20 December 2024
EMA/MB/449773/2024 - Adopted
Management Board

Minutes of the 125th meeting of the Management Board

Held virtually on 03 October 2024

The Chair of the Management Board opened the meeting, which was held as a virtual meeting. The Chair confirmed the quorum and welcomed the new member for France, Mr Alexander de la Volpiliere (Acting Director of National Agency for the Safety Of Medicine and Health Products, ANSM), new member for Lithuania, Ms Dovile Marcinke, (Director of State Medicines Control Agency of Lithuania), new alternate member for Slovenia, Ms Sabina Zalar (Head of Sector at Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) and a new member as the representative of veterinarians' organisations, Mr Christophe Buhot.

The Chair informed the Board that during the December meeting, the 2025 Programming Document would be presented, and that she had initiated engagement with the previous year's topic coordinators to confirm their participation. The Chair invited members that would like to join as a topic coordinator for this year to make contact following the meeting. *Post meeting note: Rui Santos Ivo and Franck Foures confirmed after the meeting their engagement as new MB Topic Coordinators together with the previous Topic Coordinators Eija Pelkonen and Grzegorz Cessak for the 2025 Programming Document.*

The Chair noted that the election of the new MB Vice-Chair would take place in the morning. A call for nominations had been launched in early September [redacted] The Chair reminded the Board that, according to the Rules of Procedure, applications for Vice-Chair could be submitted in writing to the EMA secretariat "no later than the start of the Management Board meeting at which the election is to take place", namely until 09:00 on the day of the Board meeting.

1. Draft agenda for the 03 October 2024 meeting

[EMA/MB/377084/2024] The agenda was adopted with no amendments.

2. Declaration of competing interests related to the agenda

The Secretariat informed members of the Management Board that it had reviewed members' declared interests in accordance with the Board's policy on the handling of competing interests. Some potential competing interests relating to the agenda were identified concerning topics *B.4 'Update on European Medicines Agencies Network Strategy (EMANS) to 2028,'* and *B.5 'EMA independence policies: Revision of EMA's policy on the handling of declarations of interests of scientific committees' members and*

experts (Policy 0044).' The Secretariat informed the board that all concerned members had been informed before the meeting.

Members were asked to declare any specific interests that could not be drawn from their current declaration of interests that could be considered to be prejudicial to their independence with respect to the items on the agenda. No conflicts of interest were declared.

3. Minutes from the 124th meeting, held on 11-12 June 2024

[EMA/MB/312765/2024] The Management Board noted the final minutes, that had been adopted by written procedure on 12 September 2024.

4. Election of the Vice-Chair of the Management Board

The election of the Vice-Chair was held *in camera* and was attended only by members or their alternates, the observers from the EEA countries and a limited number of EMA staff.

[redacted]

The Board appointed the observers from Iceland and Norway, Runa Hauksdottir Hvannberg, and Audun Hågå, to act as tellers. The vote took place by secret electronic ballot.

The Board requires 24 votes in favour to reach a decision. [redacted]

Total no. votes	Votes cast	Not present	No response	Rui Santos Ivo	Abstained
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The Management Board elected Rui Santos Ivo, representing Portugal, as its Vice-Chair for the next three years. The newly elected Vice-Chair thanked the Management Board.

A. Points for automatic adoption/endorsement

A.1 Revision of 2024 audit plan

[EMA/432239/2024], [EMA/MB/312765/2024] The Management Board adopted the revision of the 2024 audit plan.
The EMA internal audit function proposed to postpone the internal audit on 'Review of variations for

human medicines' until 2025, in light of the planned transition of the variations procedures to IRIS and considering the available internal audit resources. Therefore, the audit plan 2024 adopted in December 2023 with the aforementioned amendment was adopted

B. Points for discussion

B.1 Highlights of the Executive Director

The Board noted an oral update on ongoing efforts to address the strained network resourcing situation in the centralised procedure, with cases escalating to the EMA-HMA Strategic Resource Oversight Group. EMA will communicate these ongoing concerns to the Heads of Medicines Agencies (HMA) and emphasise the need for urgent and longstanding solutions. Members were reminded of the Multistakeholder Workshop on Submission Predictability held at the end of September, which aimed to highlight the negative impact of poor submission predictability on the network. The key message to industry was the necessity for improved and timely communication between applicants and EMA/Rapporteurs during the pre-submission phase. Several Board members expressed concern about the persisting resourcing issues and emphasised the importance of exploring all potential solutions within the network, including the establishment of Centres of Excellence, as well as addressing dossier maturity concerns. A Board member enquired about preparedness for HTA regulation and potential resource implications and was informed that an update on the implementation of the HTA regulation would be provided at the December Management Board meeting.

The Board was also updated on the Agency's latest activities to address medicine shortages, including preparations for the European Shortages Monitoring Platform to be launched in February 2025, continued success with the MSSG solidarity mechanism procedures, and recent achievements by the Critical Medicines Alliance (CMA). It was noted that the second version of the Union List of Critical Medicines (ULCM) is being prepared for adoption in early December.

Regarding the mpox public health crisis, the Board was informed that one vaccine (Imvanex) and one therapeutic (tecovirimat) have been evaluated and authorised in the EU since 2022. EMA is cooperating closely with WHO, international and EU partners to assess emerging data, to support authorisation of mpox medicinal producta in African countries and to support the initiation of large clinical studies in Africa,. with particular emphasis on gaining evidence for use in children.

The Executive Director highlighted a report from the European Court of Auditors which had concluded that EU agencies, including EMA, had successfully navigated the unprecedented challenges posed by the COVID-19 pandemic. The report recognised the effectiveness of EMA's expedited authorisation processes, but also highlighted issues of clinical trial fragmentation in the EU and the need for the Agency to improve accessibility of its public information especially for non-experts.

The Board received an update on the former EMA premises in London, with the new sub-lease contract nearing finalisation following approval by the Budgetary Authority.

The New Fee Regulation, set to take effect on 1 January 2025, will introduce additional monitoring and reporting requirements for EMA and NCAs. Following the June MB discussion on this topic, EMA will set-up a Management Board sub-group, to define and agree the details of such reporting, and will soon invite MB members to join the sub-group to prepare a proposal for agreement at the December meeting.

The Board was informed about the EMA/HMA Platform for Regulatory Science Research, which aims to enhance collaboration between academics and regulators. The platform will undergo a one-year pilot phase in Q1 2025 and will be co-chaired by EMA, the Dutch MEB, and an academic representative. A

public consultation and call for participants will occur in Nov/Dec 2024. The proposal for the platform was planned to be presented at a virtual regulatory science event scheduled for 18 November 2024.

The Executive Director also updated the Board about recent elections of new Chairs for EMA's scientific committees and the appointment of the new Head of EMA's Legal Department, Ms Georgia Gavriilidou who started on 1 July 2024.

Lastly, the Board also noted the launch of an upcoming written procedure in mid-November to adopt the final HMA/EMA guidance document on the identification of personal data and CCI within the structure of the Marketing Authorisation Application.

B.2 Report from the European Commission

The Management Board noted an oral update from the representative of DG RTD on the pharmacogenomics workshop organised by EMA, HMA and European Commission on 24 September and a number of recent DG RTD activities of relevance to medicines regulators.

The pharmacogenomics workshop served to highlight the potential of pharmacogenomics to tailor the choice of medicines to the specific needs of the individual patient and help avoid adverse drug reactions. It found that regulators can play an important role in guiding sponsors on how to include pharmacogenomic information in clinical studies, foster harmonisation in genomic guidelines and include the most relevant genomic information in the authorised product information for healthcare professionals. A workshop report will be published later in the year. EMA and several Board members acknowledged the importance of the workshop and the need to follow up on its several recommendations.

The representative of DG RTD also informed the Board about recent activities related to funding multi-country clinical trials under the European Research Area for Health (ERA4Health) and that on 1 September 2024 DG RTD had launched a new EU partnership called the European Rare Diseases Research Alliance (ERDERA). The Board was also informed about a number of initiatives: the Cancer Mission conference "Innovative palliative care for people with cancer" planned on 8 October 2024; the EU Cancer Mission bus roadshow organised by Commission earlier this year; several calls for proposals planned in 2025 under the Innovative Health Initiative (IHI) and the European Partnership for Personalised Medicines (EP PerMed).

The representative of DG SANTE informed the Board about the health-related priorities in the Mission Letter for the Commissioner-designate for Health and Animal Welfare, the progress in the examination of the revised pharmaceutical legislation, recent EC activities on shortages, matters relating to the implementation of the medical device legislation including the planned targeted evaluation of this ,and the state of play in implementing the EU veterinary medicines regulation. The Board was informed, amongst other points, that a call for proposals for a "Joint Action on Regulatory Flexibilities including the use of magistral preparations to mitigate shortages" has been published and will close by 22 January 2025. As regards the EU veterinary medicines regulation, it was noted that all implementing legislation regarding the fight against AMR has now been adopted and that the Commission is on track to adopt all outstanding implementing acts by the legal deadlines.

A Board member welcomed the work done to implement the veterinary medicines regulation and requested that National Competent Authorities further discuss the Implementing Act on GMP for veterinary medicines to ensure as much as possible its alignment with GMP standards for human medicines to avoid potential burden for industry and inspectors. The representative of DG SANTE and EMA agreed on the need to further discuss this topic in the dedicated technical groups and will provide a further update on this matter at the December 2024 Management Board meeting.

B.3 EMA Mid-year report 2024 from the Executive Director (January – June 2024)

[EMA/MB/298009/2024], [EMA/298094/2024] The Management Board noted an oral summary by EMA regarding the EMA Mid-year report 2024 from the Executive Director.

The mid-year report provides an overview of the Agency's performance and achievements until 30 June 2024 in implementing the work programme 2024. Key activities of EMA in the first part of the year included work on: enhancing the evaluation of novel medicines using oncology products as pathfinder; improving evidence generation using initiatives such as Accelerating Clinical Trials in the EU (ACT EU) and Data Analysis and Real World Interrogation Network (DARWIN EU); working with other EU agencies on initiatives under a one health approach, including on AMR; coordinating on critical shortages of medicines via the Medicines Shortages Steering Group; enhancing the transparency of CTIS; promoting international collaboration; continuing the digitalisation and automation of regulatory procedures. Trends in marketing authorisation applications and in inspections, as well as key indicators of budget performance and staff turnover and occupancy were also presented. The mid-year report will soon be made public on the Agency's website.

The Management Board also noted that the Agency is waiting for further advice from the European Commission in relation to how staff expenditure should be reported in the Agencies' budgets, therefore EMA might need to run a written procedure before the end of the year for the MB to adopt the necessary changes via an Amending Budget. RM: the previous paragraph should be further checked by Neri please, as I am not sure if I captured it well from the oral explanation. Asked about the lower-than-usual numbers of applications for CVMP limited market classifications, the Agency explained that this might be the result of changes moving from the minor uses and minor species (MUMS) framework to the new system for limited markets under the new veterinary medicines regulation and that the matter will be further discussed at the level of the EMA/HMA veterinary strategic focus group.

B.4 Update on European Medicines Agencies Network Strategy (EMANS) to 2028

[EMA/MB/434167/2024], [EMA/376542/2024] The Management Board endorsed the review and update of European Medicines Agencies Network Strategy (EMANS) to 2028 for release for consultation.

The EMA and HMA are currently working to extend the scope of its five-year strategy, which originally covered the period 2021 to 2025 (EMANS 2025), to align on the Network's goals and objectives up to 2028. The updated strategy reflects the progress outlined in the mid-term report and addresses new initiatives, technological advances, and environmental challenges that are reshaping the regulatory landscape. It also takes into account the ongoing revision of EU pharmaceutical legislation, ensuring the network is prepared for smooth implementation once finalised. Key strategic focus areas for EMANS 2028 include: accessibility; leveraging data, digitalisation and artificial intelligence; regulatory science, innovation, and competitiveness; antimicrobial resistance and other health threats; availability and supply; and the sustainability of the network. The draft strategy was endorsed by the HMA on 12 September and submitted to the EMA Management Board for endorsement. Following this approval, a two-month public consultation will be launched to gather stakeholder perspectives. A multi-stakeholder workshop will be organised in Q1 2025 to present an updated version post-consultation and address any final comments, with the aim of having the final document adopted by the HMA and EMA Management Board in March 2025.

The HMA co-lead of the EMANS Implementation Coordination team, along with the HMA Management Group chair and other Board members, expressed gratitude to all involved in finalising the document and preparing for the public consultation. The representative from DG SANTE commended the excellent work and highlighted the strategy's alignment with the mission letters from President-elect Von Der Leyen. One member support the expressed congratulations for the quality of the document and asked if an addition of a reference to pharmacovigilance and maybe antiparasitic resistance could be added in the document. The HMA co-lead reminded the Board that, following the adoption of the final strategy, the goals and objectives will be expanded into actions within the HMA Multiannual Work Plan (MAWP) and the EMA Single Programming Document (SPD).

B.5 EMA independence policies: Revision of EMA's policy on the handling of competing interests of scientific committees' members and experts (Policy 0044)

[EMA/MB/247295/2024], [EMA/54457/2024] The Management Board noted and endorsed the draft revision of EMA's policy on competing interests of scientific committees' members and experts (Policy 0044) for a four-week public consultation period.

The objective of the revision of the policy is to implement the findings of the Court of Justice in Case C-291/22 P of 14 March 2024 (Hopveus appellate judgment) and in Joined Cases C-6/21 P and C-16/21 P (Aplidin appellate judgment) of 22 June 2023. The revised policy has been drafted along the principles presented to the Management Board in June 2024, taking also into account the comments raised during the discussion by Management Board members and by the European Commission.

EMA provided a comprehensive overview of the proposed main changes to Policy 0044, including any changes compared to the principles presented in June:

- Increased and aligned restrictions across roles and groups for experts with a current interest on a product, including exclusion from procedures related to the product concerned and also products in the same declared condition. Experts with an interest as principal investigator and investigator will now be subject to the same restrictions.
- Aligned restrictions across roles and groups, including a unified 3-year cooling-off period for past employment in a pharmaceutical company, consultancy / strategic advisory role, and past activity as (principal) investigator. The same rules that already apply to Committee members will now also apply to experts involved on an ad-hoc basis.
- Strengthened handling of competing interests in the medical device industry
- New rules to handle certain interests in research organisations
- Clarification on the use of expert witnesses for providing specialist advice on specific issues

These changes aim to strike the right balance between safeguarding impartiality and independence, and access to the best scientific expertise to support EMA's assessments, whilst ensuring compliance with the recent judgements.

Several Board members, including the representatives from DG SANTE and DG RTD welcomed the constructive, transparent and balanced compromise proposed by the Agency. The importance of the concept of the expert witness, especially in Scientific Advisory Groups (SAGs), was underlined by various members. The proposal of a public consultation was viewed positively as a way to ensure transparency and to collect views from different stakeholders.

Asked about possible penalties for infringing the rules on independence, the Agency explained that a breach of trust procedure is available to deal with incorrect or incomplete declarations of interests by scientific experts and committee members, and that the Agency reports on these procedures every year in its annual report on independence.

As regards the next steps, following review and consideration of comments received during the public consultation, the final Policy 0044 will be presented to the Management Board for adoption at its December 2024 meeting. The revision of Policy 0058 on the handling of competing interests of Management Board members and of the Management Board Decision on rules concerning the handling of declared interests of EMA staff will be aligned with the revision of Policy 0044 after the public consultation and will also be proposed for adoption by the Management Board.

B.6 Report on International activities at EMA

The Management Board noted an oral report from EMA on the international cooperation activities of the Agency.

The oral report, which had been requested by some Management Board members during previous meetings, focussed on the following six areas: collaboration with US FDA; support to the African Medicines Agency (AMA); support to EU candidate countries; activities to promote global health; activities to promote reliance on EU scientific assessment by other international regulators; overview of provisions on international cooperation in the proposed reform of the EU pharmaceutical legislation.

Asked about the experience and possible evolution of reliance pathways for the EU to rely on assessments in other jurisdictions, the Agency highlighted the important steps that have been taken in the area of the mutual recognition of inspections with agreements signed with several third countries such as USA, Japan, Switzerland, Australia, Canada and others. Further to a question on whether the African Medicines Agency is focusing also on veterinary medicines, EMA clarified that the African Agency is focused on medicines for human use. However it was clarified that the African Union Model Law on Medical Products Regulation is currently being revised with a proposal to also include veterinary medicines.

B.7 Big Data Steering Group progress report

The Management Board noted an oral report from EMA on the progress of the Big Data Steering Group in implementing its work programme.

The Management Board was informed that the Agency is planning to publish very shortly the summary of an interim report on the EMA/HMA pilot on using raw data from clinical studies in medicines evaluation. The pilot started in 2022 and will continue until the new pharmaceutical legislation becomes applicable. The raw data pilot interim report describes the experience gained with submission and analysis of patient-level data from clinical studies from September 2022 to December 2023. The initial findings suggest that systematic submission of raw data for innovative products at the time of marketing authorisation application may assist the rapporteur teams to improve their understanding of the dossier more quickly and more comprehensively via deeper analysis of the data. The evaluation procedures included in the pilot experienced no delays caused by the fact that raw data was submitted. The raw data formats that are routinely requested by US FDA and the Japanese PMDA are considered appropriate also for submission in Europe.

Asked about possible impact on assessment resources, the Agency clarified that, based on feedback collected from experts involved in the pilot, there was no evidence to indicate that assessment was impaired by the need to conduct additional tasks on clinical study data. The pilot suggests that it is

more of a change of approach, rather than having more data to assess. Furthermore, the proposed risk-based approach for systematic simple descriptive analyses versus more in-depth analyses for selected dossiers will ensure best use of available resources.

B.8 Mandate of the new Network Data Steering Group

[EMA/MB/425727/2024], [EMA/419729/2024] The Management Board endorsed the Mandate of the new Network Data Steering Group. Currently, there are two data governance bodies: the Big Data Steering Group (BDSG) and the Network Data Board (NDB), which have overlapping mandates in data strategy and standardisation. To streamline oversight, it is proposed to merge these groups into a unified body called the Network Data Steering Group (NDSG). The NDSG will serve as a strategic advisory group aimed at maximising data interoperability and utilisation across the EU network, enhancing access to data, generating evidence, and leveraging AI. It will advise the HMA and EMA Management Board on prioritising and monitoring relevant actions related to the EMAN Strategy for 2028, and will engage with key stakeholders. The NDSG's mandate was endorsed by HMA in September 2024, and following Management Board approval, a call for nominations for the HMA co-chair and NCA members for the NDSG will be launched.

B.9 Report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation

[EMA/MB/440087/2024], [EMA/440088/2024] The Management Board noted the report to the Management Board on ACT EU, the operation of CTIS and the Clinical Trial Regulation.

EMA updated the Board on key milestones for clinical trials in the EU. By 30 January 2025, all ongoing trials approved under the previous Clinical Trials Directive must be transferred to the Clinical Trials Information System (CTIS) to comply with the Clinical Trials Regulation. Approximately 3,000 clinical trials have already been transitioned, and sponsors are strongly advised to submit the remaining applications promptly, as the authorisation process can take up to three months. Multiple training and information events have been held, and, in addition, a paid ads campaign was launched by EMA.

A new modernised CTIS public portal went live on 18 June 2024. The revised transparency rules in place have resulted in information on over 6,100 trials now accessible on CTIS. The new features introduced in September facilitate easier searches for specific trials, alongside improvements to the user interface. CTIS business rule simplification is ongoing, with proposals already under development for the first 3 areas of focus. The focus of change management activities linked to CTIS operations remains on supporting and engaging the stakeholder community through regular communications and events planned.

A few board members raised concerns about the January 2025 transition deadline, highlighting challenges with certain ongoing studies and the need for solutions for those potentially ongoing at end of January. While good progress was acknowledged by the Board, the complexity of some innovative trials within the current regulatory framework was emphasised, underscoring the need for improved coordination and support from EMA and NCAs. The Agency outlined plans within ACT EU for better tracking and monitoring of ongoing clinical trials being transitioned, including the development of key performance indicators to enhance compliance and outcomes. Additionally, the Board was? reminded that the ACT EU initiative will hold its annual meeting of the multi-stakeholder platform on 22 October 2024, where these matters will be addressed.

List of written procedures during the period from 04 June to 23 September 2024:

- Consultation no. 04/2024 on the appointment of Martin Mengel as CHMP alternate as proposed by Germany ended on 26 August 2024. The mandate of the nominee commenced on 27 August 2024.
- Consultation procedure for the adoption of the Agency's final accounts 2023 ended on 24 June 2024. The accounts were adopted.
- Consultation procedure for the adoption of the revised access policy for UPD ended on 26 July 2024. The revised access policy was adopted.
- Consultation procedure for the endorsement of revised JCA for UPD ended on 26 July 2024. The revised JCA was endorsed.
- Consultation procedure for the endorsement of composition of PRAC and areas of expertise ended on 29 July 2024. The composition was endorsed.
- Consultation procedure for the adoption of the minutes of the 124th Management Board meeting, held on 12-13 June 2024 ended 12 September 2024. The minutes were adopted.
- Consultation procedure for the endorsement of the updated ACT EU Steering Group mandate ended on 20 September 2024. The mandate was endorsed.

Documents for information

- [EMA/MB/292679/2024] Outcome of written procedures finalised during the period from 04 June to 23 September 2024.
- [EMA/MB/444103/2024] Summary of transfers of appropriations in budget 2024
- [EMA/MB/391795/2024], [EMA/391796/2024] Eighteenth six-monthly report on ex ante and retroactive evaluation of projects for the period 1 January to 30 June 2024
- [EMA/MB/444916/2024], [EMA/444919/2024] Network Portfolio Report

List of participants at the 125th meeting of the Management Board, held in Amsterdam, 03 October 2024

Chair: *Lorraine Nolan*

	Participants
Belgium	Hugues Malone*(member)* Charles Denonne *(alternate)*
Bulgaria	Bogdan Yavorov Kirilov *(member)*
Czech Republic	Boráň Tomáš *(member)*
Croatia	Siniša Tomić *(member)* Danica Kramarić *(alternate)*
Denmark	Mette Aaboe Hansen (*alternate*) Birgitte Faber (*support observer*)
Germany	Karl Broich *(member)*
Estonia	Katrin Kiisk *(member)*
Ireland	Rita Purcell *(alternate)*
Greece	Evangelos Manolopoulos *(member)* Spyridon Th. Sapounas (*alternate)*
Spain	María-Jesús Lamas Díaz *(member)* Consuelo Rubio Montejano[1] (*alternate*) Celia Caballero *(observer)*
France	Alexandre de la Volpilière *(member)* Franck Foures (*alternate)* Miguel Bley *(observer)*
Italy	Robert Nisticò *(member)* Marta Giovanna Toma *(observer)*
Cyprus	Helena Panayiotopoulou *(member)*
Latvia	Indra Dreika (*member*) Sergejs Akuličs *(alternate)*
Lithuania	Dovilė Marcinkė[1] *(member)*
Luxembourg	Anna Chioti *(member)* Marcin Wisniewski *(alternate)*
Hungary	Rita Pálffyné-Poor (*member*) Beatrix Horváth (*alternate)*
Malta	Anthony Serracino Inglott (*member)* John Joseph Borg (*alternate)*
Netherlands	Paula Loekemeijer (*member)* Aimad Torqui[1] *(alternate)* Roelie Marinus *(observer)*
Austria	Günter Waxenecker *(member)* Jan Neuhauser (*alternate)*
Poland	Grzegorz Cessak *(member)* Marcin Kolakowski *(alternate)* Magdalena Pajewska-Lewandowska (*observer*)
Portugal	Rui Santos Ivo (*member*)
Romania	Razvan Prisada *(member)*
Slovakia	Roman Dorcik[1] *(member)*

[1] Restrictions applied for agenda item B.4 and B.5

	Participants
	Katarína Massányiová *(alternate)*
Slovenia	Sabine Zalar *(alternate)*
Finland	Eija Pelkonen (*member*) Anna Siira[1] (*alternate*)
Sweden	Åsa Kumlin Howell[1] *(alternate)*
European Parliament	Karin Kadenbach Giovanni La Via
European Commission	Rainer Becker (DG SANTE) (*alternate*) Matus Ferech (DG SANTE) (*observer*) Irene Norstedt (DG RTD) (*alternate*) Tomasz Dylag (DG RTD) (*observer*)
Representatives of patients' organisations	Marco Greco Virginie Hivert
Representative of doctors' organisations	Denis Lacombe
Representative of veterinarians' organisations	Christophe Buhot
EEA-EFTA states	Rúna Hauksdóttir Hvannberg (Iceland) Sindri Kristjansson (Iceland) Vlasta Zavadova (Liechtenstein) Audun Hågå (Norway)

European Medicines Agency	Emer Cooke Ivo Claassen Peter Arlett Zaíde Frias Hilmar Hamman Emmanuel Cormier Alexis Nolte Nerimantas Steikunas Melanie Carr Steffen Thristrup Hilde Boone Georgia Gavriilidou Franck Diafouka Martin Harvey-Allchurch Rebecca Harding Zahra Hanaizi Alberto Ganán Sonia Ribeiro Luc Van Santvliet Estelle Coquillette Joaquim Berenguer Jornet Riccardo Mezzasalma Apolline Lambert Olga Oliver-Díaz Adeline Bessemoulin