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by marketing authorisation holders, update
Published on: *17 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/questions-answers-implementing-regulation-eu-2025-1466-amendment-regulation-eu-no-520-2012-conclusion-signal-detection-eudravigilance-pilot-marketing-authorisation-holders_en.pdf

Humanarzneimittel - EMA

Referral: Finasteride- and dutasteride-containing medicinal products
Published on: *19 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/medicines/human/referrals/finasteride-dutasteride-containing-medicinal-products

Zulassung – Regulatory Affairs

Pre-authorisation guidance
Published on: *08 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/pre-authorisation-guidance

Dossier administrative validation checklist for initial marketing authorisation applications by applicants
Published on: *08 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/template-form/dossier-admin-validation-checklist-initial_en.zip

Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (25 July - 21 August 2025)
Published on: *08 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/start-procedure-type-ii-variation-extension-indication-under-evaluation-chmp-25-july-21-august-2025_en.xlsx

Start of procedure: Extension of marketing authorisation (25 July - 21 August 2025)
Published on: *08 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/report/start-procedure-extension-marketing-authorisation-25-july-21-august-2025_en.xlsx

Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions
Published on: *10 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/regulatory-procedure-management-rpm-product-lifecycle-management-plm-frequently-asked-questions_en.pdf

PRIME eligibility requests: 2026 deadlines for submission and timetable for assessment
Published on: *10 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/prime-eligibility-requests-2026-deadlines-submission-timetable-assessment_en.pdf

Humanarzneimittel - EMA

Product Management Service (PMS) roadmap
Published on: *10 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/product-management-service-pms-roadmap_en.pdf

Orphan Drugs und neuartige Therapierichtungen (ATMP)

No news published

Qualität – Quality

No news published

(Prä-) Klinische Forschung – Research and Development

First European Medicines Agency (EMA) and Association of Clinical Research Organizations (ACRO) bilateral meeting, Event - 02 - September - 2025
Highlights available
Published on: *17 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/first-european-medicines-agency-ema-association-clinical-research-organizations-acro-bilateral-meeting

ACT EU workshop on ICH E6 R3 (principles and Annex 1), Event - 19 - 20 - February – 2025
Presentations and Videos recording available
Published on: *18 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/act-eu-workshop-ich-e6-r3-principles-annex-1

Kinderarzneimittel – Paediatrics

No news published

Pflanzliche Arzneimittel – Herbal medicines

No news published

European Commission

Update - Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 - September 2025
Published on: *12 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/update-manual-borderline-and-classification-under-regulations-eu-2017745-and-2017746-september-2025-2025-09-12_en

Presentations and recording - EUHPP Live webinar: Open Call for Proposals of EU4Health AWP2025 crisis preparedness strand – medical countermeasures (15 September 2025)
Published on: *16 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/presentations-and-recording-euhpp-live-webinar-open-call-proposals-eu4health-awp2025-crisis-2025-09-16_en

EU4Health 2025 calls for proposals: advancing crisis preparedness through diagnostics and medical countermeasures
Published on: *17 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eu4health-2025-calls-proposals-advancing-crisis-preparedness-through-diagnostics-and-medical-2025-09-17_en

EU launches GLOWACON Aviation Programme to strengthen global preparedness through wastewater and environmental surveillance
Published on: *18 - September - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/eu-launches-glowacon-aviation-programme-strengthen-global-preparedness-through-wastewater-and-2025-09-18_en

EDQM

Certification monthly report of activities: End of August 2025
Published on: *08 - September - 2025*
For more information, please refer to:
https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-august-2025

Medizinprodukte

List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment
Published on: *10 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/documents/other/list-clinical-evaluation-consultation-procedure-cecp-opinions-issued-medical-devices-awaiting-finalisation-conformity-assessment_en.pdf

CMDh

UPDATE - Contact Points
Published on: *09 - September - 2025*
For more information, please refer to:
https://www.hma.eu/human-medicines/cmdh/contact-points.html

HMA Substances Validation Group Members and Representatives
Published on: *11- September - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/working-groups/hma/hma-substances-validation-group.html#c7171

HMA MANAGEMENT GROUP
Published on: *15 - September - 2025*
For more information, please refer to:
https://www.hma.eu/about-hma/structure.html#c81

Humanarzneimittel - Deutschland

"Medikamente sind keine Bonbons"
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/HMA-Kampagne/_artikel.html?nn=986770

Sicher statt sorglos mit der „Blauen Hand“: Wie behördlich beauflagtes Schulungsmaterial vor Arzneimittelrisiken schützt
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Pressemitteilungen/DE/2025/pm11-2025.html?nn=986770

Versagungen und Rücknahmen BfArM Januar bis August 2025
Veröffentlicht am: *16 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/SharedDocs/Downloads/DE/Service/Statistik/AM-Statistik/versagungen-2025.html?nn=986770

Ankündigung des Kommentierungsverfahrens: Bereitstellung der ValueSets „Allergien Überempfindlichkeitsreaktionen Auslösende Substanz“ sowie „Allergien Überempfindlichkeitsreaktionen Manifestation“
Veröffentlicht am: *16 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/News/Terminologieserver_Kommentierung_AllergieValueSet_mit_MIO.html?nn=986770

Maßnahmen des BfArM und ergänzende Informationen zu Lieferengpässen
Veröffentlicht am: *17 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Lieferengpaesse/Massnahmen-des-BfArM/_artikel.html?nn=986770

PSUR Single Assessment (PSUSA)
Veröffentlicht am: *17 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Periodic-Safety-Update-Reports_PSURs/PSUR-Single-Assessment/_artikel.html?nn=986770

ICD-10-GM 2026: BfArM veröffentlicht endgültige Fassung
Veröffentlicht am: *18 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Kodiersysteme/News/ICD-10-GM_2026_BfArM_veroeffentlicht_endgueltige_Fassung.html?nn=986770

Humanarzneimittel - Österreich

PSUR-outcome: Nicotin (Änderung der Produktinformation für orale und oromukosale Darreichungsformen)
Veröffentlicht am: *08 - September - 2025*
Weitere Informationen finden Sie unter:
Mustertext Nicotin
Link zur Webseite der EMA

PSUR-outcome: Tapentadol
Veröffentlicht am: *09 - September - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR-outcome: Acetylsalicylsäure / Bisoprolol
Veröffentlicht am: *12 - September - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR-outcome: Phosphocreatin
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
Link zur Webseite der EMA

PSUR-outcome: Hydromorphon
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
Mustertext Hydromorphon
Link zur Webseite der EMA

PSUR-outcome: Azathioprin
Veröffentlicht am: *19 - September - 2025*
Weitere Informationen finden Sie unter:
Mustertext Azathioprin
Link zur Website der Europäischen Kommission

0925_Register bewilligter AM Betriebe Österreich.xlsx
Veröffentlicht am: *10 - September - 2025*
Weitere Informationen finden Sie unter:
Informationsfreiheit
Arzneimittelbetriebe

Gute Herstellungs- / Vertriebspraxis (GMP/GDP)
Veröffentlicht am: *12 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/bewilligung-und-zertifizierung/gute-herstellungs-/-vertriebspraxis-gmp/gdp

Humanarzneimittel - Österreich

Parallelimport
Veröffentlicht am: *12 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/fuer-unternehmen/zulassung-life-cycle/faq-zulassung-life-cycle/parallelimport

Medikamentenkauf auf illegalen Webseiten Neu
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.basg.gv.at/konsumentinnen/arzneimittel-im-internet/medikamentenkauf-auf-illegalen-webseiten

Humanarzneimittel - Schweiz

swissdamed technische Dokumentation
Veröffentlicht am: *19 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/medizinprodukte-datenbank/swissdamed-informationen/swissdamed-technical-documents.html

Aktualisierte Vorgabedokumente
Veröffentlicht am: *15 - September - 2025*
Weitere Informationen finden Sie unter:
https://www.swissmedic.ch/swissmedic/de/home/news/updates/updated_documents/sept-2025.html

Fragen an das Netzwerk

Falls Sie eine Frage haben, die Sie gerne in unserem Netzwerk diskutieren würden, senden Sie uns einfach eine E-Mail an info-as@megra.org zur anonymen Publikation im nächsten Newsletter.*

*Bei der Beantwortung der Fragen handelt es sich um eine Zusammenfassung von persönlichen Meinungen und Erfahrungswerten der MEGRA Mitglieder mit keinem Anspruch auf Rechtssicherheit. Wir empfehlen zur Absicherung die Konsultation entsprechender zugrunde liegender Regularien.

Folgende Frage ans Netzwerk erreichte uns:

„In wie vielen Landessprachen etikettieren andere Zulassungsinhaber in der Schweiz:

- Arzneimittel, die im vereinfachten Verfahren zugelassen sind
- Arzneimittel, die im meldepflichtigen Verfahren zugelassen sind?

Vielen Dank für die Informationen zu Primär- und Sekundärverpackung!

Wir bitten um Antworten auf diese Frage an info-as@megra.org

Herzlichen Dank für Ihre Mithilfe!

Veranstaltungen / Events – Behörden und andere Veranstalter

Deutschland

TOPRA Symposium 2025
Ort: *JW Marriott Hotel Berlin, Stauffenbergstrasse 26, 10785 Berlin, Germany*
Termin: *29 - September bis 01 - Oktober - 2025*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/Termine/2025-09-29-topra-symposium.html?nn=986770

"The Product is the Process – Is it?" Manufacturing and Translation of ATMPs and Tissue- & Cell-based products
Ort: *Investitionsbank des Landes Brandenburg, Babelsberger Straße 21, 14473 Potsdam, Germany*
Termin: *20 - November - 2025*
Weitere Informationen finden Sie unter:
https://www.pei.de/SharedDocs/veranstaltungen-events/DE/2025/2025-11-20-workshop-manufacturing-translation-atmp.html?nn=170994

BfArM meets Europe: Shaping the EHDS
Ort: *BfArm, Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany*
Termin: *24 bis 25 - November*
Weitere Informationen finden Sie unter:
https://www.bfarm.de/EN/News/events/2025-Health-Data/_node.html

Österreich

Keine Veranstaltungen veröffentlicht

Schweiz

Keine Veranstaltungen veröffentlicht

Europa

European Platform for Regulatory Science Research meeting September 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *29 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/european-platform-regulatory-science-research-meeting-september-2025

Veranstaltungen / Events – Behörden und andere Veranstalter

Refresher training webinar on post-authorisation procedure management in IRIS for marketing authorisation holders
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/refresher-training-webinar-post-authorisation-procedure-management-iris-marketing-authorisation-holders

Q&A clinic on web-based electronic application form (eAF) functionalities for CAPs and non-CAPs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *30 - September - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-web-based-electronic-application-form-eaf-functionalities-caps-non-caps

Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *01 to 03 - October - 2025 and 08 to 10 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-october-2025
https://www.ema.europa.eu/en/events/virtual-live-hands-training-course-clinical-trials-sponsors-using-eudravigilance-system-december-2025

PMS PUI Training: Product data submission & bulk edit made easy
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *06 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/pms-pui-training-product-data-submission-bulk-edit-made-easy

SPOR and XEVMPD status update webinar
Where: *Live broadcast*
Date: *08 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-0

HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *08 to 09 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-reporting-qualification-mechanistic-models-regulatory-assessment

Veranstaltungen / Events – Behörden und andere Veranstalter

Q&A clinic on web-based application form functionalities for CAPs and non-CAPs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-web-based-application-form-functionalities-caps-non-caps

Joint EDQM-USP Webinar on "Orthogonal Analytical Methods for the Characterisation of Pharmacopoeial Reference Standards"
Where: *Paris, France*
Date: *09 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/edqm-usp-webinar

Q&A clinic on Substance, Organisation, Referentials Management Services
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *13 - October - 2025, 10 - November - 2025, 15 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-1
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services-2
https://www.ema.europa.eu/en/events/qa-clinic-substance-organisation-referentials-management-services

Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API)
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - October - 2025, 18 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-october-2025
https://www.ema.europa.eu/en/events/questions-answers-clinic-product-management-service-pms-product-user-interface-pui-application-programming-interface-api-november-2025

Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *14 - October - 2025, 18 - November - 2025, 18 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-1
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service-0
https://www.ema.europa.eu/en/events/qa-clinic-extended-eudravigilance-medicinal-product-dictionary-xevmpd-service

Veranstaltungen / Events – Behörden und andere Veranstalter

Mandatory use of ISO/ICH E2B(R3) individual case safety reporting in the EU: hands-on training course using the EudraVigilance system
Where: *online*
Date: *13 to 17 - October - 2025, 10 to 14 - November - 2025, 01 to 05 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-52
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-53
https://www.ema.europa.eu/en/events/mandatory-use-iso-ich-e2br3-individual-case-safety-reporting-eu-hands-training-course-using-eudravigilance-system-54

Unlocking PMS API potential: Edit functionality training for MAHs
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *16 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/unlocking-pms-api-potential-edit-functionality-training-mahs

EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation
Where: *Live broadcast and European Medicines Agency, Amsterdam, the Netherlands*
Date: *17 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-roundtable-stakeholders-20th-anniversary-sme-regulation

The EU HTA Regulation: Webinar for health technology developers of medicinal products
Where: *online*
Date: *17 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/events/eu-hta-regulation-webinar-health-technology-developers-medicinal-products-2025-10-17_en

ICMRA Summit 2025
Where: *European Medicines Agency, Amsterdam, the Netherlands*
Date: *21 to 24 - October - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/icmra-summit-2025

EUHPP Live Webinar: The challenge of climate change and integrating sustainability into breast cancer trials
Where: *online*
Date: *22 - October - 2025*
For more information, please refer to:
https://health.ec.europa.eu/latest-updates/registration-euhpp-live-webinar-challenge-climate-change-and-integrating-sustainability-breast-2025-09-12_en

Veranstaltungen / Events – Behörden und andere Veranstalter

CPhI Worldwide & CEP One-to-One Sessions
Where: *Frankfurt, Germany*
Date: *28 to 30 - October - 2025*
For more information, please refer to:
https://www.edqm.eu/en/cphi-frankfurt

Workshop on the use of external controls for evidence generation in regulatory decision-making
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *03 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/workshop-use-external-controls-evidence-generation-regulatory-decision-making

CombiStats Online – Training
Where: *online*
Date: *17 to 21 - November - 2025*
For more information, please refer to:
https://www.edqm.eu/en/combistats-online-training

Annual open meeting of the European Network of Paediatric Research at EMA (Enpr-EMA) November 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/annual-open-meeting-european-network-paediatric-research-ema-enpr-ema-november-2025

HMA/EMA multi-stakeholder workshop on artificial intelligence
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *20 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence

Clinical Trials Information System (CTIS) sponsor end user training programme - November 2025
Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *25 to 28 - November - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-sponsor-end-user-training-programme-november-2025

Veranstaltungen / Events – Behörden und andere Veranstalter

2025 EDQM virtual training programme: independent modules on the Ph. Eur., reference standards and the CEP Procedure

Where: *online*
Date: *01 to 12 - December - 2025*
For more information, please refer to:
https://www.edqm.eu/en/virtual-training-ph-eur-rs-and-cep-procedure

EMA Information Day on submission predictability of initial marketing authorisation December 2025

Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *03 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-information-day-submission-predictability-initial-marketing-authorisation-december-2025

EMA/HMA annual data forum

Where: *online and European Medicines Agency, Amsterdam, the Netherlands*
Date: *09 - December - 2025*
For more information, please refer to:
https://www.ema.europa.eu/en/events/ema-hma-annual-data-forum