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To: Rugo Katre
Subject: IPA newsletter to EU candidate countries - May 2026
Attachments: Agenda - Regulators-only workshop on Reliance for PACs - 18_19 May 2026.pdf; IPA 2026 meeting planner.xlsx

Follow Up Flag: Flag for follow up
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Instrument for Pre-accession Assistance (IPA) newsletter to EU candidate countries May 2026

Dear all,

Welcome to the fifth edition of EMA's newsletter directed to EU (potential) candidate countries in the framework of the Instrument for Pre-Accession Assistance (IPA) programme. Through this quarterly update we aim to give you a more structured overview of upcoming training events, share new courses uploaded in the EU Network Training Centre and provide news and updates from your side.

We hope you will find these regular updates useful and if you have any ideas or proposals about this newsletter, do not hesitate to share your thoughts.

I Updates from candidate countries

Please see below updates from EU candidate countries:

- As of 1 February 2026, Bosnia and Herzegovina has become the **first country in the region to implement eCTD** for medicinal product marketing authorization procedures.
- During the annual **DIA EUROPE Meeting 2026**, held in Rotterdam from 24 to 26 March, the Agency presented itself with the topic "**Bosnia & Herzegovina e-CTD Journey**" as part of the South-East Townhall Session.
- **Montenegro** achieved a major legislative milestone on its EU accession path. In February 2026, all legislation constituting the key benchmark for the closure of **Chapter 1 – Free movement of goods** in the field of medicinal products was adopted:
- The **new Law on Medicinal Products** was adopted by Parliament and published in Official Gazette No 14/26, entering into force on **17 February 2026**. The Law is fully aligned with core EU legislation governing medicinal products for human and veterinary use.
- The Law provides the legal basis for the **Institute for Medicines and Medical Devices (CInMED)** to adopt the required secondary legislation. Accordingly, the Institute's Steering Committee adopted a comprehensive package of implementing acts essential for Chapter 1 closure, published in Official Gazette No 22/26 and 23/26. These include rules on:

- marketing authorisation for human and veterinary medicinal products;
- manufacture of medicinal products and active substances (human and veterinary use);
- registration of homeopathic and traditional herbal medicinal products;
- safety features for human medicines;
- good distribution practice for active substances used in veterinary medicines; and
- pharmacovigilance and adverse event reporting for veterinary medicinal products.

II News from EMA

- EMA opened the [Recruitment procedure for next Executive Director of the European Medicines Agency](#) as the mandate of the current Executive Director, Emer Cooke, ends on 30 April 2027.
- EMA has launched ['Inside EMA'](#), a podcast taking listeners behind the scenes of medicines regulation in the EU. Each episode explores how medicines are assessed before reaching patients, what it takes to ensure they are safe and effective, and the work of the scientists and experts who support public and animal health in Europe.
- EMA has issued [recommendations for the influenza virus strains for 2026/2027 flu season](#) that vaccine manufacturers should include in vaccines for the prevention of seasonal influenza from autumn 2026.
- [EMA recommends authorisation of first veterinary vaccine using RNA technology](#), Nobivac NXT HCPChFeLV, a vaccine for protecting cats against common infectious diseases.
- EMA has set up a [new advisory group on vaccine confidence](#), which will advise the Agency on issues related to vaccine hesitancy and help guide its actions to increase science outreach in this area.
- EMA has launched a [pilot programme to support the development of breakthrough medical devices](#) in the European Union (EU).

Find more news on the [EMA website](#).

III Training opportunities

Please see below the upcoming training opportunities (and also attached the updated training schedule for 2026):

- On 12 May, the [EnprEMA & ACT EU workshop on paediatric clinical trials](#) will take place with an aim to define concrete actions to support dialogue between regulators, commercial and non-commercial sponsors, including academia, research networks and patients' representatives and to identify practical outputs that can facilitate the design, approval and conduct of such trials.
- The Regulatory Agencies Global Network against AMR (RAGNA) is organising a **webinar on AMR and behavioural science** on 13 May. Link to join [here](#).
- On 18 and 19 May, EMA will host a **virtual workshop on reliance for Post Approval Changes (PACs)**. The workshop provides an opportunity to reflect on evidence and practical experience, and insights of NRA experiences regarding the value that reliance brings to their agencies. Information on registration in the attached agenda.
- EMA's [Product Management Service \(PMS\) Info-Day](#) will be held on 9 June. The event is designed to provide interested stakeholders with a clear understanding of the strategic direction of PMS and how it contributes to the broader Network objectives.

- The [Clinical Trials Information System \(CTIS\): Information day](#) will take place on 17 June to provide a comprehensive update on the CTIS, including progress made, upcoming priorities, and key legal and regulatory developments affecting CTIS.
- On 30 June, EMA will host a [workshop on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia](#) with the aim to have a multi-stakeholder's perspective on the challenges in drug development, regulation and clinical practice in immune thrombocytopenia.
- On 30 June and 1 July, EMA's Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group is organising a [two-day workshop to help shape a risk-based approach to the use of generative artificial intelligence \(AI\) in medicines manufacturing](#). The workshop will be broadcast live.
- [EMA multi-stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU](#) will take place on 1-2 July. The objective of the workshop is to enhance understanding among stakeholders on the interplay of regulation and innovation in cardiovascular medicines and medical devices.

IV EU NTC international catalogue

- Recording on [Feasibility of non-interventional studies using real-world data: recent guidance and use cases](#) has been added to the EU NTC international catalogue.
- [AI literacy programme for EU Medicines Regulatory Network](#) is a one-hour training divided in bite-sized micromodules, covering key topics you need to get up to speed on using AI at work.
- The beginner-level module on [Omics data](#) introduces the key concepts behind genomics, transcriptomics, proteomics, and metabolomics, focusing on how omics data are generated, summarised, and used in regulatory decision-making.
- The module on [Data quality](#) introduces the Data Quality Framework (DQF), explaining key data quality principles, determinants, and assessment methods.
- [Lunchtime talk on medicines in pregnancy & lactation: 'Pharmacovigilance in pregnancy and breastfeeding'](#) explores critical gaps in the information needed for effective signal detection and presented a forward-looking vision for improving how safety information is shared with women and their healthcare providers.
- Recording on [Challenges in drug development, regulation and clinical practice in lymphoma](#) has been added to the Oncology curriculum.
- Recording of the [QWP 2025 training on quality and \(bio\)equivalence aspects of locally applied, locally acting, cutaneous and gastro-intestinal tract products and oral modified release products](#) aims at ensuring the harmonisation of quality assessment principles across the Network.
- [Training on workbook for assessors on streamlining the list of questions \(clinical aspects\)](#) covers the 2026 revision of the workbook designed to further support assessors in drafting clear, focused Lists of Questions (LoQs), helping streamline assessments while saving time and resources.
- A new training [curriculum on pharmacogenomics](#) for the European medicines regulatory network (EMRN) has been launched as a key deliverable of the Network Data Steering Group (NDSG), already including the first two modules.
- A recording of a [training series organized by the Vaccines Working Party \(VWP\)](#) of seven webinars to strengthen the expertise of assessors who are currently involved, or expected to be involved, in the clinical evaluation of vaccines.
- This recorded session on [Survival in patients with non-small cell lung cancer: a comparative effectiveness study for HTA](#) of the Real-World Academy will help build shared knowledge and strengthen confidence in interpreting real-world data study results.

Find here the [EU NTC platform](#). For new users, please register [here](#).

With kind regards,
Katre & Michiel

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