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EMA/CMDh/62111/2022
Human Medicines Division

CMDh Multi-annual Workplan to 2025 – *For public consultation*

Since 2015, the CMDh operates with a 5-year multi-annual workplan (MAWP). The previous MAWP finished in 2020. By the end of 2020 and during 2021, the CMDh has been analysing the actions of the previous MAWP and worked on a new MAWP to 2025, which outlines the priorities of the CMDh for the coming years. It also reflects the need for a coordinated approach to address the multiple challenges and opportunities that the network faces. Outstanding actions from the previous MAWP have been taken over into the new MAWP to 2025, where appropriate. It should be seen as complementary to the multiple "daily" tasks of the CMDh as laid down in legislation, including providing a forum for discussion between Member States on points of disagreement in procedures, providing regulatory and procedural guidance and fostering harmonisation in the EU regulatory network.

The document has been developed in parallel and is complementary to the HMA MAWP and the HMA/EMA European Medicines Regulatory Network (EMRN) strategy 2025.

The following five main priority areas have been included:

- Availability of essential medicines and coordination during crisis
- Optimisation of procedures
- Innovative projects
- Preparation for legislative changes
- Optimisation of communication/relationship/meetings with interested parties and stakeholders

1. Availability of essential medicines / coordination during crisis

The relevant competent authorities of the Member States of the European Union constantly monitor the availability of medicines and supply disruptions of medicines. The European Union recognizes the unavailability of medicines and interruptions in the availability of medicines as a serious risk to public health. Several Member States, especially the smaller markets, are continuously facing challenges in obtaining marketing authorisation applications and/or reliable supply of small volume, yet essential medicines. These include, but are not limited to, paediatric formulations, narrow indications and other low volume and small patient groups medicines.

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The COVID pandemic of 2020/2021 has further highlighted the need to ensure the availability of critical and/or essential medicines, and to coordinate regulatory approaches to maintain this availability. Brexit is another recent event that has had severe negative impact on the availability of essential medicines in some Member States, and hugely influenced the supply chain of medicines within the EU.

The causes of unavailability of medicines are complex and cannot be handled isolated at national level. The above-mentioned situations require an understanding of the different roles of the many involved parties and the interactions between them, to ensure appropriate and efficient decision-making and continuity of supply. CMDh has the remit as outlined in Article 27 of Directive 2001/83/EC to examine any question related to marketing authorisations of medicinal products in two or more member states, which covers a variety of issues related to new applications, variations, renewals and pharmacovigilance activities. The members of CMDh should also ensure appropriate coordination between CMDh and the work of national competent authorities. Members of CMDh are also requested to support worksharing, harmonisation and avoid duplication of work between Member States. Therefore, it is considered that CMDh is uniquely positioned to promote the aspects of this work that contribute to availability of medicines and to contribute to the network to ensure issues around availability and shortages are appropriately addressed. Therefore, CMDh will undertake the following as outlined:

- CMDh will further investigate ways/procedures to obtain a marketing authorisation in Member States where the product is needed and not authorised yet in a more efficient way than ordinary repeat use procedures, through provision of advice on the use of accelerated procedures and the inclusion of further CMS in DCP procedures on request.
- CMDh will investigate / promote initiatives aimed at reducing barriers to national access or distribution, for example through the promotion of multilingual packaging or linking to the MAWP Theme 3 (innovation) for the investigation of electronic product information (ePI). This should facilitate marketing of medicines in all Member States and redistribution of medicines available in other Member States to countries experiencing shortages or where medicines are not marketed.
- When implementing new regulatory guidance and legislation, CMDh will carefully consider the risk of 'regulatory triggered' shortages and availability implications and mitigate against this where possible.
- CMDh will explore which lessons can be learned from the COVID-19 crisis in the area of regulatory flexibilities. This includes investigating whether certain regulatory flexibility measures can be also applied in case of shortages for critical (non-Covid) medicinal products
- The EC Pharmaceutical Strategy for Europe paper proposes increased EU coordination in shortage management. CMDh will consider the work of the EMA EU Executive SG on shortages of medicines caused by major events to define any situations in which EU coordinated actions involving CMDh should be considered and to further define the role and responsibilities of CMDh/NCA's in respect of shortages for NAPs. Furthermore, as the SPOC network currently provides information sharing on shortages for critical medicinal products, CMDh will follow the work of this group and examine guidance documents on prevention of shortages, reporting of shortages, shortage management and monitoring (metrics) and public communication, to ensure the respective roles are adequately defined.
- As HMA and EMA coordinate initiatives in the area of availability e.g. HMA/EMA TF on Availability (TF-AAM) and its thematic working groups and subgroups, currently:
    - Thematic group 1: Marketing Authorisations

- Thematic group 2: Supply Disruptions
- Thematic group 3: Communication

- CMDh will follow the work of these groups and liaise in order to participate or discuss issues of mutual interest, in particular, Thematic Working Group 1 on Marketing Authorisations which may include actions for CMDh.
- CMDh will consider the outcome of the European Commission report on 'Future-proofing pharmaceutical legislation - a study on medicine shortages' and the Roadmap on pharmaceutical legislation, to determine any relevant CMDh implications and actions. Areas where changes to EU or national legislation could improve supply will be highlighted as identified. The implications of any suggested changes to documentation requirements for marketing authorisation applications will be reviewed for the MR/DCP procedures.
- CMDh will consider the outcome of the EC ad-hoc group on vulnerabilities, including dependencies, of the global supply chains, to determine any relevant actions under the remit of CMDh.

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Investigate ways/procedures to obtain a marketing authorisation in MSs where the product is needed and not authorised yet in a more efficient way than ordinary repeat use procedures	CMDh* in collaboration with TWG1 HMA/EMA TF-AAM	MS are able to easily and timely authorise critical / essential medicines	Medium term
Closely follow the outcome of the EC study "Future-proofing pharmaceutical legislation - a study on medicine shortages" and agree on CMDh actions, if applicable (implications for MRP/DCP, implications documentation requirements MAA, suggest areas where changes to EU or national legislation could improve supply)	CMDh* in collaboration with relevant stakeholders (e.g. EMA)	CMDh guidance is updated in line with the outcome of the study where relevant	Based on study availability
Facilitate increased EU coordination in shortage management (define situations in which EU coordination should be considered, further define role/responsibilities EMA vs. NCAs/CMDh)	CMDh* in collaboration with EMA	The roles and responsibilities of member states, CMDh, EMA and other cross-functional groups are clarified in order to determine whether CMDh has a relevant additional input here	Medium term

Investigate / promote initiatives aimed at reducing barriers to national access or distribution (including MLP, ePI (link to Theme 3 / Innovation)	CMDh MLP WG	Guidance is available and updated as required, on the expectations of member states for multilingual packaging	Medium term
Explore which lessons can be learned from the COVID-19 crisis (Investigate whether certain regulatory flexibility measures can be also applied in case of shortages for critical (non-Covid) medicinal products	CMDh* in collaboration with EMA and HMA and EC	The Commission paper on regulatory flexibility and any relevant 'lessons learnt' communications from EMA/HMA are reviewed, along with the Commission Roadmap on pharmaceutical legislation and the EC Pharmaceutical Strategy for Europe paper and relevant proposals are discussed and agreed as appropriate at CMDh	Medium term
Investigate ways to mitigate against 'regulatory triggered' shortages when implementing new guidance and legislation	CMDh* in collaboration with EMA, HMA and EC	The timing and necessity of new guidance or legislation is carefully considered to mitigate against the risk of shortages	Medium term

* Rapporteur(s) to be appointed.

2. Optimisation of procedures

The HMA/EMA European Medicines Regulatory Network (EMRN) strategy 2025 stresses the need for the network to ensure a framework for continuous optimisation that creates the right environment for change and improvement now and in the future, not only supporting better public health but allowing a vigorous and innovative regulatory European framework.

Ensuring an adequate use of resources by the competent authorities of the network is key to its continued role in safeguarding public health in the EU.

Regulatory optimisation to ensure best use of scarce resources, capacity, expertise and IT capabilities, therefore improving efficiency and resiliency of the network, is linked to the availability and the continuous supply of medicines in all EU member states, promoting generics and biosimilars, adapting/implementing new pharmaceutical legislation, a flexible regulatory environment and preparing for crisis response.

The network should address reduction of regulatory burden and CMDh should actively participate in the HMA/EMA Regulatory Optimisation Group to develop network thinking assisted by information technologies.

Aiming at simplification and streamlining of procedure and sharing of resources namely through worksharing will address some of the challenges faced by the network.

As foreseen in the Pharmaceutical Strategy, review of legislation will play a major role for optimisation in the next years. Nevertheless, there are several initiatives that can be considered outside the legislative framework, that could allow a more effective way of working:

- Measure the efficacy of optimisation procedures already in place to address the need for further improvement.
- Strive for sustainability of the network and operational excellence by strengthening the collaboration within the network.
- Build on the experience with work-sharing to improve work-sharing already in place and the network resilience and use of resources through new work-sharing procedures.
- Flexibility of authorisation procedures is important in case a product should be made available in another MS (especially in case of shortages of medicinal products in MSs). This could be a case to use an ongoing DCP under assessment.
- CMDh should investigate if further simplification of renewals under the legal framework is possible.
- Data analytics, digital tools and digital transformation is one of the key areas of the European Medicines Agencies Network Strategy. CMDh should promote actions to further progress digital transformations of regulatory procedures with a view of simplification, data standardisation and reuse and regulatory efficiency.
- Combat antimicrobial resistance is one of the six strategic focus areas of the European Medicines Agencies Network Strategy, and harmonisation of product information is one of the measures envisaged. CMDh should collaborate within the network to promote such harmonisation using work-sharing.

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Undertake a review of the efficacy of optimisation procedures	CMDh MS rapporteur for the optimisation measure	Adherence to validation checklist Additional guidance for companies to fill in validation checklist Shared validation checklists form for new MAA in CTS Perceived flexibility of how RUPs allow getting a marketing authorisation in MSs where the product is needed Evaluate use of early DCP closure Assess in what extent the initiative regarding data integration between DADI and CTS has contributed to regulatory optimisation, namely by reducing workload, better	Short term Medium term

		interchangeability of data and/or promoting transparency Further discuss the inclusion of new CMS(s) in ongoing applications (beyond the already agreed CMDh position paper)	
Strengthen the collaboration within the network by exploring the use of multinational assessment teams	CMDh Chair	Explore the interest, feasibility and usefulness of multinational assessment teams in DCP Questionnaire to Member-States regarding previous experience from MS, practicalities, and potential impact on resource use Possibility to start a pilot and retrieve experience from member states	Medium term
Further promote and improve work-sharing already in place: ASMF; HaRP; harmonisation of therapeutic indications (link to Theme 4 / Prepare for legislative changes)	CMDh working parties / working groups	Increase use of ASMF work-sharing. Expand to ASMFs previously assessed in DCP/MRP/CAP and national applications Simplify procedure by omitting ASMF Rapporteur switch during evaluation within current legal framework Assess in what extent the HaRP initiative resulted in more substances with safety concerns reviewed, facilitates assessment of RMP and promotes its harmonisation Promotion by CMDh of harmonisation of therapeutic indications of national procedures through work-sharing	Long term Medium term Short term Medium term
To promote and encourage new work-sharing procedures (link to Theme 4 / Prepare for legislative changes)	CMDh	Discussion with the European Commission, especially related to EC Pharmaceutical Strategy paper, on the adoption of new procedures for worksharing: - Bioequivalence studies - Sharing of similarity assessments	Long term

		- Core product information for generics - Core product information for antimicrobials (AMR)	
Working within the current legislation and regulatory framework, streamline and allow more flexibility in the procedures for renewals (link to Theme 4 / Prepare for legislative changes)	CMDh	Flexibility of submission date for renewals Extend the scope of short renewals	Medium term
Work within ROG to investigate and put in place ways to optimise procedures using information technologies	CMDh ROG member	Discuss the need for supplemental databases and data interoperability to better support current and new work-sharing or other use cases Discuss the integration of variations directly in a database, considering the new veterinary regulation (link to Theme 4 / Prepare for legislative changes)	Medium term
Promote new practices in the MAAs to improve assessment report processing	CMDh	Explore the possibility of integration of Assessment Report generation into DB-Systems, including e.g. Automatically fill out the administrative part of assessment reports and interactive mode of creating/ updating reports with parts for industry (e.g. Responses to objections) and authorities (e.g. evaluation of Response with outcome) in connection with DADI and SPOR projects. Allow use of CTS as a document repository, to empower the detection of possible work-sharing candidates and to reduce regulatory burden in NCAs.	Long term

3. Innovative Projects

The EU regulatory network is always striving to improve its operational efficiency, to improve the access of patients to medicines and to make information better accessible by all involved partners (including health care professionals and patients). Throughout the recent years, several innovative projects have been launched within the EU regulatory network and the CMDh is determined to contribute to these projects as an active partner.

- Electronic product information (ePI): A medicine's product information is regulated, scientifically validated information that assists healthcare professionals in prescribing and dispensing and informs patients and consumers about their medicine and its safe use. The development of ePI is intended to improve access to up-to-date product information on medicines when and where it is needed. The CMDh has been involved in the development of key principles to guide the development and use of ePI in the EU. The further involvement of the CMDh in the project is essential to ensure a smooth implementation for MRP/DCP and national procedures with the aim of gaining efficiency for the regulatory system.
- EU projects related to innovation: Several initiatives are ongoing in the EU e.g. to foster innovation, ensure safe and timely access of medicines to patients, to address emerging health threats and in the framework for repurposing of existing medicines. The CMDh has to play an active role in these initiatives. The role of the CMDh and relevant actions within the remit of the CMDh should be defined in collaboration with HMA.
- Repurposing of existing medicines: Repurposing is defined as the process of facilitating the justification of a new therapeutic use for an existing medicine outside the scope of the original indication(s), with the purpose of seeking a marketing authorisation. The CMDh will explore its role in identifying new/ongoing applications for known active substance with new indications with the aim to assess these in a harmonised way. Furthermore, CMDh will give advice for smooth and simple implementation of these data into existing marketing authorisations.

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Support development and implementation of electronic product information (ePI) NB this topic is connected to Regulatory optimization in chapter 2.	CMDh (rapporteur to be appointed for participation in EMA working/project groups)	CMDh participation in EMA project on development of ePI. Implementation of ePI for MRP/DCP and national procedures. Striving for efficiency gains for regulatory systems / additional benefits for NCAs	Short term Long term (but hopefully first pilot for MRP/DCP Medium term) Medium term
Ensure CMDh involvement in EU projects related to innovation (including STAMP repurposing project). E.g exploring the role of CMDh in	CMDh/HMA	Define possible role of CMDh in collaboration with HMA.	Short term

collecting information based on national scientific advices/ or ongoing applications for old substances for new indications (repurposing) and discuss with EMA the need for regulatory pathways or other ways to assess these in a harmonised way		Conclude on relevant actions within the remit of CMDh, as appropriate.	Medium term

4. Preparation for legislative changes

The existing legislation is the essential backbone for the authorisation and the supervision of medicinal products in the European Economic Area (EEA) and to build the framework for the practical implementation of the aims of the legislators via guidelines and advice given by national competent authorities and the Agency.

Legislation in the area of medicinal products as well as in more operational and regulatory aspects needs to allow some flexibility to accommodate new scientific approaches and practices. Working in a network of independent member states, this is a challenge, as the flexibility has to be based on a harmonised approach. Especially administrative procedures have to be aligned to be able to safeguard public health on the one side, but also try to avoid unnecessary administrative burden.

The CMDh is a unique tool for the Member States

- to align the interpretation of legislation and to reach a common understanding;
- to react to new challenges based on new scientific approaches;
- to have a common understanding of a risk-based approach within the existing legal framework;
- to give high quality guidance to all stakeholders.

CMDh is aimed to achieve this by close collaboration with

- member states, the HMA and it’s working groups e.g. EMACOLEX;
- the NTA through the Member States;
- the EMA and European Commission Services;

on the potential areas

- for improvement of existing legislation and Guidelines;
- on the need to further develop legislation and Guidelines;
- on potential pitfalls of new guidance on legislation in respect of unnecessary administrative burden.

In the view of upcoming changes to the legislation already announced in the Pharma strategy paper by the European Commission it is of utmost importance to consider already existing tools in other areas (e.g the new veterinary regulation) as well as rapidly developing IT tools (e.g. SPOR) and to carefully consider the possibility of using those also for an amendment of the legislation for medicinal products for human use. However, well-functioning structures should not necessarily be amended, only advantageous aspects should be considered for an update.

Changes to the legislation should make use of new telematic features and support a reduction of the administrative burden for both, national competent authorities as well as applicants. Facilitations for the joint assessment should be introduced like the single assessment of ASMFs, mandatory worksharing for harmonisation of indications and safety information and the possibility of using the worksharing also for other procedures like BE study or similarity assessment. The new legislation should also be used to delete unnecessary burdensome processes like renewals or RMPs for generic applications and to strengthen procedures to facilitate the availability and safe use of medicines as well as enable a better harmonisation of medicinal products throughout Europe.

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Carefully consider the New Veterinary Legislation for future updates of the legislation for human medicinal products and learn from experience; adapt useful aspects but do not amend well-functioning structures	EC/EMA/CMDh/HMA	Less administrative burden for both, NCAs and industry	Long term as NVR is not yet implemented
Make use of features to improve harmonisation of product information in Europe, e.g. mandatory worksharing, ePI (see also action points theme 3)	EC/EMA/CMDh/HMA	Increase the number of worksharings, especially with harmonization content by introducing the mandatory worksharing Strive to have the ePI included in the new legislation	Long term, when legislation will be amended
To be actively involved in the preparation of the new legislation as part of the EC pharma strategy and to allow procedural changes that are currently not possible, see also point 4 of action theme 2; e.g. use amendment of legislation to delete unnecessary procedures, e.g. renewals or RMPs for generic applications etc.	EC/EMA/CMDh/HMA	Delete the necessity for submitting renewals by deleting them in the new legislation Reduce the number of RMPs for generic medicinal products to be assessed by deleting them in the new legislation Explore possibilities for new procedures to be included into the new legislation, e.g. • Worksharing for BE studies	Long term, when legislation will be amended

		• Sharing similarity assessments • Provide Core SmPCs • Provide core safety information • Etc.	
Make use of new telematics features to facilitate the handling of applications. (see also tasks of the ROG)	EMA/CMDh/HMA/ROG	Support for SPOR: data mapping and preparation for the implementation of PMS. Web-based application forms for all types of applications, introduce ePI in legislation (see also theme 3) Close monitoring of UPD implementation	Short term Medium term
Discuss options for introducing single assessment of ASMFs into the new legislation	ASMF WP EC/EMA/CMDh	Improved handling of ASMF assessment with a single lead MS with inclusion of single assessment into the new legislation	Long term

5. Optimisation of communication/relationship/meetings with Interested Parties and stakeholders

The EU Medicines Agencies Network Strategy to 2025 establishes effective communication as paramount not only to optimise the operation of the network but also to achieve a network of excellence, whereby proactive communication and cooperation should be fostered at both national and EU level.

The CMDh is formed of representatives of the EU Member States plus the three EFTA States - Iceland, Lichtenstein and Norway. These representatives empower the CMDh to pursue and ensure proactive and harmonised EU communication between Member States by creating its own communication strategy with the support and commitment of National Agencies. In this respect, the alignment of the CMDh strategy with the HMA strategic communication plan, EMA and EC workplans and those of the National Agencies is crucial.

The CMDh is transparent and open in the majority of its activities including the publishing of agendas, minutes, press releases, Questions & Answers, procedural guidance, pharmacovigilance activities, annual work plans and face-to-face meetings, but there are still areas and aspects which need to be improved. The interaction with Interested Parties could be extended to provide efficient, targeted and timely information in a proactive manner, expectations from IP should be considered by CMDh, especially on specific topics. CMDh should also indicate to Interested Parties what they expect from

them. It should be explored whether Interested Parties could in the future also be integrated in specific CMDh projects like e.g. the multilingual packaging project or HaRP.

A key prerequisite for efficient, effective and productive CMDh operation is a pragmatic and proactive communication strategy to attain increased CMDh relevance within the network, as well as awareness and understanding of the role and significance of CMDh within the EU.

The CMDh Communication Strategy should cover all main areas of its activity and influence and is regarded necessary in the following situations:

- Among MSs;
- Between the CMDh and CMDv;
- Communication with National Agencies through the CMDh member
- Communication with EMA, for example to discuss whether meetings from EMA with stakeholders on some topics can be combined with CMDh to avoid separate discussions on same/common topics
- Communication with industry including face-to-face Interested Party (IP) meetings;
- Communication between specific industry stakeholders and CMDh or CMDh working groups in meetings on specified topics
- Communication with health care professionals and patients;
- Communication with the EC and the NTA, especially with regard to an update of the legislation for human medicinal products
- Communication with HMA on common topics, e.g. availability of medicines or procedural optimisation;
- Interaction between the CMDh and the ROG (regulatory optimisation group of HMA)
- Close interaction with telematics working groups in order to ensure IT development according to business requirements
- Participation in EU communication Working Parties and contact with experts in communication;
- Communications among MSs in all scientific discussions including those at the CMDh plenary meetings, breakout sessions and during CMDh referrals;
- Communication with EMA Scientific Committees and Working Parties;
- The provision of comments to EMA Scientific Guidance Documents during consultation.
- Discussion of the scientific background for possible referral procedures
- Communication between the CMDh and International bodies where relevant with the aim of increasing collaboration.

To ensure an effective Communication Strategy, the four key features of CMDh communications are:

1. All communication should be focused on objectives.

2. All communication of the CMDh should be necessary, relevant, clear, concise, correct, unambiguous, factual, objective, and authoritative, and where relevant, the communication should be binding, executable and harmonised across the EU.

3. Communication models, frameworks and channels should be sufficiently flexible to be adapted to ongoing change.

4. Outcomes and results of key communications issued should ideally be measurable in terms of appropriateness, effectiveness and followed up to establish that objectives have been achieved.

Action points

Actions	Lead	Performance indicators	Priority/Timeline
Improve interaction with IPs and provide efficient, targeted and timely information in a proactive manner	CMDh chairs/secretariat	Survey to IPs to investigate both their needs/expectations/ideas for meetings/interaction and usefulness of current Q&As/Practical Guidance documents and Best Practice Guides Review outcome survey and propose action as appropriate	Short term Medium term
Explore possibility of separate meetings with e.g. one trade association and CMDh or CMDh WG.	CMDh chairs/secretariat/chair respective WP	Arrange separate meetings as appropriate	Short term
Include IPs in ongoing CMDh projects as needed	CMDh	To identify topics that would benefit from early input from IPs	Medium term
To continue/further improve bi-directional communication between: • CMDh and CMDv • CMDh and EMA • CMDh and European Commission • CMDh and HMA • CMDh and NtA	CMDh chairs/CMDh secretariat in collaboration with EMA/EC/HMA/CMDv	Identification, assessment and publication of common CMDh & CMDv agreements on the CMDh webpage. To consider topics from NVR that are relevant Liaise with EMA on their meetings with stakeholders to decide whether it would be beneficial to hold combined stakeholder meetings with EMA and CMDh or whether separate stakeholder meetings with CMDh only are needed (depending on the topic) see also action 2 Identification of issues for discussion with the European Commission, especially	Continued action from previous MAWP, plus addition of interaction with NtA and telematics WGs

• CMDh and telematics WGs		related to EC Pharmaceutical Strategy paper: revision Directive 2001/83/EC Liaison with the HMA on common action points. Also make sure that meetings with IPs and HMA are known and vice versa Liaison with NtA to bring guidances in line with updated legislation Liaise with telematics working groups to ensure that IT development supports business requirements	