13 May 2025
European Medicines Agency

Summary of the Medicine Shortages (SPOC) Working Party meeting

10-11 April 2025, hybrid (Face-to-face and Webex)

Chair: Monica Dias (EMA), Magdalena Rychter (GIF, Poland)

Item	Topic
1.	**Welcome, declarations of interest, adoption of draft agenda** The Chair and Vice-Chair welcomed participants to the face-to-face (F2F) meeting of the Medicine Shortages SPOC Working Party at 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 18 March 2025** The Vice-Chair informed the working party that the minutes of the meeting held on 18 March 2025 had been distributed one week prior to the meeting. No comments were received before or during the meeting. The minutes were adopted.
3.	**Member States updates**
	a) SPOC WP lightning round – most critical issues at national level SPOC WP members exchanged information on most critical issues at national level linked to medicines supply and availability and measures taken to address these.
	b) Polish presidency of the EU: initiatives on medicine shortages for H1 2025 SPOC WP Vice-Chair presented a summary of the work undertaken and planned by Poland in the area of security of supply under the Polish Presidency of the Council of the European Union (EU), highlighting the progress made on the revision of the pharmaceutical legislation, the Critical Medicines Alliance and activities linked to the HERA Board. The Vice-Chair further noted activities related to broader public health priorities such as digital transformation, health promotion and disease prevention.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

Item	Topic
	c) 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 legal frameworks on shortages, contingency stockpiling projects, ongoing work on national lists of critical medicines, IT-related projects (e.g. updates to national shortages' websites, prescription systems) and activities to support medicine substitutions on pharmacy level for critical shortages. Ways to improve controlled distribution from wholesalers to pharmacies for the prescriptions of specific medicines were also activities mentioned. A few SPOC WP members shared details on implemented contingency stockpiling requirements for essential medicines. A SPOC WP member also noted that a serious shortage protocol pilot (SSP), which enables pharmacists to change the prescribed medicine to an alternative in case of a serious shortage, will be facilitated by 2026. **Agreed action:** • SPOC WP to consider further discussing the best practices for public communication on treatment alternatives.
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 EMA and a SPOC WP member provided an update from the first two meetings of the subgroup, which included presentations from two SPOC WP members regarding crisis monitoring and preparedness activities in their territories.
	b) Oral status update on the availability of human and veterinary medicines in MSs (only for new emerging information) A SPOC WP member provided an update on the shortage of quetiapine which is linked to manufacturing issues. One SPOC WP member noted a shortage of lithium carbonate. Many SPOC WP members noted the availability of alternatives on their markets and shortages of lithium carbonate not being critical. Additionally, a SPOC WP member informed about shortage of an antiviral medicinal product for the treatment of HIV infections due to supply issues of raw materials and increased demand. A few SPOC WP members confirmed supply issues, but alternative MAHs are currently able to mitigate the issue.
5.	**Critical shortages escalated to the SPOC Working Party:**
5.1	**Ongoing shortages**
	a) Oncology medicinal products from MAH Teva EMA presented the latest information about the supply situation of several oncology products manufactured by Teva and mitigation measures suggested by the company. In addition, EMA updated on activities conducted to mitigate the impact of the shortage of fludarabine such as contacting alternative MAHs.
	b) Medicinal products from MAH Cheplapharm

Item	Topic
	• **Overview of the overall shortage situation ("Closed session" for SPOC WP members)** EMA provided an update on the planned allocation and regulatory procedures for Visudyne. EMA also provided an update on the actions taken to manage the ongoing critical shortage of Zypadhera, including meetings of the SPOC WP subgroup, meetings with the company and outreach to international regulators.
	• **Presentation delivered by MAH: Cheplapharm, with respect to Zypadhera followed by a Q&A session** The MAH presented the supply plan and short- and long-term mitigation actions for Zypadhera drug product and finished goods manufacturers and noted that by Q3 2025 the situation should stabilise. Finally, the company informed SPOC WP about their efforts to improve the shortage notification process. <u>Comments raised</u> EMA and SPOC WP stressed the need for equitable and fair allocation across the globe. Additionally, SPOC WP members noted critical shortages in their territories and highlighted the need to improve the shortage notification process, transparency and communication between MAH HQ and local affiliates with the NCAs. **Agreed actions:** • MAH to identify additional mitigation measures, including allocation of available stocks from other jurisdictions and re-allocation of stocks to EU/EEA in an equitable and fair manner across the globe. • MAH to improve communication with NCAs.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members).** SPOC WP discussed next steps following the presentation of Cheplapharm.
	c) Medicinal products from MAH Viatris EMA provided an overview of medicinal products manufactured by Viatris and affected by shortages, including a list of MSs affected and the resolution timelines for each product. **Agreed actions:** • EMA to follow up via email to obtain information from the SPOC WP on the criticality of shortages of medicinal products from MAH Viatris.
4.2	**Status update on other critical shortages escalated to the SPOC WP (only comments to the written updates)** a) Pegasys CAP (peginterferon alfa-2a) – MAH: Pharmaand GmbH b) NovoSeven CAP (eptacog alfa) – MAH: Novo Nordisk c) Ecalta CAP (anidulafungin) and Zirabev CAP (bevacizumab) – MAH: Pfizer d) Medicinal products containing salbutamol (inhalation use)

Item	Topic
	SPOC WP members discussed the timelines for ongoing regulatory procedures related to Pegasys and product allocation. SPOC WP members exchanged information on the current supply situation of salbutamol, with the majority of the members confirming that while there are shortages the situation is not critical. A few SPOC WP members noted shortages of salbutamol combination products and EMA will follow up to understand the criticality.
6.	**Shortage Prevention and Mitigation Plans (SPP/SMP) pilot: initial findings** EMA and one SPOC WP member presented an update on the SPP/SMP pilot, MAHs involved, submissions received and initial findings of the first set of SPP/SMPs assessed, highlighting different levels of details and quality in the information provided. Lastly, an example of the SPPs received was presented. As not enough SMPs have been received, SMPs will be proactively requested by the participant Competent Authorities until mid-May 2025.
7.	**Revision of EMA policy 0044 on handling of competing interests** EMA presented the revision of policy 0044 (policy on the handling of competing interests of scientific committee members and experts), which will enter into force on 1 May 2025. Changes impacting the SPOC WP were presented, including a unified cooling off period, restrictions on medical device interests, and new rules for research organisations. It was highlighted that the policy revisions require experts to update DOI by 1 May, with the new form available since 27 March; failure to update the DOI will prevent participation in EMA activities until updated.
8.	**EDQM: Progress of the European Drug Shortages Formulary and other EDQM initiatives on shortages** EDQM representative presented the progress of the European Drug Shortages Formulary and other EDQM initiatives on shortages, including the accelerated certification procedure for alternative production of active substances subject to shortage, ad-hoc testing support and advice to EMA for evaluation of authorised finished products, as well as other actions related to pharmaceutical compounding. EDQM also highlighted technical recommendations of the EDSForm WP on particular INNs.
9.	**EC DG SANTE update** EC DG SANTE provided an update on the Critical Medicines Act (CMA) and the link and potential impact on the SPOC WP and the MSSG in regard to scientific and regulatory support. Comments raised A SPOC WP member asked about the role of the designated authority. DG SANTE informed that MSs will be asked to nominate a designated authority to the EC, with their role to confirm whether projects fulfil the "Strategic Project" characteristics.
10.	**EC DG HERA update** EC DG HERA presented an update on the development of ATHINA (Advanced Technology for Health INtelligence and Action IT system), including its function, highlighting the survey module to gather information, state of play and interoperability with relevant stakeholders, including the ESMP. Comments raised

Item	Topic
	SPOC WP Chair asked what information can be gathered through the survey. DG HERA noted that data collected can be adapted to the purpose of the survey and can be further enriched with additional data via a reporting module. **Agreed actions:** • DG HERA to present ATHINA survey module at a future SPOC WP meeting.
11.	**Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)-led activities:**
	a) Draft procedure for the update of the Union list of critical medicines EMA informed about the plan for the review procedure for updating the Union list of critical medicines, outlining the governance and objectives of the revision, as well as the timelines and the process. As the next steps, a proposal will be shared with the SPOC WP for review and consultation, followed by endorsement by the MSSG.
	b) Medicine Shortage Communication (MSC) pilot update EMA provided an update on the pilot, outlining the background, objective, duration and highlighted the 2-month extension until end of May 2025. EMA further presented early findings of the pilot such as benefits of the implementation of MSC at national level and the pilot recommendations. Comments raised SPOC WP members discussed national experiences with recent MSCs both in terms of review responsibilities within the NCAs and dissemination decisions, and prior national communication on the respective shortages. The importance of providing the MSC in timely manners was highlighted by the SPOC WP. **Agreed action:** • SPOC WP members to share their experiences during the MSC review on the distribution and implementation at the national level.
	c) Feedback from the MSSG meeting on 1 April 2025 SPOC WP Vice-Chair provided the feedback on the topics discussed during the MSSG meeting on 1 April 2025, highlighting the Co-Chair election and results, discussions on the Critical Medicines Act and its potential impact on the MSSG, the MSSG support on the recommendations to address the vulnerabilities in the supply chain of radiopharmaceuticals, and the presentation of the EMA Health Threats Plan.
	d) Feedback from the MSSG WG on the Vulnerability Assessment Methodology EMA provided feedback from the first meeting of the Working Group (WG) held on 3 April 2025, which covered the agreement on the mandate, presentations on the legislative basis for the vulnerability assessment and work previously caried out by the EC, by Member States and under the Critical Medicines Alliance. EMA noted that the discussion focused on organisation of the group, need for consultation of specific experts, and frequency of technical meetings.
12.	**Shortage management systems**:
	a) Germany – presentation of national system

Item	Topic
	DE SPOC WP member presented their national shortage monitoring system, process of shortage reporting, evaluation and management, as well as the Advisory Council for Delivery and Supply Shortages. Limitations of the current system and an outlook of future activities including an early warning system composed of different data sources were also presented. Comments raised SPOC WP Chair asked for further information on the early warning system and its focus on paediatric formulations. DE SPOC WP member explained that wholesalers voluntarily provide information for a list of APIs, which includes critical substances for paediatric care. One SPOC WP member asked for clarification on recommendations developed by the Advisory Council, to which DE SPOC WP member explained that recommendations are provided in situations of urgent shortages.
	b) Belgium – new features in PharmaStatus on unavailability identified by FAMHP BE SPOC WP member presented an update on their national shortage management system PharmaStatus and its latest functionalities. Specifically, BE SPOC WP member explained that now, pharmacists and wholesaler-distributors can contact MAHs directly via the system if a shortage, or a prolongation of a shortage is suspected but not yet reported in the system. These signals allow FAMHP to identify shortages and ensure transparent communication and accurate information on medicines availability. Comments raised SPOC WP members discussed possibilities to link shortage notifications to data on prescriptions, MAH response rates to these supply queries, PharmaStatus' potential ability to identify regional distribution issues at pharmacy level, and applicability of the system for both human and veterinary medicines.
	c) European Shortages Monitoring Platform (ESMP) update EMA provided an update on the launch of the ESMP and current efforts to facilitate interoperability with national and industry IT systems, including activities on the application programming interface (API). EMA provided insights from the survey to assess whether MAHs have started using ESMP to report shortages of CAPs to EMA, to gather insights on awareness, ease of use, challenges, and areas for improvement. EMA also flagged some changes in communication processes between EMA and NCAs via ESMP. Lastly, EMA pointed out that they are looking into a solution to make the information on shortages reported via the ESMP available to all SPOC WP members. Comments raised A SPOC WP member asked about MAH compliance in reporting shortages through ESMP and any discrepancies in information received on EU level compared to national level. EMA responded that so far they are not aware of any discrepancies or other issues. SPOC WP members requested a short document that can be used to communicate to MAHs in their countries regarding all ESMP requirements in a summarised and simple manner. EMA responded such a document is being worked on already and will be shared with the SPOC WP as soon as possible. **Agreed actions:**

Item	Topic
	• EMA to share ESMP requirements summary with SPOC WP members for their use in their communication materials to MAHs.
13.	**Technical topics**
	a) **Shortage definition: SPOC WP subgroup proposal for harmonisation** A SPOC WP member and EMA presented the subgroup's proposals for a harmonised application of the definition of a shortage. The subgroup analysed various elements linked to the shortage definition and presented proposals for their harmonised application (e.g., timeframe, thresholds, point in the supply chain where the definition applies). Comments raised SPOC WP agreed with the harmonisation proposals and congratulated the subgroup on the efforts regarding the harmonisation of the shortage definition in the EU/EEA. The group discussed a potential expansion of the subgroup's work towards harmonisation of definitions of an actual and potential shortage as well as a harmonised approach to shortage case management across the EU/EEA, which could include the impact assessment of shortages. **Agreed actions:** • Subgroup to continue the work and further expand to cover aspects linked to harmonised shortage management. • JA CHESSMEN WP 6 Lead to present their work on shortage impact assessment harmonisation at a future SPOC WP meeting and contribute to the activities of the SPOC WP subgroup on the shortage definition.
14.	**a) Global Regulators Working Group on Drug Shortages: update from Q1 meeting** EMA and PL SPOC WP member provided feedback from the meeting held on 19 March 2025. Information on the shortages of concerns discussed in the meeting were presented together with an overview on the Stable Supply of Drugs and Structural Reform in the Generic Drug Industry in Japan, and information on priority topics of the Drug Shortages Global Regulatory Working Group for 2025. Comments raised A SPOC WP member asked for activities in other jurisdictions regarding specific shortage cases and EMA replied noting that dedicated bilateral meetings with international regulators are taking place to understand mitigation plans and background. SPOC WP Chair noted that information gained from other jurisdictions could be used as an early warning system.
15.	**Critical shortages escalated to the SPOC Working Party: ongoing shortages (continued)**
	a) Shortage and discontinuation of selected insulin containing medicinal products EMA provided an overview of the ongoing risk assessment of the marketing cessation of selected insulins from Novo Nordisk and the ongoing discussions with MAHs of alternative medicinal products on their manufacturing capacity and marketing plans for insulin products. Additionally, EMA provided the feedback from the clinical expert group meeting on insulins and GLP-1 RAs that took place on 2 April 2025 and explained that the discussion was focused on the

Item	Topic
	methodology to understand the need to increase supply of alternative products. As one of the next steps, a survey was designed and will be sent to EMA's Healthcare Professionals Working Party (HCPWP) in due course.
	b) Supply and availability of immunoglobulins
	• **Overview of the supply and availability situation ("Closed session" for SPOC WP members and NCAs experts)** EMA provided an update on the draft MSSG recommendations to address anti-D immunoglobulin supply chain vulnerabilities.
	• **Presentation delivered by International Plasma and Fractionation Association (IPFA) and Plasma Protein Therapeutics Association (PPTA)** IPFA and PPTA representatives presented the immunoglobulin supply chain from blood donation to plasma derived medicinal products, highlighting specificities across the supply chain for plasma-derived medicinal products (PDMPs), and challenges for feasibility and supply of anti-D immunoglobulins.
	• **Debrief on next steps/actions ("Closed session" for SPOC WP members and NCAs experts)** The SPOC WP discussed the identified dependencies with focus on anti-D immunoglobulins. EMA further provided feedback on supply chain of immunoglobulins from the EDQM Stakeholder Event on Plasma Supply Continuity in March 2024, and the 13th International Plasma Product Biotechnology Meeting in April 2025. Lastly, EMA noted that the recommendations of the MSSG to address anti-D immunoglobulin supply chain vulnerabilities are being drafted by the SPOC WP subgroup on immunoglobulins and in close cooperation with the EC, EDQM and other experts. Comments raised A SPOC WP member noted the value of the MSSG recommendations due to the criticality of the product and thanked EMA for their work.
16.	**Technical topics (continued)**
	b) Communication on shortages: presentation of EMA strategy EMA gave an overview of communication activities carried out in 2024 and highlighted communication objectives and planned activities for 2025, which include a webinar for patients and HCPs, social media campaigns and a factsheet on EU shortages. Comments raised One SPOC WP member inquired about any interest received from patient associations for the webinar, to which EMA noted general support from EMA's Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties and indication of interest in such an event. SPOC WP members discussed national shortages communication activities such as annual reports or newsletters. The group further inquired about information that will be published in the EMA factsheet and the frequency of publication. EMA noted that it will focus on the number of shortages reported to EMA by MAHs and NCAs and will show the numerical representation of

Item	Topic
	shortages discussed in the SPOC WP and MSSG meetings. In terms of frequency, the fact sheet will likely be published on an annual basis.
17.	**Exchanges on national practices:**
	b) Pilot project on English-only common Nordic packages for human medicinal products NO representative presented a pilot project to test the usability of English packages in the Nordic countries, with an aim to ensure the security of supply of essential hospital products. NO representative noted that the pilot project is running from 1 January 2025 for an estimated five-year period for a selected number of medicines, and that MAHs will be able to request additional active substances to be included into the pilot. Comments raised It was discussed that there are specific requirements that need to be fulfilled in order for the products to be included in the pilot. However, English labelled packs can still be used in a shortage situation even if this is outside of the pilot project. SPOC WP members discussed packaging specificities such as package design, sources of packages for CAPs and NAPs as well as the guidance on existing language and package exemptions obligations. **Agreed actions:** • SPOC WP to be provided with list of products exempted from labelling and language and package leaflet obligations. *Post-meeting note: the list of products are available here (old format up to February 2020) and here (new format October 2018 – March 2025).* • Labelling and language and package leaflet obligations to be discussed at a future SPOC WP meeting.
	c) Case study: management of shortages of old, life-saving medicines with limited alternatives A SPOC WP member presented the mitigation strategy for the shortage of an old, inexpensive medicine, where the MS oversaw a centralised import with supplies then distributed to the regional authorities in cooperation with pharmacies and wholesalers. The SPOC WP member emphasised the national network and intensive dialogue with all stakeholders as critical factors and noted the need to formalise these 'good practice' cases as these types of shortages are a recurring issue. The SPOC WP member finally noted that work to develop forecasting models is currently ongoing at national level. Comments raised SPOC WP members discussed the structural problem surrounding older, inexpensive medicines with high usage rates and no alternatives, making them especially vulnerable during shortage. The group noted that this vulnerability is further heightened when the marketing authorisation (MA) is transferred from larger pharmaceutical companies to smaller ones.

Item	Topic
	EMA asked whether incentives are provided to MAHs via drug price revisions. The SPOC WP member noted that this is an important way to ensure that life-saving medicines remain available. SPOC WP Chair asked for additional information on the forecasting model, to which the SPOC WP member replied that this is meant to be used as an early warning system for critical shortages and goes beyond identifying supply chain vulnerabilities and historical shortages.
18.	**Joint Action on Shortages (CHESSMEN): Work Package (WP) 5 – root cause analysis** ES SPOC WP member updated the group on the root cause analysis activities undertaken by WP 5 and presented the industry's feedback on the driving factors for root causes. It was noted that some of the driving factors include supply quotas imposed by MAHs, change in reimbursement or parallel trade. ES SPOC WP member presented the final recommendations which include the implementation of a common template to register root causes of shortages and that the SPOC WP could consider expanding the previously established root cause classification. Comments raised The SPOC WP welcomed the proposal to continue the work at SPOC WP level. The SPOC WP discussed the survey results from industry and the need for further clarification regarding their answers. **Agreed actions:** • SPOC WP to continue the work on the root cause classification under the subgroup on the definition of a shortage.
19.	**AOB** No points raised under AOB.
20.	**Wrap-up and next steps** The agreed actions are detailed above.
21.	**Closing remarks** The Chair thanked the SPOC WP for their active participation at the F2F meeting and informed that the next F2F meeting will take place in the second half of 2025 at EMA premises in Amsterdam.

Next meeting: 13 May 2025 (Teams)

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).

List of participants

List of participants including any restrictions with respect to involvement of members/experts following evaluation of declared interests for the 10-11 April meeting, which was held in hybrid mode (in EMA Office and via Webex).

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
Monica Dias	EMA	Chair	No interest declared
Magdalena Rychter	Poland	Vice-Chair	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
Mateja Mervić	Croatia	Member	No restrictions applicable to this meeting
Stela Lilek	Croatia	Alternate	No interest declared
Vasileios Loutas	Cyprus	Alternate	No interest declared
Jakub Velík	Czechia	Member	No interest declared
Michaela Kosová	Czechia	Alternate	No interest declared
Mathilde Moe Møldrup	Denmark	Member	No interest declared
Anita Tuula	Estonia	Alternate	No interest declared
Julia Lehtinen	Finland	Member	No interest declared
Camille Ramahefarivony	France	Member	No interest declared
Flore Demay	France	Member	No interest declared
Laurent Fabry	France	Alternate	No interest declared
Thomas Brouwers	Germany	Member	No restrictions applicable to this meeting
Gabriele Eibenstein	Germany	Member	No interest declared
Andrea Stippler	Germany	Alternate	No interest declared
Inke Reimer	Germany	Member	No interest declared
Roger Pally	Germany	Alternate	No interest declared
Theoni Kousteni	Greece	Member	No interest declared
Veronika Horváth	Hungary	Member	No interest declared
Gyöngyi Petró	Hungary	Alternate	No interest declared
Margret Heidarsdottir	Iceland	Member	No interest declared
Hafdís Birna Baldursdóttir	Iceland	Alternate	No interest declared
Ellen McGrath	Ireland	Member	No interest declared
Mary Kinane	Ireland	Alternate	No interest declared
Oscar Cruciani	Italy	Alternate	No interest declared
Kristīne Edolfa-Kalniņa	Latvia	Member	No interest declared
Linas Mažeika	Lithuania	Member	No interest declared
Maura Olechnovic	Lithuania	Alternate	No interest declared
Maxime Salade	Luxembourg	Member	No restrictions applicable to this meeting
Jessica Zarb	Malta	Alternate	No interest declared
Eric Hergarden	Netherlands	Alternate	No interest declared
Guri Wilhelmsen	Norway	Member	No interest declared
Andreas Sundgren	Norway	Alternate	No interest declared
Helena Ponte	Portugal	Member	No interest declared
Susana Penedo Alves	Portugal	Member	No interest declared
Viviana Anghel	Romania	Alternate	No interest declared
Alina Iordache	Romania	Member	No interest declared
Jaroslav Kollárik	Slovakia	Member	No restrictions applicable to this meeting
Simona Palovcikova	Slovakia	Alternate	No restrictions applicable to this meeting
Saša Martinc	Slovenia	Member	No interest declared
María Esplugues Argente	Spain	Member	No restrictions applicable to this meeting
Patricia Rodríguez	Spain	Alternate	No restrictions applicable to this meeting

Name	Member State or affiliation	Role	Outcome restriction following evaluation of e-DoI
Samuel Silkestrand	Sweden	Member	No interest declared
Karl Högström	Sweden	Alternate	No interest declared
Olga Rögelsperger	Austria	Expert	No restrictions applicable to this meeting
Rita Rom	Austria	Expert	No interest declared
Maria Paile-Hyvärinen	Finland	Expert	No interest declared
Pia Pihlavisto	Finland	Expert	No restrictions applicable to this meeting
Outi Mäki-Ikola	Finland	Expert	No interest declared
Stephanie Tuinenburg-Hoogerwerf	Netherlands	Expert	No interest declared
Frank Blommaert	Netherlands	Expert	No interest declared
Willem Woldring	Netherlands	Expert	No interest declared
Nina Malvik	Norway	Expert	No interest declared
João Simões	Portugal	Expert	No interest declared
Nuno Simões	Portugal	Expert	No interest declared
Isabelle Barabas	Romania	Expert	No interest declared
Maria Criado	Spain	Expert	No interest declared
Laura Marrero Ortiz	Spain	Expert	No interest declared
Camilla Ledin	Sweden	Expert	No interest declared
Representatives from the European Commission and EDQM attended the meeting.			
Meeting run with the help of EMA staff.			