29 May 2026
EMA/127390/2026

Final Minutes – HMA-EMA joint Network Data Steering Group meeting

21 May 2026, 15:30-17:30pm, MS Teams Meeting

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
1.	Adoption of the draft agenda & minutes	Karl Broich, Peter Arlett	For adoption	5’
2.	Setting the scene: 2026 priorities and long-term vision • Long-term priorities and vision– 5’ • Priorities for 2026 – 10’ Group discussion – 5’	Karl Broich Hilmar Hamann All	For information	20’
3.	Use cases for structured medicinal product master data • Overview of use cases - 10’ • PMS data for EHDS cross border use – 5’ • Pilot public release of PMS data to stakeholders (via API) – 5’ Group discussion – 15’	Isabel Chicharo Isabel Chicharo Isabel Chicharo All	For agreement	40’
4.	Quality of structured medicinal product master data • Findings from the ROG PMS data qualification feasibility study - 10’ • Ensuring fit-for-purpose quality data driven by use cases - 5’ • Current measures in place - 5’	Georg Neuwirther Ana Cochino Ana Cochino	For discussion	50’

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
	• Next steps for data quality and EMRN working arrangement – 10' Group discussion – 15'	Hilmar Hamann All		
5.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Ana Cochino (EMA), Isabel Chicharo (EMA), Siobhán O'Sullivan (Ethics), Eleonora Agricola (EU-IN), Ana López de la Rica Manjavacas (AEMPS, ES), Joerg Zinserling (BfArM, DE), Aimad Torqui (MEB, NL), Georg Neuwirther (AGES, AT), Vincent Gazin (ANSM, FR), Katrien Oude Rengerink (CBG-MEB, NL), Kaisa Immonen (EMA), Jacobus van Wyk (EMA), Laure Baduel (CVMP), Anastasia Pagida (EC), Anne-Marie van Nederkassel (EMA), Hilmar Hamann (EMA), Pelle Persson (MPA, SE), Steven Le Meur (EMA), Christopher Javris (EDQM), Kristin Karlsson (MWP), Dennis Kruse (EC), Paul Lynn (EMA), Rico Slingerland (CMDv), Gianmario Candore (EMA), Claus Møldrup (DKMA, DK), Niklas Hedberg (HTA), Ivelina Gushlekova (CTCG), Paolo Alcini (EMA), Flora Musuamba Tshinanu (SAWP), Frank Petavy (EMA).
Apologies:	Dag Jordbru (NOMA, NO), Anthony Oshea (EDQM), Aina Staisiuniene (EMA), Patricia McGettigan (PRAC), Stefanie Prilla (EMA), Gabriel Westman (MPA, SE), Vaia Apostolidou (EC), Edurne Lazaro (AEMPS, ES), Angelo Molinaro (AIFA, IT), Konstantina Boumaki (EPF), Florian Klinglmueller (AGES, AT), Jerome De Barros (EC), Carla Torre (CHMP), Francisco Penaranda (EMA), Momir Radulovic (Jazmp, SI), Marta Slomka (Payers), Christina Kyriakopoulou (EC), Sandra Bertulat (BVL, DE (vet)), Javier Martínez Arribas (Payers), Markus Kalliola (SITRA, FI), Pier Paolo Olimpieri (AIFA, IT), Kimmo Porkka (EHA), Patrice Verpillat (EMA), Pero Ivanko (CIPH, HR), Alessandro Blasimme (Ethics representative), Michael Vogl (EMA), Bruno Delafont (CHMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The minutes of 15th April 2026 NDSG meeting were adopted as final.

2. Setting the scene: 2026 priorities and long-term vision

The NDSG co-chairs introduced the meeting objectives, which focused on reaffirming the long-term vision for Product Management Service (PMS), confirming the priorities for 2026 and discussing related key NDSG deliverables.

Karl Broich (BfArM, DE) highlighted the strategic importance of PMS in the evolving European regulatory data landscape and explained that PMS is intended to become the EU's shared centralised repository for human medicinal product information, supporting the product data lifecycle through a single-entry point for regulatory submissions. It will be a key enabler of the network strategy to 2028, supporting interoperability, standardisation, and implementation of the new legislative requirements of the European Health Data Space (EHDS) and new pharmaceutical legislation. The importance of data quality was emphasised as a key success factor to maximise the use of PMS data for key EMRN use cases.

Hilmar Hamann (EMA) introduced the PMS priorities for 2026, across the 3 key domains: IT delivery, data and processes. Activities will focus on increased public access to PMS data (through a public API), continuously improving PMS data quality, and engaging the network and stakeholders on EMRN working arrangements and simplification of processes for PMS data.

3. Use cases for structured medicinal product master data

Isabel Chicharo (EMA) presented the use cases that structured medicinal product master data already supports and potential new use cases. The purpose of this session was to align on a common understanding on PMS use cases and on a common agreement that the PMS data quality approach should be driven by its use cases i.e. that data quality is fit for specific purposes.

The group discussed how PMS data, of data quality that is fit for purpose, already supports core regulatory activities thought the medicinal product lifecycle. This includes:

- pharmacovigilance, where structured data enables signal detection and analysis across products. It was noted that additional data elements (e.g. manufacturing information) will further enhance these analyses,
- shortages monitoring, PMS data supports identification of alternatives and assessment of supply capacity. The availability of structured data improves timeliness and coordination of regulatory responses,
- electronic product information (ePI), which will allow patients to access 'patient friendly' medicines information by scanning a barcode on a package.

In addition, the group discussed:

- the opportunity with the new pharmaceutical legislation to optimise variations type IA processes through direct data submission in PMS. This could reduce administrative burden for both marketing authorisation holders and national competent authorities, noting that further scoping and agreement is needed.
- How PMS could be the foundation for cross-border e-Prescription and e-Dispensation by providing a common EU reference for medicinal product to support EHDS use cases and acting as a bridge between national formularies for accurate data exchange.

Finally, the group discussed the upcoming 'beta-release' of PMS data via public application programming interface (API), which will provide access to structured product data for regulators, industry, and external stakeholders. The API is expected to support transparency, facilitate reuse of data, and allow development of digital health applications by external service providers. A phased approach is foreseen to gather feedback from stakeholders and continuously improve data quality in 2026 before moving to full release in early 2027.

4. Quality of structured medicinal product master data

Georg Neuwirther (AGES, AT) presented the outcomes of the ROG PMS data qualification feasibility study, which aimed to ensure consistency between PMS and national data sources. The study confirmed that initial qualification activities could focus on a first subset of core PMS data elements (including product name and marketing authorisation holder) with minimal effort, while qualification of other PMS data elements will require further enrichment (e.g. ESMP related data elements like packages) before the qualification process can start. It was noted that full qualification of legacy data will be resource-intensive and will require prioritisation, as well as the development of supporting tools and approaches, including opportunities for workload sharing across the network. As the next step, the ROG PMS operational group will discuss progressing the data qualification for the first subset of data elements and engaging with industry on the proposed process. This will inform the drafting of the roles and responsibilities for the PMS Data Quality Framework.

Ana Cochino (EMA) presented the current PMS data quality measures and summarised the activities to continuously improve data quality that will be undertaken in 2026. Data Quality aims at fit-for-purpose data for supported use cases - it should address the needs of key use cases, focusing on key data fields and rules, and build up incrementally.

EMA runs a centralised data quality process for PMS data and measures are in place to ensure structured product data quality for the current EMRN use cases. The existing data quality measures, including data validation at submission, use of controlled vocabularies and manual verification of data against regulatory documents, ensures a baseline level of data quality for PMS data.

Ongoing work to be completed in 2026 will focus on addressing known technical issues (e.g. duplicates, outdated information and data gaps), data corrections and improving monitoring through the development of analytics tools for the Network. Additionally, the NDSG deliverable on PMS data quality framework is being developed and will provide a structured and transparent approach to data quality management. The framework will define processes, metrics and governance arrangements, and will operationalise the "fit for purpose" data quality principle across PMS use cases.

Hilmar Hamann (EMA) then presented a roadmap on PMS data and implementing the target operating model, highlighting that successful delivery will require close collaboration with the Network and stakeholders.

As part of the discussion, the group agreed that PMS is a key priority and is an enabler for the future regulatory and digital health activities. It is important to progress with data quality and learn from the veterinary domain colleagues for the development of the data quality dashboards for PMS data. Participants discussed the need for clear ownership, strategic decision-making, and alignment across NCAs and EMA, especially regarding the use of PMS for national marketing authorisation applications and variations, and the integration with other regulatory systems.

Work will continue to develop the data quality framework, refine the qualification processes, and engage with stakeholders, including industry and external users of PMS data. Follow-up discussions and updates will be brought to future NDSG meetings.

5. A.O.B.

Not applicable