4 May 2026
EMA/77606/2026
Regulatory Science and Innovation Task Force

Meeting Summary - Medicine Shortages SPOC Working Party

16 March 2026, F2F + TEAMS
17 March 2026, F2F + TEAMS

Disclaimer

Some of the information discussed during Medicine Shortages SPOC Working Party (SPOC WP) meetings are considered commercially confidential or sensitive and are therefore not disclosed. Of note, the meeting summary is a working document primarily designed for SPOC WP members and the work the SPOC WP undertakes.

Note on access to documents

Some documents mentioned in the meeting summary cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

Explanatory notes

Only shortages or availability issues that require EU level coordination are brought to the SPOC WP meetings, either by EMA or SPOC WP members. These are listed under agenda point 'Critical shortages escalated to the SPOC Working Party'. Updates on shortages or availability issues that have been previously discussed at the SPOC WP meetings and are being monitored, but do not require any specific input, are provided in writing and disseminated to SPOC WP members prior to the meeting. If required, SPOC WP members may provide comments under agenda point 'Status update on other critical shortages escalated to the SPOC WP (only comments relating to previously circulated written updates)'

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

Monday, 16 March 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. The agenda was adopted with one additional point under AOB. • Reminder to SPOC WP members to update their declarations of interests (DoIs).
2.	**Adoption of draft minutes of the SPOC WP meeting held on 17 February 2026** The Vice-Chair informed that the minutes of the meeting held on 17 February 2026 had been distributed on 10 March 2026. 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 the 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, highlighting strengthened coordination on medicine shortages with other relevant bodies at national level, planned or ongoing developments of shortage management systems, as well as work on national lists of critical medicines.
4.	**Potential impact of the international situation on the supply of medicinal products for human and veterinary use to the European market:**
	a) Feedback from the SPOC WP subgroup on crisis monitoring and preparedness • **Update on the geopolitical situation** EMA provided feedback from the most recent SPOC WP subgroup meeting, including an update on the ongoing conflict in the Middle East. It was noted that the initial analysis by EMA and information received from Member States, industry associations, certain MAHs and international regulators suggests that, while there are some isolated supply challenges, no immediate signals of concern have been identified. Discussion

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Item	**Topic**
	SPOC WP members exchanged information on the current situation in the Middle East and shared ongoing activities at national level. **Agreed actions:** • EMA, together with SPOC WP subgroup on crisis monitoring and preparedness will continue close monitoring of the ongoing geopolitical situation. • SPOC WP members to report any signals related to the conflict in the Middle East to EMA. **Availability of antibiotics: update on preparedness activities** EMA presented feedback received from SPOC WP members and MAHs confirming that the antibiotic supply situation continues to be stable across EU/EEA. A number of localised supply issues were identified; however, these are not considered critical and are being managed at national level. **Agreed action:** • In light of the stable situation, SPOC WP agreed that this topic will no longer be included as a standing item at upcoming SPOC WP meetings. It will be revisited again ahead of the 2026–2027 autumn/winter season.
5.	**Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information)** No new emerging issues were raised by SPOC WP members under this point.
6.	**Critical shortages escalated to the SPOC Working Party:**
6.1	**Ongoing shortages**
	a) Medicinal products manufactured by Pharmathen • **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA presented an overview of the current status of shortages of products manufactured at Pharmathen, with shortages continuing for a number of products, including quetiapine prolonged-release tablets, atomoxetine and lanreotide. To mitigate the situation, EMA has been assessing alternative supply options. It was noted that a number of alternative MAHs indicated they may be able to provide additional quantities of quetiapine and lanreotide, if required. Further discussions with these companies are planned, including confirmation of contact details to enable MSs to liaise with suppliers directly regarding potential additional supply.
	• **Presentation delivered by Pharmathen, followed by a Q&A session** Representatives of Pharmathen presented an overview of the inspections recently conducted as well as the quality improvement plan to address the observations and findings from the inspections. In addition, Pharmathen presented an overview of the production plan for their products such as quetiapine and atomoxetine and outlined their shortage mitigation plans, including expected timelines. Discussion

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	EMA reiterated that the shortage of quetiapine remains one of the most critical shortages currently affecting the majority of MSs, with limited therapeutic alternatives available. Pharmathen confirmed that improvements in quetiapine supply are anticipated throughout the year with short term mitigation measures currently being implemented. However, full resolution of the manufacturing issues, and consequently complete stabilisation of supply, is not expected before mid-2027. Pharmathen noted that they are prioritising quetiapine due to its critical importance for patients. **Agreed action:** • Pharmathen will continue to provide monthly updates to EMA on the supply situation of quetiapine.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members only)** SPOC WP members debriefed on next steps and actions following the presentation by Pharmathen. **Agreed actions:** • EMA to continue engagement with Pharmathen via bi-weekly meetings. • SPOC WP members to share information about critical shortages of products manufactured by Pharmathen.
	b) Medicinal products from MAH: Cheplapharm • **Feedback from the SPOC WP subgroup on Cheplapharm** EMA provided an update on the ongoing work of the SPOC WP subgroup on Cheplapharm, including the planned approach for monitoring the supply of medicines in Cheplapharm's portfolio. EMA also outlined the mitigation measures to address the ongoing critical shortages of Visudyne and Zypadhera, such as the identification of additional stocks of Visudyne by Cheplapharm. **Agreed action:** • EMA and SPOC WP to continue monitoring the supply situation of Cheplapharm medicinal products via the SPOC WP subgroup.
	d) Holoxan NAP (ifosfamide), Endoxan NAP (cyclophosphamide), MAH: Baxter • **Overview of the overall shortage situation ("Closed session" for SPOC WP members only)** EMA provided an update on the completed and ongoing mitigation activities to address these shortages, including the creation of a SPOC WP subgroup, communication activities such as the publication of shortage catalogue entries and Medicine Shortage Communications (MSCs), the identification of alternative suppliers, and ongoing support to MSs and Baxter to restore normal supply as quickly as possible. Discussion

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	SPOC WP members discussed mitigation activities, including engagement with alternative suppliers to explore the potential increase of supply to the EU/EEA markets. • **Presentation from MAH Baxter, followed by Q&A session** Baxter representatives presented a detailed overview of the root causes of the shortages, short and long-term mitigation efforts, and expected supply plan for the year. They further presented ongoing communication activities, including collaboration on the shortage catalogue entries and MSCs. Discussion SPOC WP members discussed details of the supply projection and asked for clarification regarding the timeline for the return to normalised supply. The MAH confirmed that the supply is expected to stabilise by 2027. SPOC WP members further reminded the MAH of the importance of submitting national shortage notifications in a timely manner. EMA further stressed the importance of promptly informing EMA and MSs of any significant changes to supply changes. EMA Chair inquired about long-term preventative measures to ensure timely notification of any future issues at the contract manufacturing organisation (CMO). Baxter noted that clear and regular communication pathways have been established with the contract manufacturer. • **Debrief on next steps/actions ("Closed session" for SPOC WP members only)** SPOC WP members and EMA debriefed on the session. **Agreed actions:** • Baxter to share feedback post-meeting on concerns outlined by SPOC WP members regarding supply data, sharing of information and late shortage notification. • SPOC WP subgroup to continue work with Baxter on their expected supply for the EU/EEA, improving communication and other mitigation measures. In addition, EMA to continue explore other ongoing mitigation measures such as dialogue with alternative MAHs. • MSSG recommendations to be finalised and published along with MSCs.
6.2	**Status update on other critical shortages escalated to the SPOC WP** (only comments relating to previously circulated written updates)
	a) Dynastat CAP (parecoxib), MAH: Pfizer b) Praziquantel containing medicinal products c) Medicinal products containing salbutamol (inhalation use) **Agreed action:** • EMA to continue monitoring the ongoing shortages listed above and to keep SPOC WP informed about latest developments.
7.	**Drug Shortage Global Regulatory Working Group: feedback from Q1 meeting** EMA and SPOC WP Vice-Chair provided feedback from the Q1 Drug Shortages Global Regulatory WG meeting, which amongst others discussed the adoption of the group's 2026 work plan, an overview of jurisdictions' priority areas, shortages that impact several jurisdictions and mitigation measures.

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8.	**Urban Wastewater Treatment Directive** • Presentation from DG ENV A representative from DG ENV provided an overview on the Urban Wastewater Treatment Directive (UWWTD), outlining the new Extended Producer Responsibility (EPR) mechanism which requires the removal of micropollutants from urban wastewater. The Directive requires the removal of micropollutants from urban wastewater through advanced (quaternary) treatment. To finance this, it mandates EPR schemes under which pharmaceutical and cosmetic producers, identified as the main sources of micropollutants, must cover at least 80% of the associated treatment costs. The presentation focused on a cost assessment and attribution and planned implementation timeline. • Presentation from Dutch Ministry of Health, Welfare and Sport A representative from the Dutch Ministry of Health, Welfare and Sport presented a national perspective on the implications of the UWWTD for pharmaceutical supply, highlighting several concerns specific to the healthcare sector. <u>Discussion</u> SPOC WP members raised questions on how the Directive addresses specificities of the pharmaceutical market, such as parallel trade, the cost attribution related to APIs, and the potential financial impact on healthcare systems. The EC clarified that cost attribution should be determined collectively by MAHs, drawing on experience from the solid-waste sector where similar challenges have been managed. EC further noted ongoing work on Q&A and guidance documents in collaboration with the ECDC, which will provide further clarification. **Agreed action:** • Topic to be revisited in future SPOC WP meetings, as appropriate.
9.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Feedback from the MSSG WG on the Vulnerability Assessment Methodology EMA provided an update on the progress made under the WG on the vulnerability assessment methodology, including the identification and agreement of the 19 INNs to be included in the first assessment batch, based on criteria proposed by EC and agreed by MSSG. EMA also outlined the data elements to be requested from MAHs. Lastly, EMA informed about the upcoming workshop intended to provide key information to the MAHs of the medicines in scope. The workshop is scheduled for 18 March 2026 and SPOC WP members have received an invitation. <u>Discussion</u> A SPOC WP member inquired about the possible inclusion of products belonging to the 19 INNs in the assessment which are not marketed in any of the EU/EEA markets. EMA confirmed that if a medicine is authorised but not marketed, it is important to receive certain information to inform the overall vulnerability assessment. **Agreed action:**

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	• MSSG WG on Vulnerability Assessment Methodology will continue its work on assessing the vulnerability of the supply chain of chosen INNs and update SPOC WP regularly.
	b) Union list of critical medicines EMA provided an update on the current status of the annual review of the Union list of critical medicines, which was followed by presentations from representatives from the Healthcare Professionals Working Party (HCPWP) and from the Patient and Consumers Working Party (PCWP) who presented their organisations' view on the Union list. This included reflections on the inclusion of specific medicines, suggestions to enhance involvement of healthcare professionals and patients and consumers, and proposals for process improvements, including earlier and more transparent communication on the rationale for including certain medicines. Discussion: SPOC WP members discussed the involvement of healthcare professionals in the Union list activities and also acknowledged the need for ongoing process improvements and their importance. **Agreed action:** • SPOC WP to continue discussions on the Union list of critical medicines with healthcare professional and patient organisations via the HCPWP and PCWP.

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	c) Closure of the MSSG WG on Voluntary Solidarity Mechanism (VSM) and Policy EMA informed the SPOC WP of the decision to formally close the MSSG WG on VSM and Policy as the objectives of the group have been achieved. Related activities will continue in other existing structures. EMA stressed that the MSSG will continue to have final oversight and sign-off on all activities.
10.	**SPOC WP subgroup on shortage definition — Proposal for update of root cause classification** EMA provided a brief update on the progress of the harmonisation of the root cause classification and outlined the planned next steps. It was noted that the draft proposal will be shared with industry associations for consultation followed by SPOC WP endorsement and subsequently MSSG adoption.
11.	**Impact of the parallel trade on the availability of medicines in EU/EEA** • **Presentation from Bulgaria** BG SPOC WP member presented the national perspective on parallel trade in Bulgaria outlining current trends in parallel distribution and its impact on medicine availability. Discussion SPOC WP members discussed measures to address medicine shortages linked to parallel trade. BG SPOC WP member noted that weekly, product-specific export bans had the most immediate impact in limiting excessive exports while still allowing legitimate parallel trade to continue. SPOC WP members also highlighted structural challenges, including limited regulatory tools and low penalties for exports without adequate reporting or limited transparency. A SPOC WP member emphasised the need for stronger verification in receiving Member States to ensure that exported products are exported legally. • **Presentation from Germany** DE SPOC WP member provided national perspective on parallel trade in Germany describing criteria governing parallel trade, current trends observed in parallel distribution and the resulting effects on shortages of medicines. Discussion SPOC WP members discussed the limited role of parallel trade as an effective mechanism in mitigating medicine shortages. A SPOC WP member raised concern about the impact of parallel trade in hospital markets, where low-price tenders can result in contracts being awarded to parallel traders who have no control over manufacturing volumes. The SPOC WP member noted that this dependency creates vulnerability when supply fluctuates in exporting countries. • **Presentation from Affordable Medicines Europe (AME), followed by a Q&A session** A representative from AME presented current trends in parallel trade within the EU/EEA pharmaceutical market. The speaker outlined the observed impact of parallel trade on medicine availability, emphasising that parallel imports can support supply redistribution

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	during medicine shortages, while also describing challenges such as export restrictions. AME further highlighted measures implemented by parallel distributors to support supply continuity, including monitoring national shortage catalogues, voluntary notifications of medicines shortages, and cooperation with national authorities. Discussion AME representative noted that they have insufficient visibility over many exporters in the supply chain and therefore have limited evidence to identify shortages. AME expressed support for export restrictions when they are applied in response to confirmed shortages and highlighted that well designed national frameworks can strengthen parallel import practices and overall supply resilience. • **Debrief and closing remarks** SPOC WP members discussed next steps following the exchange with AME. **Agreed action:** • Topic to be revisited in future SPOC WP meetings, as appropriate.
12.	**Joint Action on Antimicrobial Resistance and Healthcare-Associated infections (EU JAMRAI-2):** • **France – Regulation governing medicine withdrawals from the market** A representative from ANSM (National Agency for the Safety of Medicine and Health Products in France) presented the national regulatory framework governing the withdrawal of medicines from the market, which was introduced in response to the rising number of withdrawals of anti-infective medicines. A new decree imposes stricter obligations for MAHs ceasing marketing of essential medicines, including mandatory efforts to identify a new MAH, and, where no MAH is found, enabling ANSM to temporarily transfer manufacturing and marketing rights to a public pharmaceutical establishment to ensure continued supply. Discussion The ANSM representative clarified that the new withdrawal procedure was introduced in 2025. Additionally, the ANSM representative explained that when no successor MAH is identified, a public pharmaceutical establishment may be designated by the regulation to temporarily manufacture and market the product under the same licence number, although this may not always be feasible due to capacity constraints.
13.	**Joint Action on Shortages (CHESSMEN) update** **Work Package 1 - Coordination, management and evaluation** The WP 1 representative provided an update on the confirmed JA CHESSMEN project extension until January 2027, citing ongoing work on harmonisation, documentation development, and study visits as key reasons for the extension. **Work Package 2 - Communication, dissemination and exploitation** The WP 2 representative described ongoing communication activities, which included study visits, the development of the 2025 wrap-up document and future workshops and events. Among events mentioned were the CHESSMEN month in June 2026, a CHESSMEN dialogue

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	event planned for June 2026 in Lisbon to discuss deliverables with stakeholders and to gather feedback and discuss improvements, and the final CHESSMEN Conference planned for November 2026. **Work Package 4 – Sustainability** The WP4 representative informed the SPOC WP about the revision of the sustainability report to be delivered at the end of the JA, which will reflect strategies to ensure the JA policies and good practices are adopted, also taking into account the new pharmaceutical legislation which will come into force soon. **Work Package 5 – Root causes of observed shortages of medicines** The WP 5 representative detailed the addition of a new deliverable (D5.4) focusing on activities to support harmonising the classification of root causes for medicine shortages, including the recommendation to implement the new root cause classification system co-developed with the SPOC WP and EMA. Finalisation of D5.4 report is planned by November 2026. **Work Package 6 – Best practices to address medicine shortages** The WP 6 representative outlined two new tasks, firstly the mapping of pharmacists' competencies during shortages and secondly, the adaptation of a time series demand forecasting model for regular shortages including model validation and data governance considerations. Related to the first task, the WP 6 representative explained that a survey will be shared with SPOC WP members to identify pharmacists' competencies in their jurisdictions. **Agreed action**: • SPOC WP secretariat to support dissemination of survey on the pharmacists' competencies mapping. **Work Package 7 - Digital Information Exchange for Monitoring and reporting medicine shortages** The WP 7 representative reported the finalisation of the video demonstrator which summarises the results and conclusions of the work package and incorporates the feedback received. The video demonstrator will be publicly available after adoption. In addition, supporting reports have also been developed to improve understanding of the activities. **Work Package 8 – Shortages preventive and mitigation strategies** The WP 8 representative announced the approval of several deliverables, including shortage prevention and mitigation plan, and an implementation plan for the activities. The representative also outlined plans for a survey to assess the status of these measures and the preparation of a position paper for further implementation.
14.	**EDQM: Update on the EDQM Initiative on Shortages** An EDQM representative provided an update on EDQM's activities related to shortages, including fast-track certification procedures for active substances affected by shortages, development of a compounding methodological guide, and recent and upcoming developments in the European Drug Shortage Formulary (EDSForm) project, among others. Discussion

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Item	**Topic**
	EDQM representative clarified that fast-track procedures can be initiated by national competent authorities or MAHs.
15.	**Shortage management systems**:
	a) Croatia – Shortage monitoring tool HR SPOC WP member presented a new shortage monitoring tool developed with EU funding as part of Croatia's Recovery and Resilience Plan investment. <u>Discussion</u> SPOC WP discussed the various features of the Croatian shortage management system. HR SPOC WP member clarified that notification obligations apply equally to CAPs, NAPs and parallel-imported products. Wholesalers involved in parallel trade must also report any supply interruptions and notify when supply is re-established. It was further noted that the tool covers all prescription-only medicines authorised in Croatia. HR SPOC WP member also noted the intention to ensure interoperability between their tool and the ESMP, and highlighted that, as the tool has only recently been launched, practical experience with its operation is still being gathered.
	b) Finland – PowerBI tool for availability and preparedness FI SPOC WP member presented a new PowerBI tool for availability and preparedness. The database consolidates sales data, stock levels at warehouses, hospitals, and pharmacies, as well as shortage notifications. <u>Discussion</u> SPOC WP discussed the various features of the Finnish shortage management system. FI SPOC WP member explained that stock-reporting obligations were introduced during the COVID-19 period and continue to apply, supported by provisions in national pharmaceutical legislation. Early experience shows that the tool helps prioritise the most critical cases and reduce manual workload, providing earlier visibility of emerging risks even when MAH notifications are delayed.
	c) European Shortages Monitoring Platform (ESMP) update EMA updated the group on upcoming new functionalities in the ESMP platform, including the VSM submission process, critical shortage reporting, and the launch of a data analytics platform for CAP shortage reports accessible to MSs. A short demonstration on the VSM submission process and the CAP shortage report feature was provided. <u>Discussion</u> EMA clarified several aspects of the data analytics platform including access rights and filter criteria. EMA also noted that shortage notifications are submitted in the system by MAHs and that impact assessments on the shortage criticality are also self-reported by MAHs. Finally, EMA noted that information outlined via the CAP shortage report platform will help MSs to identify discrepancies between what was submitted in ESMP and what has been reported nationally by MAHs.
16.	**AOB**

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Item	**Topic**
	SPOC WP Secretariat shared a kind reminder with SPOC WP members to update DOIs in case not yet done.
17.	**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.
18.	**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 June 2026 at EMA premises in Amsterdam.

Next meeting: 15 April 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 March 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	
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	
Jakub Velik	Czechia	Member	No interest declared	
Michaela Kosová	Czechia	Alternate	No interest declared	
Stine Buchholdt	Denmark	Alternate	No interest declared	
Anita Tuula	Estonia	Alternate	No restrictions applicable to this meeting	
Marie-Laure Veyries	France	Alternate	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	
Inke Reimer	Germany	Member	No interest declared	
Linda Holtkamp	Germany	Alternate	No interest declared	
Roger Pally	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	
Margrét Lilja Heiðarsdóttir	Iceland	Member	No interest declared	
Ellen McGrath	Ireland	Member	No interest declared	
Lisa Recchia	Italy	Member	No interest declared	
Linas Mažeika	Lithuania	Member	No interest declared	
Maura Olechnovič	Lithuania	Alternate	No interest declared	
Sébastien Scaini	Luxembourg	Alternate	No interest declared	
Caroline Muscat	Malta	Member	No interest declared	
Jessica Zarb	Malta	Alternate	No interest declared	
Hanneke Mulder	Netherlands	Member	No interest declared	

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Erik Hergarden	Netherlands	Alternate	No interest declared	
Guri Wilhelmsen	Norway	Member	No interest declared	
Rebwar Saleh	Norway	Alternate	No interest declared	
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	
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	
Karl Högström	Sweden	Alternate	No interest declared	
Anna Gerhartl	Austria	Expert	No restrictions applicable to this meeting	
Rita Rom	Austria	Expert	No interest declared	
Verena Hofer	Austria	Expert	No interest declared	
Maud Donckers	Belgium	Expert	No restrictions applicable to this meeting	
Carla Maione	Italy	Expert	No interest declared	
Frank Blommaert	Netherlands	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	
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.				