30 July 2026
EMA/154897/2026
Regulatory Science and Innovation Task Force

Meeting Summary — Medicine Shortages SPOC Working Party

16 June 2026, hybrid meeting – F2F + TEAMS

17 June 2026, hybrid meeting – F2F + TEAMS

Chair: Monica Dias (EMA), Vice-Chair: Vasileios Loutas (PhS, Ministry of Health, Cyprus)

Tuesday, 16 June 2026 (10:00-18:00)	
Item	**Topic**
1.	**Welcome, declarations of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed all participants, both those attending in person and those joining online to the hybrid meeting of the Medicine Shortages SPOC Working Party held at the EMA premises in Amsterdam. The SPOC WP Secretariat reviewed members' and experts' declared interests in accordance with the Agency's policy on handling of declarations of interests (DoI) of scientific committees, applicable to members and experts of the SPOC WP and announced that according to the topics on the agenda no restrictions are applicable.
2.	**Adoption of draft minutes of the SPOC WP meeting held on 12 May 2026**

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	The Vice-Chair informed that the minutes of the meeting held on 12 May 2026 had been distributed one week prior to the meeting. No comments were received before or during the meeting. The minutes were adopted.
3.	**Updates from Member States**
	a) SPOC WP lightning round – most critical issues at national level SPOC WP members exchanged information on the most critical issues at national level linked to medicines supply and availability and measures taken to address these.
	b) Status update on any new strategic measures implemented at national level (e.g., critical medicines lists, stockpiling requirements) SPOC WP members exchanged information on new strategic measures at national level.
4.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	• **Feedback from the SPOC WP subgroup on crisis monitoring and preparedness** **Update on the geopolitical situation** EMA presented an update on the potential impact of the ongoing conflict in the Middle East on the availability of medicines in the EU/EEA. No critical shortages linked to the conflict were identified. **Agreed actions:** • EMA, in collaboration with the SPOC WP subgroup on crisis monitoring and preparedness, will continue to closely monitor the ongoing situation in the Middle East on the availability of medicines in the EU/EEA. • SPOC WP members are requested to report to EMA any signals related to the situation in the Middle Easton that may affect the availability of medicines in their territories. • **Hantavirus and Ebola – update** EMA presented the current status of the Andes hantavirus outbreak and also the current status of the Bundibugyo Ebola virus (BEBOV) outbreak in the Democratic Republic of Congo, which has been declared a public health emergency of international concern (PHEIC) by the World Health Organisation (WHO).

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	EMA noted that there are currently no authorised vaccines or therapeutics available for Bundibugyo Ebola virus. Possible interventions including diagnostics, vaccines, and therapeutics are under discussion, with remdesivir, obeldesivir, and monoclonal antibodies as potential treatment options. **Agreed actions:** • EMA to provide updates to SPOC WP if the situation deteriorates.
5.	**Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)** A SPOC WP expert reported an ongoing shortage of a medicinal product used in erectile dysfunction due to manufacturing issues. The shortage started in early June 2026 and is expected to last until end of July 2026. No alternatives are available on the national market. Initial feedback suggests that the shortage is primarily national in scope as most MSs reported limited or no impact. EMA will discuss with the MAH and affected MS for further information. The SPOC WP expert reported an ongoing shortage of an antihemorrhagic medicinal product due to increased demand. The shortage started in early June 2026 and is expected to last until the end of June 2026 with no alternative medicinal products available in the Member State. Other MSs have not reported shortages of this product. EMA continues monitoring shortages of these medicines. The SPOC WP expert also reported an intermittent shortage of a rabies vaccine due to distribution issues. No alternatives are currently available in the Member State. Initial feedback suggests that the shortage issue is primarily national in scope as most MSs reported limited or no impact and EMA have not been notified of this shortage.
6.	**Critical shortages escalated to the SPOC Working Party:**
6.1	**Ongoing shortages**
	a) Ifosfamide containing medicinal products and cyclophosphamide containing medicinal products EMA provided an update on the ongoing shortages of ifosfamide and cyclophosphamide, highlighting continued manufacturing constraints at Baxter's contract manufacturing organisation (CMO). It was noted that the supply of both critical medicines remains insufficient across the EU/ EEA. EMA also outlined ongoing regulatory engagement with the United States (US) Food and Drug Administration (FDA) and EU supervisory authority to monitor remediation efforts and support the restoration of supply. Updates were also shared from an ad hoc MSSG meeting held on 12 June 2026, with an oral explanation from the MAH.

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	In addition, EMA informed the SPOC WP of ongoing efforts to identify alternative ifosfamide-containing medicinal products. Manufacturers in third countries have been contacted, and two companies have confirmed their capacity to supply additional quantities to the EU/EEA. Discussion SPOC WP discussed the possibility of compounding ifosfamide and cyclophosphamide, subject to Baxter being able to provide the sterile active pharmaceutical ingredient (API) to compounding centres, hospitals, or other facilities. Several SPOC WP members provided updates on the national supply situation, with one MS highlighting a risk of stock-out by the end of June if planned deliveries are delayed. EMA confirmed that this concern will be raised with Baxter, including a request to consider redistribution of stocks to MSs most in need. **Agreed actions:** • EMA to continue monitoring the development of these shortages and the implementation of MSSG recommendations with concerned MAH through discussions with SPOC WP subgroup and Baxter. • EMA to draft proposal for updates to MSSG recommendations to include specific recommendations to manufacturers. • SPOC WP to consider if any manufacturing or quality deviations preventing release of batches of ifosfamide or cyclophosphamide could be coordinated centrally.
	b) Availability of anti-tuberculosis medicines EMA presented preliminary results of the criticality survey circulated to Member States on the availability of anti-tuberculosis medicines across the EU/EEA. The most critical issue identified is the ongoing shortage of Mycobutin (rifabutin), marketed by MAH Pfizer, due to a discontinuation of the registered starting material (RSM) supplier, leading to manufacturing constraints. EMA also outlined ongoing and planned mitigation measures being implemented by the MAH and noted ongoing engagement with potential alternative suppliers of rifabutin. **Agreed actions:** • MSs to fill in the survey on the availability of anti-tuberculosis medicines. EMA to analyse the results and bring the topic for discussion at a future SPOC WP meeting. • Mycobutin (rifabutin) ongoing shortage: EMA to continue engagement with current MAH (Pfizer) and alternative suppliers of rifabutin. A shortage catalogue entry is under development.

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	c) Medicinal products manufactured by Pharmathen International site EMA provided an update on the GMP compliance status of the Pharmathen International site. EMA also presented a newly identified issue affecting solid oral dosage forms. As a result, Pharmathen has temporarily suspended manufacturing, packaging, and batch release activities pending completion of the investigation and implementation of corrective and preventive actions (CAPAs). A product impact assessment is currently being conducted by the company and will be reviewed by the supervisory authority to determine the potential impact on products already on the market. Discussion A SPOC WP member confirmed awareness of the issue, noting that multiple products are expected to be affected in their country. Additionally, one SPOC WP member reported supply constraints related to quetiapine in their territory. **Agreed actions:** • SPOC WP to monitor shortages of products manufactured by Pharmathen, paying special attention to atomoxetine, quetiapine and venlafaxine which have been escalated to the SPOC WP in the past for EU coordinated actions and to inform EMA if the supply situation at national level deteriorates and becomes critical for any of the monitored medicines.
	d) Fibclot NAP (human fibrinogen), MAH: Laboratoire français du Fractionnement et des Biotechnologies S.A. EMA provided an update on the supply of medicines containing human fibrinogen in the EU/EEA and outlined ongoing mitigation measures, including regulatory support from a MS to accelerate the registration of an alternative manufacturing site for these medicines. EMA also noted possibility to import human fibrinogen from third countries. No member states are currently considering importing human fibrinogen medicines from third countries.
	e) Azactam NAP (aztreonam), MAH: Delbert Pharma EMA provided an update on the critical shortage of Azactam in the EU/EEA, ongoing since Q2 2026. The root cause is linked to manufacturing issues at a new production site. This means that new batches of Azactam 1g and 2g powder for injection or infusion cannot be released, which has resulted in supply shortages, with no immediate timeline for resolution. It was noted that the MAH is developing a risk mitigation plan to support supply continuity in the short term; however, its implementation remains subject to regulatory and manufacturing constraints. The shortage is expected to last until the end of June 2027.

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	EMA further outlined mitigation measures planned by the MAH, including allocation of available stock through a quota system, implementation of a patient prioritisation strategy, and the establishment of a central EU stock repository. In addition, a Medicine Shortage Communication (MSC) has been disseminated in affected member states to inform healthcare professionals of the shortage and the proposed prioritisation approach. Discussion SPOC WP members discussed the issue and noted that currently available stock would provide only short-term coverage and is insufficient to meet overall demand. A SPOC WP member noted that imports from other countries are being explored as a mitigation measure in their country. **Agreed actions:** • MSs to inform EMA if they plan to accept Delbert's risk mitigation plan and to inform EMA of any discussions with alternative MAHs regarding supply of alternative product. • EMA to continue close monitoring of the situation and communications with MAH Delbert.
	f) Medicinal products from MAH Cheplapharm EMA provided an update on the ongoing critical shortages of Visudyne (verteporfin) and Zypadhera (olanzapine). For Visudyne, EMA outlined the status of the new supply chain and the next steps towards restoring stable supply. For Zypadhera, updates were provided on current allocation mechanisms and planned actions to improve supply availability. In addition, EMA presented a list of products from MAH Cheplapharm identified for targeted follow-up, with the aim of proactively monitoring potential supply risks and preventing further shortages. Discussion A SPOC WP representative reported supply constraints affecting Visudyne to which EMA responded that additional supply for the national market may be secured and will provide confirmation once feedback is received from Cheplapharm. **Agreed actions:** • SPOC WP subgroup to continue work on prioritised subset of medicines for targeted monitoring, measures to be taken (requests for SPP, updates in bimonthly reports) and need for escalation to SPOC WP/MSSG.

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7.	**EC DG SANTE** EC DG SANTE representative outlined Member States' responsibilities in implementing the new pharmaceutical legislation, focusing on aspects relevant to shortages and security of supply. In particular, the speaker noted the direct applicability of the Regulation and emphasized the need for national coordination to ensure readiness and to inform necessary changes to national legislation or administrative procedures.
8.	**Implementation of the New Pharmaceutical Legislation: Provisions related to shortages and security of supply** EMA provided an overview on the implementation activities of the new pharmaceutical legislation in relation to shortages and security of supply, focusing on MSSG-coordinated activities and their current status and an overview of Member State-led activities. The group was asked to identify Member State-led activities that may benefit from a harmonised approach to implementation, which could be coordinated via the SPOC WP. An initial discussion of the submitted proposals was held.
9.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG meeting on 20 May 2026 and ad-hoc MSSG meeting on 12 June 2026 EMA provided a high-level update on the points discussed at the MSSG meeting on 20 May 2026. These included an update on Critical Medicines Act presented by DG SANTE and update from EMA on the ongoing critical shortages of ifosfamide and cyclophosphamide. The meeting also covered the process for adopting and updating the Union List of critical medicines and the Union long list in line with the new pharmaceutical legislation and feedback from industry associations on the 2026 Vulnerability Assessment Exercise. In addition, MSSG discussed the potential impact of restrictions on per- and polyfluoroalkyl substances (PFAS) on the supply of medicines, as well as preparedness activities related to the conflict in the Middle East and ongoing hantavirus and Ebola virus outbreaks. Furthermore, EMA provided brief feedback from the ad hoc MSSG meeting held on 12 June 2026, during which the ongoing critical shortages of ifosfamide and cyclophosphamide were discussed.
	b) Feedback from the MSSG WG on the Vulnerability Assessment including Shortage Prevention Plans EMA presented feedback from the MSSG Working Group on the Vulnerability Assessment Methodology (VAM), with a focus on the ongoing vulnerability assessment exercise, outlining next steps and continued engagement with the MSSG Working Group. In particular, EMA noted the semi-automated Excel tool developed to support Rapporteurs in conducting vulnerability

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	assessments and generating draft reports. The tool aims to ensure consistency and reproducibility of approaches across Rapporteur teams. In addition, EMA informed the SPOC WP that the Shortage Prevention Plan (SPP) template and guidance are being updated in line with the new pharmaceutical legislation and will be shared with MSSG for adoption. To support this work, a technical workshop will take place with nominated industry representatives and members of MSSG WG on VAM and ESMP. The outcome will be shared with the SPOC WP afterwards. **Agreed actions:** • For the vulnerability assessment exercise: Consolidated data per INN to be shared soon with Rapporteurs, followed by assessment by Rapporteurs using the agreed template and guidance provided.
	c) Union list of critical medicines and Union long list - update EMA provided an update on the annual review of the Union list of critical medicines and noted that a request for classification has been circulated to the SPOC WP. In addition, EMA provided an update on the Union long list including proposed next steps for the final adoption of this list. EMA clarified that the Union long list includes all medicines considered critical at Member State level according to the common EU methodology to identify critical medicinal products. Under the new pharmaceutical legislation, MAHs are required to offer their marketing authorisation for transfer if they intend to withdraw certain medicines covered by the transfer provision, including medicines that have been identified as critical in a Member State and are included in the Union long list. Finally, EMA proposed reactivating the relevant focal group to further discuss updates to the methodology for identifying critical medicines as well as the approach for updates to the Union list and in line with requirements under the new pharmaceutical legislation. **Agreed actions:** • Re-activation of the Focal group was agreed, with an initial meeting to be scheduled in the coming weeks.

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10.	**National competent authorities on pricing and reimbursement and public healthcare payers (NCAPR)** • **NCAPR and its objectives** NCAPR representative from Ministry of Health in Spain introduced NCAPR and presented its objectives in relation to shortage of medicines. NCAPR is a voluntary European collaboration platform made up of national health officials, government bodies, and public payers across the EU/ EEA. It was established to enhance collaboration between the Member States in the field of pricing and reimbursement of medicines and medical treatments. The speaker noted that pricing and procurement decisions may contribute to structural vulnerabilities and increase the risk of shortages. Ensuring coordinated action at EU and national level to support sustainable supply and access to medicines was underlined. • **Using pricing policy to improve the availability of medicines** NCAPR representative from PT NCA (Infarmed) presented the use of pricing policies in Portugal to support the availability of medicines, outlining existing measures to manage shortages, including stakeholder coordination, controlled supply, and critical medicines list. It was noted that shortages are predominantly driven by manufacturing and logistical issues, although pricing factors also contribute, particularly for low-cost medicines which account for the majority of reported shortages. The speaker described targeted price increases for lower-cost medicines implemented between 2023 and 2025, mainly affecting generics, and a case study indicating a modest reduction in shortages for medicines subject to price increases. However, these measures also led to higher public and patient expenditure. Overall, the importance of ensuring price sustainability while safeguarding access and security of supply was emphasised. <u>Discussion</u> SPOC WP members discussed the findings of the analysis done by Infarmed.
11.	**Impact of marketing authorisation withdrawals and permanent marketing cessations of medicinal products in the EU/EEA** EMA presented the results of a survey that was circulated to SPOC WP and Drug Shortages Global Regulatory Working Group (DSGR WG) on the impact of marketing authorisation withdrawals and permanent cessations on the availability of medicines. The findings indicate that several EU countries have observed an increase in such discontinuations, with variable impact on

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	patient care depending on the availability of therapeutic alternatives. The main drivers of discontinuations were identified commercial factors, manufacturing issues and raw material constraints. The survey results highlight the need for more tailored approaches to managing discontinuations and for enhanced information sharing across jurisdictions to support timely and coordinated action.
12.	**Drug Shortages Global Regulatory Working Group: feedback from Q2 meeting** EMA provided a high-level update from the latest meeting of the DSGR WG held on 10 June 2026. The discussions covered, inter alia, an update on the GLP-1 receptor agonist drug utilisation study, the potential impact of the ongoing conflict in the Middle East on the availability of medicines, and ongoing shortages of concern.
13.	**Short shelf-life of medicinal products and its impact on the availability** SE SPOC WP member presented the impact of short shelf-life of medicines on medicine availability, noting that current approaches focus on quality considerations and may not fully account for supply risks. Short shelf-life of medicines was highlighted as a contributing factor to reduced stockholding, limited flexibility, and increased risk of shortages and discontinuations. SE SPOC WP member proposed to draft a reflection paper to highlight the issue from both quality and availability perspectives, as a joint effort between the SPOC WP and Quality WP. **Agreed actions:** • Agreement for drafting of a reflection paper, call for interest will be launched for drafting group participation under SE leadership.
14.	**Shortage management systems**:
	a) Belgium - Approach in ensuring interoperability with EMA systems BE SPOC WP member outlined the national approach to ensuring interoperability with EMA systems and noted ongoing work to support data exchange with the ESMP, including integration of PMS and package IDs into national system and development of a system for data collection and data exchange. <u>Discussion</u>

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	Number of SPOC WP members confirmed that similar interoperability work is ongoing in their countries and discussed technical aspects of the activities presented by Belgium. **Agreed actions:** • Topic to be revisited in future SPOC WP meetings, as appropriate.
	b) European Shortages Monitoring Platform (ESMP) update EMA provided an update on the ESMP, confirming that the voluntary solidarity mechanism (VSM) functionality is now live and that an initial testing phase has been successfully completed, with phase two to commence soon. Once implemented, NCAs will be able to submit VSM requests directly through ESMP, which will serve as the main channel for all VSM submissions. NCAs will be informed in due course of the timeline for transitioning to ESMP.
	c) Bulgaria - EMVS data: market monitoring and use by MS BG SPOC WP alternate presented the use of data from the Falsified Medicines Directive (FMD) verification system (EMVS), highlighting its legal basis under Commission Delegated Regulation (EU) 2016/161, in particular Article 39, which allows access for NCAs. BG SPOC WP alternate demonstrated how available reports can provide insights into the number of packs placed on the market, their batch information, and their status (active or decommissioned), enabling NCAs to better assess availability and potential shortages. <u>Discussion</u> SPOC WP discussed the potential use of EMVS data for shortage monitoring. It was noted that the system is capable of handling high volumes of data and can provide accurate, real-time information on released and decommissioned packs. However, limitations of the data were also highlighted, particularly in relation to demand forecasting and coverage of hospital use. **Agreed actions:** • Topic to be revisited in future SPOC WP meetings, as appropriate.
15.	**SPOC WP subgroup on shortage definition — Proposal for update of root cause classification**

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	EMA presented the proposed harmonised classification of shortage root causes developed by the SPOC WP subgroup, aligned with requirements in the new pharmaceutical legislation. The harmonised classification aims to enhance consistency, comparability, and reporting of shortages across Member States. The final report and harmonised categories (including descriptions and examples) have been shared with SPOC WP for review. The report will be circulated to MSSG for adoption thereafter. Further implementation activities will be continued through JA CHESSMEN WP 5. SPOC WP Chair congratulated the subgroup on the work achieved and noted that the subgroup will continue its work on harmonisation of other shortage-related elements. <u>Discussion</u> SPOC WP discussed the implementation and future use of the harmonised root cause classification, including its potential integration into existing systems and its role in supporting harmonisation across Member States.
16.	**Status update on other critical shortages escalated to the SPOC WP** (only comments relating to previously circulated written updates)
	a) Medicinal products affected by fire incident at Viatris manufacturing site b) Creon NAP (pancrelipase), MAH: Viatris No comments were raised by SPOC WP members. EMA will continue monitoring the ongoing shortages listed above and will keep SPOC WP informed of any developments.
17.	**AOB** No comments were raised.
18.	**Wrap-up and next steps** SPOC WP Chair summarised key follow-up actions from the two-day hybrid meeting. The agreed actions are detailed above.
19.	**Closing remarks** The Chair and Vice-Chair thanked the SPOC WP for their active participation at the hybrid meeting and informed that the next hybrid meeting will take place in October 2026 at EMA premises in Amsterdam.

Next meeting: 15 July 2026 (TEAMS)

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 16-17 June meeting, which was held in hybrid mode (in EMA Office and Microsoft TEAMS).

Based on the review of the conflict of interests, no restrictions were identified.

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Monica Dias	EMA	Chair	No interest declared	
Vasileios Loutas	Cyprus	Vice-Chair	No interest declared	
Anna Gerhartl	Austria	Member	No restrictions applicable to this meeting	
Andrea Kugi	Austria	Alternate	No interest declared	
Sybille Schotte	Belgium	Member	No interest declared	
Sanne Vandelanotte	Belgium	Alternate	No interest declared	
Emilia Stoyanova	Bulgaria	Member	No interest declared	
Radoslav Ruitchev	Bulgaria	Alternate	No interest declared	
Mateja Mervić	Croatia	Member	No restrictions applicable to this meeting	
Stela Lilek	Croatia	Alternate	No restrictions applicable to this meeting	
Mathilde Moe Moeldrup	Denmark	Member	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Camille Ramahefarivony	France	Member	No interest declared	
Flore Demay	France	Member	No interest declared	
Laurent Fabry	France	Alternate	No interest declared	
Julia Lehtinen	Finland	Member	No interest declared	
Minna Myllyntausta	Finland	Alternate	No interest declared	
Theoni Kousteni	Greece	Member	No interest declared	
Gabriele Eibenstein	Germany	Member	No restrictions applicable to this meeting	
Andrea Stippler	Germany	Alternate	No restrictions applicable to this meeting	
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting	
Inke Reimer	Germany	Member	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Linda Holtkamp	Germany	Alternate	No interest declared	
Kinga Csécsei	Hungary	Member	No interest declared	
Veronika Horváth	Hungary	Member	No interest declared	
Gyöngyi Petró	Hungary	Alternate	No interest declared	
Hafdís Birna Baldursdottir	Iceland	Alternate	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Rosemary Heneghan	Ireland	Alternate	No interest declared	
Domenico Gi Giorgio	Italy	Member	No interest declared	
Lisa Recchia	Italy	Member	No interest declared	
Oscar Cruciani	Italy	Alternate	No interest declared	
Kristīne Edolfa-Kalnina	Latvia	Member	No interest declared	
Maura Olechnovič	Lithuania	Alternate	No interest declared	
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting	
Sébastien Scaini	Luxembourg	Alternate	No interest declared	
Hanneke Mulder	Netherlands	Member	No interest declared	
Erik Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Magdalena Rychter	Poland	Member	No restrictions applicable to this meeting	
Martyna Jakubowska	Poland	Alternate	No interest declared	
Helena Ponte	Portugal	Member	No restrictions applicable to this meeting	
Susana Penedo Alves	Portugal	Member	No interest declared	
Alina Iordache	Romania	Member	No interest declared	
Simona Paľovčíková	Slovakia	Member	No restrictions applicable to this meeting	
Erik Mokroš	Slovakia	Alternate	No interest declared	
Saša Martinc	Slovenia	Member	No interest declared	
Barbara Razinger	Slovenia	Alternate	No interest declared	
María Esplugues Argente	Spain	Member	No restrictions applicable to this meeting	
Marta Casalengua	Spain	Alternate	No interest declared	
Andreas Sundgren	Sweden	Member	No interest declared	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	Austria	Expert	No interest declared	
Lucia Rychvalská	Czechia	Expert	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Nuno Simões	Portugal	Expert	No interest declared	
João Simões	Portugal	Expert	No interest declared	
Isabelle Barabas	Romania	Expert	No interest declared	
Melita Tovornik	Slovenia	Expert	No interest declared	
Laura Marrero Ortiz	Spain	Expert	No interest declared	
Maria Criado	Spain	Expert	No interest declared	
Patricia Rodríguez Molla	Spain	Expert	No restrictions applicable to this meeting	
Camilla Ledin	Sweden	Expert	No interest declared	
Fayeza Suleiman	Sweden	Expert	No restrictions applicable to this meeting	
Representatives from the European Commission and EDQM attended the meeting. Observers from pre-accession countries attended a non-sensitive portion of the meeting. Meeting run with the help of EMA staff.				