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Summary report of the annual Network Data Steering Group meeting with industry stakeholders

14 July 2026 – co-chaired by Karl Broich (BfArM) and Peter Arlett (EMA), Teams

1. Welcome and opening remarks

The co-chairs opened the meeting and welcomed participants from the Network Data Steering Group (NDSG) and pharmaceutical industry associations of Vaccine Europe, AESGP, Association of Veterinary Consultants, EFPIA, EUCOPE, ACRO, Medicines for Europe and EuropaBio.

2. Key progress of NDSG workplan

A progress update on the revised NDSG workplan was provided to the group, highlighting developments across the six workstreams.

Specific updates were provided on the Product Management Service (PMS), including the launch of a public API, ongoing work on data quality and data qualification, and the development of future working arrangements to support a trusted and fit-for-purpose source of medicinal product master data. Progress was also reported on AI-related activities, including publication of the AI Observatory Report, development of AI research priorities, international collaboration activities and the establishment of an AI coordination group to oversee the AI guidance development across different regulatory domains. On RWE, the expansion of DARWIN EU® was highlighted, publication of new guidance documents, and the 4th report on regulatory-led studies using real-world data to support regulatory decision-making.

Additionally, several stakeholder engagement activities are being planned where industry can provide feedback, including workshops and public consultations (e.g. on data standardisation and ADR data quality).

Industry representatives welcomed the progress report and provided a joint industry perspective on the NDSG workplan, noting a strong alignment between NDSG priorities and industry objectives. The feedback provided by industry focused on data interoperability and activities linked to the PMS master data.

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Industry supported the establishment of PMS as trusted source for the EU Network, replacing legacy systems like xEVMPD, streamlining the regulatory data flows, reducing duplication and enabling interoperability across regulatory systems through the reuse of structured data.

Industry representatives called for building on the momentum of the recent PMS Information Day to support delivery of the ambitions set out in the New Pharmaceutical Legislation (NPL). They emphasised that any future solution should be integrated with PMS data, enabling a single submission approach and establishing PMS as the single source of product data, including replacement for xEVMPD. To achieve this, the Network should continue prioritising and investing in:

- Improving data quality for business cases supported with efficient processes to identify and resolve data inconsistencies between stakeholders.
- Optimising Type 1A variation process, transitioning from document-based to data-driven submissions, with plans for further workshops and pilot testing to validate new approaches.
- Integrating electronic product information (ePI) into the product lifecycle and regulatory processes was emphasised. ePI is currently a standalone process, disconnected from the product lifecycle, and Industry called for better integration using structured, reusable PMS data to enable efficient regulatory variations and reduce duplication.
- Establishing an optimised reporting mechanism, harmonised EU definitions and re-use of structured data for shortage and marketing status reporting. Industry proposed a single, harmonised dataset for reporting, aligned with ISO IDMP and PMS data, and supported the API-based submissions to streamline processes and reduce manual entry.

A discussion took place and the following was noted:

- The Inter-Association Network Portfolio Alignment and Connection Team (INPACT) is the main industry coordination group for data-related matters. It was created to align with the agile methodology and the Network portfolio governance, including Regulatory Optimisation Group (ROG), NDSG, Network ICT Advisory Committee (NICTAC) and Quarterly Strategic Portfolio Review (QSPR).
- Participants highlighted the need to move from planning to delivery, focusing on practical implementation, interoperability and process simplification (with data flow improvements). It was noted that successful implementation would require continued co-design, clear governance arrangements and close collaboration between regulators and industry.
- The importance of integrating PMS, electronic product information (ePI), electronic common technical document (eCTD) and related systems was highlighted to support an end-to-end, data-centric regulatory process and avoid duplication of data entry and reporting activities. There is an opportunity to further align on these three elements. **Action**: EMA/NDSG to further explore how PMS, ePI, eCTD, electronic application forms and related regulatory systems can be better aligned.
- The discussion also addressed ongoing PMS data qualification activities and the need to have a clear PMS data qualification process (rules and framework). The collaboration on both technical and process-related aspects is ongoing and further discussions are planned. This work will feed into future PMS working arrangements document and will explore opportunities to leverage automation and AI-enabled approaches to support data quality activities. **Action**: Industry (Remco Munnik) to provide EMA with a list of key challenges associated with the current XEVMPD acknowledgement process/messages to the group for discussion at the next ROG PMS Industry meeting in August.
- Industry participation in the upcoming ePI user acceptance testing activities was encouraged, to continue discussions and identify improvements.

- The group also agreed that there are huge opportunities for reuse of data collected for other purposes (e.g shortages).

3. Looking ahead and new EU legislation: Impact and opportunities for data: Industry perspectives

Industry representatives presented the opportunities and implications for data emerging from the New Pharmaceutical Legislation and related legislative initiatives. It was noted that these changes have the potential to accelerate digital transformation in the network, through close cooperation across stakeholders and a coordinated approach to implementation.

The industry-proposed digital principles for NPL implementation were presented, including 'digital by default', system coherence, simplification, leveraging existing systems, predictability, emphasising the need for robust data exchange and transition periods.

The key topics for NPL implementation with impact to the EMRN Strategic Portfolio presented by Industry included the need for a single-entry point for procedures, the digitalisation of variations, integration of the electronic product information (ePI), harmonised shortage reporting, and improved linkage of clinical trial and paediatric data. These initiatives are intended to enhance interoperability, streamline regulatory processes, and reduce duplication of effort and administrative burden across the network. Speakers also highlighted the importance of ensuring alignment between centralised and decentralised procedures and leveraging existing European and international initiatives where possible.

The group welcomed the feedback and highlighted that implementation activities are already ongoing in preparation for the new legislative changes. It was agreed on the need to focus on practical, future-proof solutions that simplify procedures rather than add new layers of complexity. The industry standing group will remain as the main reference point for updates and escalation, ensuring continuity and coordination across multiple working groups and platforms.

4. Wrap up and conclusions

The NDSG co-chairs thanked the meeting attendees for their participation and contribution to this meeting.