EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2017
EMA/184549/2017
International Affairs

Making Article 58 and other EMA outputs more relevant for non-EU regulators

Workshop with the Committee for Medicinal Products for Human Use (CHMP)
2-3 March 2017, Mediterranean Conference Centre, Valletta, Malta

Contents

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5505
Send a question via our website www.ema.europa.eu/contact

Introduction

Access to medicines is an issue for patients across the world and the ability to assess and supervise medicines once in use are common issues facing public health authorities and regulators in all parts of the world. It was with this in mind that the European Medicines Agency (EMA), working together with the Maltese presidency of the European Union, brought together regulators from across EU and Africa in Malta on 2 and 3 March 2017 to discuss EMA procedures and role in facilitating access.

The World Health Assembly Resolution WHA67.20 from May 2014 stresses the importance of effective regulatory systems within the health system context. The European Union Medicines Agencies Network Strategy to 2020 also emphasises this, and specifically talks about promoting reliance and work-sharing, supporting capacity-building.

With these in mind, the objectives of the meeting were to:

- Increase awareness and understanding of the Article 58 procedure, and other EMA reliance and collaborative procedures and initiatives;
- Increase awareness and understanding of specific needs of African regulators, in both the pre-approval and post-approval/pharmacovigilance areas; and
- Identify specific proposals to improve procedures to enable target regulators to increase reliance and use of EMA/CHMP work medicines.

Executive summary

The meeting was attended by EMA CHMP members, experts and staff, and African national regulatory authorities, the African Union NEPAD agency, and World Health Organization, the World Bank with support by the Bill & Melinda Gates Foundation,

The workshop was organised with the financial support of the Bill & Melinda Gates Foundation.

This meeting report highlights the main points of discussion during the two-day workshop, and the actions and recommendations made during the meeting. These will be taken into consideration for implementation in the EMA and committees' work programmes.

Action point
The CHMP assessment report
Consider how to improve the quality aspects of the CHMP assessment report for medicines going through the Article 58 and WHO collaborative registration procedures, for example consider including WHO Quality Information Summary as standard part of assessment reports.
Consider how to include reviews of bridging studies from EU to non-EU patient populations in CHMP assessment reports for Article 58 medicines.
Review the elements used by CHMP to support benefit-risk methodology approach for Article 58 medicines. How can this be better tailored to consider specific benefit-risk for each target country or region, building consensus before opinion?
Consider how to improve the risk management plans for Article 58 medicines to ensure they are more appropriate and suitable for target countries.
Provide guidance on biosimilar medicines in the Article 58 procedure, and adapt the assessment report template as appropriate.
Consider revising the structure and level of content of European public assessment reports (EPARs) for Article 58 medicines, taking into account the specific target audience and the way in which they may be used by non-EU regulators.
Post-opinion issues and interactions
Explore possibility for systematic exchanges between CHMP and target country authorities after each opinion for Article 58 medicines and candidate medicines for the WHO collaborative registration procedures to facilitate national registration decisions.
Improve communication flows between EMA, WHO and non-EU regulators that rely on Article 58 opinions for their national decisions. Explore how to improve trace of which countries have approved Article 58 medicines.
Clarify and ensure effective two-way communication flows on post-opinion pharmacovigilance and variation decisions. Clarify flow of information on adverse drug reaction reports for Article 58 medicines. Clarify the process for sharing rapid alert information.
Clarify how periodic safety update reports (and their assessment) for Article 58 and collaborative registration medicines are shared with WHO and target countries.

Action point
Experts and observers from target countries
Ensure earlier and deeper involvement of both experts and regulators from target country (as observers or experts/shadow assessors). Improve timing of nominations to ensure better involvement of non-EU regulators from earliest stage possible.
Clarify the roles and expectations of all actors involved in Article 58 procedures and in the sequence for collaborative registration procedures.
Scientific advice for potential Article 58 medicines
Raise awareness with sponsors that they can get scientific advice for potential Article 58 medicines.
Facilitate involvement experts and regulators from target countries in early phases of development and scientific advice procedures.
Inform sponsors and in public guidance that Article 58 medicines can be considered for support under the Agency's Priority Medicines (PRIME) initiative.
Other issues
Clarify roles of EMA, WHO and target country authorities with respect to GMP and other inspections for Article 58 medicines.
Increase training and capacity-building opportunities (including in the area of biosimilar assessment).
Clarify how medicines are selected for the WHO-EMA collaborative registration pilot and opportunity for participating regulators to indicate medicines of interest.
Clarify how to manage an Article 58 medicine with 'conditional marketing authorisation'-type opinion where this regulatory tool is not available in target countries.
Review the conduct of CHMP and SAG meetings for Article 58 medicines to facilitate the input and contribution from WHO and target country experts and regulators.
Continue EMA-WHO discussions on clarifying and streamlining the Article 58 and Prequalification (PQ) procedures, and the place of new Article 58 medicines in WHO programmatic guidelines.
Explore the possibility to include WHO country suitability assessment in CHMP assessment report package, i.e. before opinion rather than post-opinion.
Make Article 58 EPARs identifiable and searchable in the EMA website.

Discussions

Welcome and introduction

The meeting was opened by the Hon. Minister Dr Helena Dalli, Maltese Minister for Social Dialogue, Consumer Affairs and Civil Liberties, and Professor Anthony Serracino Inglott, chairman of the Malta Medicines Authority. In addition to recognising the support of the Bill & Melinda Gates Foundation, both speakers emphasised the commitment of European network to strengthening collaboration with African regulators, and the need for this meeting to be the start of a process of effective activities and interactions.

The sessions on 2 March 2017 were co-moderated by Tomas Salmonson, chair of the CHMP, and John Borg, CHMP member. The sessions on 3 March 2017 were co-moderated by Tomas Salmonson and Gugu Mahlangu, Zimbabwe.

Tomas Salmonson spoke about the importance of collaboration, trust and reliance as illustrated by the European medicines network and the EMA. That trust is not established by rules and regulations, but through experience and working together. Within the European network different sized agencies take on different workload according to their capacity, but when it comes to decision-taking all members are equal. For him, this first meeting of the CHMP with non-EU regulators was not so much explaining how the EMA operates but about how to foster trust and develop more reliance opportunities.

The CHMP assessment report

The discussion was led by Kristina Dunder, CHMP member, with contributions from Mercy Acquaye, Ghana, and Emer Cooke, WHO.

The CHMP assessment report is the key scientific output, whether for medicines that will be approved for use in the EU or as the basis for opinions on use outside of the EU (Article 58). The purpose of the discussion was in particular to understand the methodology for assessing the benefit-risk balance of medicines. The possibility of extrapolating the benefit-risk in a European population to non-EU populations was discussed, taking the expected impact on extrinsic factors into account. The differences between the confidential CHMP assessment report and the published EPAR were also explained.

Mercy Acquaye presented the Ghanaian experience with the CHMP assessment and how it is used to facilitate the approval of a medicinal product. For their national approval they review the published EPAR and then focus on module 1 (administrative sections) of the submitted dossier. This allows a timely approval of medicines without duplication of a detailed assessment of the other sections of the dossier.

The possibilities and challenges of collaboration between the European system and African regulators were highlighted by Emer Cooke. She identified the target population as the key issue but also the relevance of the conditions of use in the concerned countries. Another important factor was the pharmaceutical stability of the medicine in the target countries, as well as the feasibility of the risk management plan. In addition the need to manage and communicate any post-authorisation changes was highlighted. It was proposed that applicants and sponsors should focus on relevant differences between the European storage conditions and those in the African countries. She emphasised that the expectations from all stakeholders, including any non-state actors should be clarified.

The process of quality assurance of the CHMP assessment was outlined, highlighting the two independent rapporteur assessment teams, peer review with EMA support, possible comments from all

Member States, and the involvement of scientific advisory groups and patients. It was emphasised that quality is built into the assessment rather than having quality measures at the end. In addition the on-going project of continuous improvement of EMA templates was mentioned

The relevance of the CHMP benefit-risk assessment for all African countries was questioned, considering the variability of local conditions. It was clarified that it would be up to the national regulatory authority (NRA) to make its own assessment on the relevance of the CHMP benefit-risk conclusion. It was agreed that NRAs understand the risk profile of their own communities best and would have to make their own decision on the approvability of a medicinal product in their country. The point of ownership and responsibility was considered a key aspect which may require further discussion.

Overall, the feedback was that the assessment report and EPAR are not granular enough to address country-specific issues and that there were missed opportunities for consensus building in the benefit–risk assessment.

Participants pointed out that some companies have no interest in seeking approval of a medicine in smaller African countries, and this was seen as something to be addressed through improved dialogue with industry stakeholders.

The possibility of African regulators to indicate EMA procedures of specific interest was discussed, and will be further investigated. A possible role for regional economic communities and other African continental initiatives was suggested here.

The discussion turned to post-approval procedures. It was flagged that the communication on post-approval decisions should be further improved as not all African countries have a framework in place to ensure an appropriate follow-up.

Debate then focused on possible reasons for the low uptake of the Article 58 procedure. The intention to make the procedure more attractive for sponsors and regulators was welcomed by participants.

Evolutions in clinical trial methodology

Rob Hemmings, CHMP member, spoke about evolutions in clinical trial methodology, including basic features in clinical trial design and analysis, and developments at the level of the International Council for Harmonisation (ICH) in particular the addendum to E9 guideline on statistical principles for clinical trials. He also spoke about the scientific assessment of validity of clinical trials conducted in one region for other regions.

During the discussion it was confirmed that scientific advice is possible – and indeed encouraged – for medicines intended for the Article 58 procedure, as well as for those intended for the WHO-EMA collaborative registration pilot. Advice can be given on any aspect of the clinical and non-clinical development of medicines, including the clinical trial design.

The EMA also highlighted out that the Agency's Priority Medicines (PRIME) initiative to support actively development of medicines that target an unmet medical need, applies to medicines that will go through the Article 58 procedure. This voluntary scheme is based on enhanced interaction, early dialogue with developers of promising medicines to optimise development plans, and accelerated evaluation so these medicines can reach patients earlier.

Some participants pointed out that clinical research organisations in Africa are not always subject to adequate local supervision to ensure they follow established good clinical practice (GCP) standards, and an improvement in this area was seen as necessary.

The WHO African Vaccine Regulatory Forum (AVAREF) was also mentioned for their role in assessing clinical trials, in relation to regulatory requirements. Partnership with AVAREF was seen as necessary.

Reliance and collaboration: Future solutions for facilitated pathways

WHO-EMA collaborative registration pilot

This discussion was led by Luther Gwaza, WHO, and Fred Siyoi, Kenya. The WHO-EMA collaborative registration pilot was launched at the end of 2014 and has been used for three centrally approved medicines and one medicine with an Article 58 opinion. Luther Gwaza presented the process, which allows the exchange of non-public confidential information from EMA through the WHO with participating regulators to foster an accelerated registration process, with the aim to avoid duplication of efforts and saving overall resources.

Acknowledging that reliance on assessment done by other regulators is a challenge for many national authorities in Africa and elsewhere, he said that the pilot showed promising results on agreements on consolidated lists of questions and assessment reports and reducing registration timelines (time to decision has decreased from more than 2 years to 3-12 months).

The pilot also suggested the limited usefulness of EPARs and CHMP assessment reports for some African regulators, as the quality part of the assessment was not always sufficient for an abridged review process. One solution to address these quality issues part was the making available of WHO quality information summaries (QIS), a standardised document template for relevant quality information.

Fred Siyoi spoke of his experience of the pilot with a focus on the procedural requirements. He suggested aligning the common technical document with the East African Community compendium registration, including additional quality specifications. Another issue is that applicants were not always sufficiently aware of national labelling requirements and responsibilities, which often leads to delays in registration. In addition, he suggested strengthening the pharmacovigilance communication process, and allowing observers from African medicines authorities to participate in CHMP discussions.

The discussion focused on identifying which aspects of the CHMP assessment report were the most problematical for regulatory authorities involved in the collaborative registration pilot, with quality assessment seen as the key area.

Article 58 procedure

This discussion was led by Jan Müller-Berghaus and Greg Markey, CHMP members, with contribution from Martin Harvey Allchurch, EMA. Participants also heard a pre-recorded video presentation of the 2015 strategic report and recommendations on the Article 58 procedure, carried out by the EMA, European Commission and Bill & Melinda Gates Foundation, to look at the first 10 years' experience of the procedure

Jan Müller-Berghaus and Greg Markey explained their practical experience as rapporteur and co-rapporteur for the Article 58 opinion for Mosquirix (RTS,S) malaria vaccine, highlighting the different steps of the assessment, including the involvement of experts and observers from WHO and regulators in target countries. Overall the procedure was seen as sufficiently flexible to allow input from different stakeholders.

Reliance is underpinned by sharing of assessment reports, while retaining the ability to take national decisions. Martin Harvey Allchurch presented the possibilities for non-EU national regulatory authorities

(NRA) requesting to receive CHMP assessment reports (independently of Article 58). Depending on whether or not the company or sponsor agrees, the EMA is able to share either the full assessment report or a redacted version at the request of the NRA. It was clarified that the redacted CHMP assessment report will be different to the EPAR which is specifically prepared for the public. In addition, companies and sponsors are entitled to share assessment reports for their medicines under their responsibility for the protection of personal data and confidential information. Various initiatives, such as the International Generic Drug Regulators Programme (IGDRP) information sharing, were discussed.

It was noted that the EMA publishes EPARs for all medicines it evaluates (both positive and negative outcomes) and has also begun publishing clinical study reports of trials assessed as part of the benefit-risk evaluation.

Since the CHMP is only responsible for evaluation of medicines for centralised European approval and for Article 58, the EMA can only share assessment reports for these medicines.

Participants felt that companies and sponsors should be encouraged to use Article 58 more, but a proposal that African countries should identify the medicines they would like to see go through the procedure was not considered feasible as the use of the tool is on a voluntary basis. The solution was therefore to work to improve and promote the procedure.

Participants noted that one of the key strengths of the procedure was the collaboration of the 'three voices' of local regulators, WHO and EMA. This is also seen as one of the reasons that Article 58 is gaining awareness with non-governmental organisations and medicine development partnerships for medicines of specific public health interest for African and other target countries.

In order to make the involvement of regulators from target countries more effective, it was suggested that experts and observers should be nominated as early as possible and that greater clarity was needed on their roles. Some participants noted that practical issues such as visas and funding can be an obstacle.

Quality aspects: assessment, stability, storage

This discussion was led by Jean-Louis Robert, CHMP member, and Evangelos Kotzagiorgis, EMA, who emphasised that the same scientific standards apply for review of Article 58 medicines as for all medicines marketed in the EU.

For the quality part, however there are differences relating to the stability evaluation and declaration of storage conditions relevant for climatic zones II and IV. Examples of storage conditions of Article 58 medicines were presented and the importance of the supply chain conditions was emphasised. Current ways and limitations of sharing information particularly in relation to the Quality aspects of applications and the respective ARs were discussed. The Quality Information Summary (QIS) has been developed as part of the WHO prequalification programme and is a condensed summary of the key quality information in medicine dossiers. The QIS is a possible solution that could be annexed to CHMP assessment reports of medicines of potential interest to non-EU regulators, including for Article 58 and collaborative registration medicines.

Paediatric medicines and maternal health

This discussion was led by Dirk Mentzer, chair of the Paediatric Committee (PDCO). He outlined the paediatric investigation plan (PIP). He also reflected on medicinal product development in special populations, including pregnant women.

The participants were then asked on their view of the Zika virus and the problematic issue of conducting clinical trials in women who are or might become pregnant to study whether immunisation prevents neurologic malformations. It was questioned whether a suitable animal model exists. In addition the autonomy of pregnant women to decide whether to participate in a clinical trial was acknowledged. Overall the ethical aspects require further discussion with the countries where the trials would be conducted. Reference was made to the recently published WHO guidelines on Managing Ethical Issues in Infectious Disease Outbreaks.

Biosimilar assessment and experience

This discussion was led by Martina Weise and Sol Ruiz, both CHMP members.

The principles of establishing biosimilarity as well as the challenges from the quality and clinical side were presented. It was clarified that US Food and Drugs Administration (US FDA) and EMA accept foreign reference products in clinical studies.

The question was raised as to which reference products would be acceptable for the African regulators, as in most cases the originator was not assessed or authorised in the concerned country. It was noted that the WHO guidelines say that regulators can accept reference medicines from outside their jurisdiction. It was flagged that the PIC/S Programme accepts other reference products for small molecules. Some countries requested data on the reference product.

Another comment was made that reference products approved by 'stringent regulatory authorities' (SRA) would be acceptable. The group learned that in some cases companies submit biosimilar applications in African countries before they have been assessed in Europe. In those cases the African regulators have to decide whether to wait for the CHMP assessment or whether the national situation requires an earlier assessment and registration in the concerned country. The advice was given to focus in these cases on the quality of the medicine, for example impurities, good manufacturing practice (GMP) compliance and a consistent manufacturing, rather the pharmacokinetic profile as would be the case for small molecules.

Given the complexity of the topic, a dedicated workshop for assessors was considered useful to build knowledge and share experience in assessment.

Ebola and tuberculosis

This discussion was led by Marco Cavaleri, EMA, who informed participants about developments in the treatment of tuberculosis (TB) with recently new approved medicines. It was outlined that the CHMP guideline for development of new agents to treat pulmonary TB is expected to be adopted later in 2017, including requirements for entirely new TB regimens. The need for strengthened capacity for observational studies based on registries and microbiological surveillance was highlighted as important in the setting of TB.

Moving to Ebola, the group was reminded that clinical trials for Ebola vaccines took place rather late in relation to the epidemic outbreak curve. Despite the broad and satisfactory interaction with developers of potential medicinal products for prevention and treatment of Ebola, it is obvious that a good preparedness for such situations is essential.

The WHO R&D Blueprint initiative for action to prevent epidemics was mentioned which identified pathogens with the potential to cause outbreaks in future. An EMA working group had been set up shortly after the start of the outbreak to discuss the development plans with companies and to liaise with international partners including US FDA, Health Canada and WHO. During the Ebola outbreak the CHMP also reviewed all available knowledge on available medicines for treatment of Ebola under development. The summarised information on those developmental medicines supported national agencies to make an informed decision on which medicines to use in case of an emergency.

The Ebola outbreak showed also the value of initiatives such as the joint review of clinical trial protocols through AVAREF which was coordinated by WHO with the contribution of regulatory authorities from both involved countries and other regions such as North America and Europe.

As a regulatory tool to quickly approve medicinal products in an emergency situation the conditional marketing authorisation process was explained. This type of European marketing authorisation allows the approval of a medicine in case of an emergency situation based on less comprehensive clinical and non-clinical data, provided the benefit-risk is considered positive, and that there is a commitment to provide additional data post.

It was clarified that a conditional marketing authorisation could be applicable for an Article 58 procedure. As a complement, it was flagged that, in some African countries, pathways exists that can be used in case of public health challenges, allowing an expedited drug approval. The participants agreed that further clarification on possible expedited approval processes should be sought under the auspices of WHO in order to be prepared in case of an emergency. The involvement of African regulators in this process was considered essential.

Post-approval and pharmacovigilance

This discussion was led by June Raine, chair of the Pharmacovigilance Risk Assessment Committee (PRAC), who explained the key post-approval regulatory activities for Article 58 medicines. All medicines assessed by the CHMP include a risk management plan agreed with the PRAC and this applies equally for Article 58 medicines. Participants were challenged to consider the usefulness and relevance of the risk management plans adopted so far and look for ways to improve them.

Detection of safety signals is a key part of the pharmacovigilance cycle. European regulators have developed a free mobile phone app for public, care-givers' and healthcare professionals' reporting as part of the WEB-RADR project that can be tailored by regulators for their local language and needs. It was noted that pilots for the app are currently ongoing in two African countries. A number of participants spoke about innovative mobile phone initiatives in Africa for consumers to verify medicines, identify falsified products and submit reports to the national regulator.

Participants suggested that most of attention had been focused on pre-approval processes but that there was still a great deal of variability in the level of post-marketing responsibilities and capabilities. A wealth of materials has been developed to assist EU regulators develop and strengthen their pharmacovigilance systems under the SCOPE project (Strengthening Collaborations for Operating Pharmacovigilance in Europe). All the training and other content is available on the SCOPE website for other regulators to look at as a possible model.

Another area for improvement was the flow of information for post-marketing variations. It was clarified that all variations or other regulatory actions for Article 58 medicines will be communicated to the WHO and all countries that are known to have approved the medicine. A more robust tracking and tracing of the lifecycle of Article 58 medicines was considered to be useful. Some participants raised the question on enforceability of sponsors fulfilling their responsibilities on monitoring and evaluation

of new safety data. It was noted that for an Article 58 procedure the sponsor needs to be established in the EU (or wider European Economic Area); this allows the Agency to be able to engage with the sponsor in case of post-opinion and pharmacovigilance non-compliance issues and for the possibility of appropriate enforcement. In addition, it always remains open to the EMA to conduct pharmacovigilance inspections if necessary. It was noted that EMA through the PRAC offers advice to the WHO on pharmacovigilance issues on request.

Inspections

This discussion was led by Anabela Marcal, EMA, and Deusdedit Mubangizi, WHO. As for other aspects of the Article 58 procedure, it was clarified that the same principles for GMP and GCP inspections apply for Article 58 procedures as for the evaluation of centrally authorised medicinal products. The presentation also included information on the EudraGMDP database, which contains public information on GMP certificates, manufacturing and import authorisations and other documents allowing the verification of the GMP status of manufacturing sites.

Two areas of EMA and WHO cooperation were highlighted. The first was that EMA distributes all rapid alert notifications to the WHO, which are in turn distributed to WHO member states as appropriate. The second is that the Agency issues Certificates of Pharmaceutical Products in accordance with the WHO model, and these are available in all EU official languages including English, French and Portuguese.

Comprehensive guidance is available from WHO on international norms, standards and guidelines for inspection activities. Speaking about the possibility of collaborative or reliance arrangements that can be put in place for inspections, WHO clarified that it generally relies on the GMP inspections carried out by SRAs for medicines going through prequalification process. However certain changes post-prequalification may trigger an inspection.

Increasing reliance and use of EMA outputs

Improving communication and interaction between CHMP and partners

Tomas Salmonson reflected on how to improve communication, both written and other. In addition to improving the communication of CHMP outcomes, one suggestion was greater involvement of different stakeholders, possibly through webinars or question and answer sessions, following the adoption of opinions for Article 58 medicines. Communication flows throughout the lifecycle of medicines that have gone through the Article 58 and collaborative registration procedures was considered to be critical.

Training and capacity-building opportunities

Samvel Azatyan, WHO, and Agnès Saint-Raymond, EMA, led the discussions on training and capacity-building opportunities. Creating opportunities to learn, train and understand each other better was supported by all participants. The May 2014 World Health Assembly Resolution WHA67.20 on regulatory systems strengthening mandated WHO to continue supporting member states, on their request, including gap analysis to identify the needs, generating and analysing the evidence of regulatory system performance and providing technical support to national regulatory authorities and governments based on identified needs. The WHO NRA benchmarking policy was explained leading to an outcome assessment report, including a new rapid benchmarking process that allows a snapshot of critical regulatory functions to be performed by the groupings of the countries associated in the regional economic communities. In addition the new business model and innovative approaches were presented, including the Coalition of Interested Partners (CIP) and Centres of Regulatory Training Excellence (CoRTEs).

The EMA has also put in place a toolbox of training possibilities, including the EU network training centre (EUNTC) that offers high-quality training to the EU regulatory network via an online platform. Access to courses offered by the EUNTC will soon be available through the WHO training portal. Other opportunities presented include participation in EMA workshops, webinars, etc. Participants also noted that participation in Article 58 procedures were seen as valuable capacity-building opportunities.

Globalisation and collaboration: EMA and international partners

On behalf of Guido Rasi, EMA Executive Director, Agnès Saint-Raymond spoke about the public health imperatives for greater collaboration and cooperation between international partners to increase the availability of medicines to patients. She emphasised the importance of meeting unmet public health needs, ensuring supply and data integrity and the effective use of global regulatory resources.

Close of meeting

The European Medicines Agency thanked the Malta Medicines Authority and the Maltese presidency of the EU for their cooperation in the preparation, organisation of and contribution to the workshop. The support of the Bill & Melinda Gates Foundation is gratefully acknowledged as well as the cooperation of the World Health Organization.

The organisers also thanked the regulators from Africa and the CHMP members for their participation and engagement. The interactions and exchanges of views during the meeting were seen as extremely valuable by the participants and continued communication and collaboration in future is envisaged.

List of participants

Name	Surname	Delegation
Massumba Vasco	Chilunda	Angola
Andrea	Laslop	Austria
Bart	Van der Schueren	Belgium
Shyam	Bhaskaran	Bill & Melinda Gates Foundation
Murray	Lumpkin	Bill & Melinda Gates Foundation
Sinah Matlhodi	Selelo	Botswana
Mila	Vlaskovska	Bulgaria
Carla Djamila	Reis	Cape Verde
Tomas	Salmonson	Chair, Committee for Medicinal Products for Human Use (CHMP)
Dirk	Mentzer	Chair, Paediatric Committee (PDCO)
June	Raine	Chair, Pharmacovigilance Risk Assessment Committee (PRAC)
Katarina	Vucic	Croatia
Radka	Montoniova	Czech Republic
Kristina Bech	Jensen	Denmark
Kairi	Rooma	Estonia
Alar	Irs	Estonia
Dagmar	Stará	European Commission
Pia	Chambers	European Medicines Agency
Marco	Cavaleri	European Medicines Agency
Olivier	Duquesne	European Medicines Agency
Martin	Harvey Allchurch	European Medicines Agency
Verena	Janiak	European Medicines Agency
Evangelos	Kotzagiorgis	European Medicines Agency
Jordi	Llinares	European Medicines Agency
Anabela	Luis De Lima Marçal	European Medicines Agency
Sonia	Ribeiro	European Medicines Agency
Agnès	Saint-Raymond	European Medicines Agency

Name	Surname	Delegation
Outi	Maki-Ikola	Finland
Edwige Hélène	Ndakissa	Gabon
Markieu Semega	Janneh Kaira	Gambia
Harald	Enzmann	Germany
Jan	Mueller-Berghaus	Germany
Martina	Weise	Germany
Mercy Acquaye	Owusu-Asante	Ghana
Aminatu	Fernandes Baldé	Guinea-Bissau
Cristolindo	Mendes Da Costa	Guinea-Bissau
Agnes Gizella	Gyurasics	Hungary
Patrick	Salmon	Ireland
Fred Moin	Siyoi	Kenya
Jacinta Nasimiyu	Wasike	Kenya
Jacqueline	Genoux-Hames	Luxembourg
Jean-Louis	Robert	Luxembourg
John-Joseph	Borg	Malta
Mark	Cilia	Malta
Gavril	Flores	Malta
Jonathan	Gerada	Malta
Kevin	Gauci	Malta
Anthony	Serracino Inglott	Malta
Tania Vuyeya	Sitoie	Mozambique
Saren	Shifotoka	Namibia
Paul	Tanui	NEPAD
Paula	van Hennik	Netherlands
Monica	Eimunjeze	Nigeria
Yetunde	Oni	Nigeria
Aishatu	Yinusa Elagbaje	Nigeria
Bjørg	Bolstad	Norway
Piotr	Fiedor	Poland

Name	Surname	Delegation
Fatima	Ventura	Portugal
Nela	Vilceanu	Romania
Wiltshire	Johnson	Sierra Leone
Nevenka	Trsinar Brodt	Slovenia
Jacques	Joubert	South Africa
Jeanette	Lotter	South Africa
Mabatane Davis	Mahlatji	South Africa
Mawien Atem	Arik	South Sudan
Concha	Prieto-Yerro	Spain
Sol	Ruiz	Spain
Kristina	Dunder	Sweden
Jane Humphrey	Mashingia	Tanzania
Asiimwe Donna	Kusemererwa	Uganda
Apollo	Angole	Uganda
Rob	Hemmings	United Kingdom
Greg Stephen	Markey	United Kingdom
Nithyanandan Andiappa	Nagercoil	United Kingdom
Apollo Edson	Muhairwe	World Bank Group
Stanislav	Kniazkov	World Health Organization, AFRO
Samvel	Azatyan	World Health Organization, Geneva
Emer	Cooke	World Health Organization, Geneva
Luther	Gwaza	World Health Organization, Geneva
Deusdedit	Mubangizi	World Health Organization, Geneva
Zuma	Munkombwe	Zambia
Gugu Nolwandle	Mahlangu	Zimbabwe
Tariro Daphney	Sithole	Zimbabwe

Meeting agenda

MALTA EU2017

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MALTA MEDICINES AUTHORITY

Making Article 58 and other EMA outputs more relevant for non-EU regulators

Workshop with the Committee for Medicinal Products for Human Use (CHMP)

2–3 March 2017, Valletta, Malta

Agenda

Workshop with the Committee for Medicinal Products for Human Use (CHMP)

Maltese Presidency Strategic Review and Learning Meeting

African regulators and other colleagues are invited to join the final session of the CHMP Strategic Review and Learning meeting organised by the Maltese Presidency

Thursday, 2 March

Moderators: Tomas Salmonson and John Joseph Borg

09:00–09:10	**Welcome and introduction**	John Joseph Borg (CHMP)
09:10–10.00	**Introduction to the European Medicines Agency Article 58 procedure and experience to date**—50′	Tomas Salmonson (Chair of CHMP)
10:00–12:15	**Specific scientific and regulatory topic**	
	The CHMP Assessment Report—20′	
	Understanding and using the CHMP assessment report (with Article 58 case studies) Benefit-Risk Assessment and how can benefit-risk in a European population be used in non-EU populations?	Kristina Dunder (CHMP)
	Feedback on use (and usefulness) of CHMP assessment reports by African regulators and WHO	Mercy Acquaye (Ghana) Emer Cooke (WHO)
	Q&A and Discussion—15′	
	Evolutions in clinical trial methodology…and beyond—15′	Rob Hemmings (CHMP)
	Q&A and Discussion—15′	
12:15	**Close of Strategic Review and Learning Meeting**	Moderators
12:20—12:40	Welcome by the Chairperson of the Malta Medicines Authority and the Maltese Minister for Social Dialogue, Consumer Affairs and Civil Liberties	Anthony Serracino Inglott Hon. Minister Dr. Helena Dalli
12:40—13:30	Lunch	

Thursday, 2 March

Moderators: Tomas Salmonson and John Joseph Borg

13:30	**Introduction to afternoon session**	Moderators
13:35–15:15	**Reliance and collaboration: Future solutions for facilitated pathways**	
	WHO–EMA Collaborative Registration Pilot	
	WHO introduction—10′	Luther Gwaza (WHO)
	African regulators' experience—10′	Fred Siyoi (Kenya)
	Article 58 procedure	
	CHMP experience of the Article 58 procedure: a case study of Mosquirix (RTS,S)—15′	Jan Müller-Berghaus (CHMP) Greg Markey (CHMP)
	Lessons learned: How to make Article 58 more attractive? —10′ (pre-recorded video)	Matthew Wilson (McKinsey & Co)
	Sharing CHMP assessment reports and reliance EMA introduction—5′	Martin Harvey (EMA)
	Q&A and Discussion	
15:15–15:30	Coffee break	
15:30–17:00	**Specific scientific and regulatory topics**	
	Quality aspects: Quality assessment, storage conditions, etc, —10′	Jean-Louis Robert (CHMP) Evangelos Kotzagiorgis (EMA)
	Paediatric medicines and maternal health (SDG 2030)—10′	Dirk Mentzer (Chair of PDCO)
	Q&A and Discussion	
17:00	**Close of meeting**	
17:20	Transfer to hotel	
19:00	Bus transfer to official dinner venue	
20:00–22:30	Official dinner	

Friday, 3 March

Moderators: Tomas Salmonson and Gugu Mahlangu

09:00	**Introduction to the morning session**	Moderators
09:05–10:30	**Specific regulatory topics (continued)**	
	Biosimilar assessment and experience—10′	Martina Weise (CHMP) Sol Ruiz (CHMP)
	Ebola and TB—10′	Marco Cavaleri (EMA)
	Q&A and Discussion—60′	
10:30–10:50	Coffee break	
10:50–12:00	**Post-approval issues**	
	Post-approval and pharmacovigilance—10′	June Raine (Chair of PRAC)
	GMP inspections—10′	Anabela Marçal (EMA) Deusdedit Mubangizi (WHO)
	Q&A and Discussion—45′	
12:00–12:45	**Increasing reliance and use of EMA outputs**	
	Improving communication and interactions between CHMP and partners—5′	Tomas Salmonson (Chair of CHMP)
	Training and capacity-building opportunities—10′	Agnès Saint-Raymond (EMA) Samvel Azatyan (WHO)
	Globalisation and collaboration EMA and international partners—10′	Guido Rasi (EMA)
	Q&A and Discussion—30′	
12:45–13:00	**Close of meeting**	Guido Rasi (EMA) Murray Lumpkin (BMGF) Emer Cooke (WHO) Anthony Serracino Inglott (MMA)
13:00–14:00	Lunch will be available	

Notes

European Medicines Agency

30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Telephone +44 (0)20 3660 6000
Facsimile +44 (0)20 3660 5555
Send a question www.ema.europa.eu/contact

www.ema.europa.eu

Making Article 58 and other EMA outputs more relevant for non-EU regulators
EMA/27034/2017