Submission of comments on CMDh Multi-Annual Workplan to 2025

EMA/CMDh/62111/2022

Comments from:

| Name of organisation or individual |
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| EFPIA – European Federation of Pharmaceutical Industries and Associations |

CMDh MAWP:

<https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/About_CMDh/CMDh_Activities/Workplans/CMDh_Multi-annual_Workplan_to_2025.pdf>

# Introduction

EFPIA welcomes the CMDh multi-annual workplan (MAWP) to 2025, which is complementary to the HMA multi-annual workplan and the HMA/EMA European Medicines Regulatory Network (EMRN) strategy 2025.

EFPIA member companies fully endorse the overall priority objectives:

* 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

Within the priority objectives the MAWP provides a clear framework of tangible actions and transparency. EFPIA is pleased to offer comments on the draft consultation and trusts that these remarks will be useful as the plan is finalized and implemented. EFPIA and its member companies stand ready to partner with CMDh and other stakeholders to realize the collective actions outlined.

Specific comments: Availability of essential medicines / coordination during crisis

| Action points | Comment and rationale; proposed changes |
| --- | --- |
| 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 | EFPIA support agile processes to obtain marketing authorisation and ensure products are authorised where they are needed. However, agile approaches should ensure relevant regulatory evidentiary standards continue to be met and where regulatory data protection exists, this is done in partnership with the MAH of the reference product. |
| 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) | The EC’s structured dialogue process clearly demonstrated that shortage mitigation and management measures need to be adapted to the specifics of each particular situation, e.g. therapeutic area, category of product and presence of alternatives on the market, etc. One-size-fits-all will not work, and EFPIA therefore calls for the future legislation to differentiate among the products, to allow the flexibility that will ensure the different actors can take the necessary steps in order to ensure the availability of the respective medicines. In this regard, some measures put forward by a few stakeholders in the context of EU Structured Dialogue on Supply of Medicines such as mandatory dual sourcing of Active Pharmaceutical Ingredients (APIs) could fail to deliver on their objective, and at worst be counterproductive, for example for innovative and/or low volume products. Priority should be given to critical products, assessed based on potential medical impact of a shortage, likelihood of a shortage and presence of an alternative product on the market. |
| Facilitate increased EU coordination in shortage management (define situations in which EU coordination should be considered, further define role/responsibilities EMA vs. NCAs/CMDh) | Action will be most efficient and relevant if organized and coordinated at above-country level. Companies run global supply chains and are more likely to be able to ensure continuous supply to all EU countries if the action is coordinated at international level. The EU offers the right political and legal platform to build a European integrated system, based on Member States’ solidarity and coordination. This should be based on a continuous dialogue between competent EU and national competent authorities and manufacturers with a view to addressing any imbalances between demand and supply. Concrete actions taken by the European Commission and the European Medicines Agency in the COVID-19 crisis led to clear improvement after the early weeks of the crisis and demonstrated the relevance of a European coordinated action. Action taken on a national level can have a detrimental effect on the supply of medicines in other countries, e.g. mandatory national stockpiling requirement of finished products would be duplicative and suboptimal, preventing the reallocation of stocks where most needed by patients. This structural inefficiency can result in waste and shortages. |
| Investigate / promote initiatives aimed at reducing barriers to national access or distribution (including MLP, ePI (link to Theme 3 / Innovation) | [Ref. IATF letter appendix] |
| 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 | EFPIA research has confirmed that regulatory flexibilities[[1]](#footnote-1) provided during the pandemic have been of critical value to provide accelerated rapid innovation and facilitate lifecycle management, and a number of these flexibilities will be of importance to maintain in the post-pandemic era. These flexibilities should not be read as lowering the standards, but more to streamlining the procedures and removing red tape to make the system more agile to operate in. They can serve two of the objectives outlined for the review of the current legislation: (1) removing unnecessary often historically grown administrative challenges in the system to free resources for innovation, and (2) improving EU’s competitiveness in access to innovation by facilitating development, approval and supply. |
| Investigate ways to mitigate against ‘regulatory triggered’ shortages when implementing new guidance and legislation | As always when dealing with a complex environment with multiple factors interplaying one with another, policy measures can have undesirable side-effects. EFPIA is concerned that some of the measures meant to prevent shortages are likely to have an impact on the availability of current and future medicines and could eventually affect patients. Measures requiring a disproportionate use of resources will typically have a deterrent economic effect on the marketing of products. This calls for policy measures that have demonstrated their ability to deliver on their objective (evidence-based), and applied meaningfully (risk-based approach). |

Specific comments: Optimisation of procedures

| Action points | Comment and rationale; proposed changes |
| --- | --- |
| Undertake a review of the efficacy of optimisation procedures | As part of EMA’s digital business transformation vision, the agency has expressed the need to move away from purely document-based processes to more data driven assessments. DADI is going to play an instrumental role in this transformation, for the entire network. This action point here assumes that the data integration that DADI brings to regulatory optimisation will be reviewed, especially around reducing workload, better interchangeability of data and/or promoting transparency. However a lot of this data has the potential to be reused further down the line, so it will be key to not just take a short-sighted view to the effect of data use during the procedural step(s) but also review and consider the benefits that this data, once fully assessed or validated and therefore a single source of truth, can bring to numerous other use cases: ePI, EMVO, shortages, integration with (e-)prescribing systems, and many more. |
| Strengthen the collaboration within the network by exploring the use of multinational assessment teams | EFPIA welcomes further strengthening collaboration within the network and is open for further discussions on resources / capacity.  |
| To promote and encourage new work-sharing procedures (link to Theme 4 / Prepare for legislative changes) | This action includes a performance indicator concerning new procedures for worksharing on core product information for antimicrobials. EFPIA is of the view that careful consideration needs to be given prior to initiating efforts to harmonise product information as a measure to help combat antimicrobial resistance. Harmonisation of product information would not necessarily be appropriate across all MSs as the epidemiology and resistance profiles of infections is different, and the resulting worksharing procedures could result in a high administrative burden.  |
| Work within ROG to investigate and put in place ways to optimise procedures using information technologies | Currently, disproportionate levels of resources are allocated to the variations process in view of the overall benefit they provide to patients and the entire regulatory system. Raising efficiency and streamlining regulatory processes is a prerequisite for a modern regulatory system that can respond to the changes in the environment. Developments in new information technology (IT) systems provide the opportunity to incorporate efficiency and innovation into the management of variations. EFPIA acknowledges the important work that the ROG has already undertaken in this area and fully supports the proposal for further work to ensure that this opportunity, facilitated by a review of the legislative provisions, is realized. Digital solutions offer enormous opportunities to maintain administrative details associated with the marketing authorization directly in an EU database, with Competent Authorities having full access to the content. This processing principle already accounts for changes related to the Qualified Person for Pharmacovigilance (QPPV) and the location of the pharmacovigilance system master file (PSMF) via the Article 57 database and is now further recognized in the Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 on Veterinary medicinal products.EFPIA believes that lowering the volume of submissions and thereby reducing the average time spent on Type IA notifications through a combination of processing changes and optimal use of IT systems (including substance, product, organizational and referential (SPOR) master data) could lead to a substantial reduction in the manpower currently engaged in these largely administrative tasks. The technology upon which the solutions are built needs to be robust yet flexible to enable fast adoption along with changing legislative requirements. SPOR, and its Target Operating Model (TOM) provide a platform and process by which data-only submissions (following the FHIR data standard) are possible; the use of this mechanism should be established to enable simplified processing of Type IA notifications.Finally, it is important to acknowledge that the proposed improvements in efficiency through process optimization are intended only to reflect a re-prioritization of regulatory oversight and should not undermine the overall financial stability of Competent Authorities. |
| Promote new practices in the MAAs to improve assessment report processing | As stated above, EFPIA sees several opportunities in the reuse of structured product data in multiple use cases. This example, of automatically filling out administrative parts of assessment reports and interactive mode of creating/updating reports with parts for industry and authorities connected to DADI and SPOR, seems to be a perfect one of how authoritative product data can be leveraged. As we understand it, there are likely many more opportunities, thus it would be key to establish a broader vision for how and where the data can be reused to eliminate duplicate submissions, duplicate data entry and repetitive re-typing of information.EFPIA recommends that the improvement of assessment report processing be added as a specific project in the overall strategic roadmap and data requirements be added to the SPOR master plan to ensure that master data will be available for this purpose |

Specific comments: Innovative Projects

| Action points | Comment and rationale; proposed changes |
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| Support development and implementation of electronic product information (ePI)NB this topic is connected to Regulatory optimization in chapter 2. | [Ref. IATF letter appendix] |

Specific comments: Preparation for legislative changes

| Action points | Comment and rationale; proposed changes |
| --- | --- |
| 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 | EFPIA notes the progress with the implementation of the New Veterinary Legislation and fully supports extending some of the more progressive principles and concepts, where applicable, to revisions of the legislation for human medicinal products. In particular, the pragmatic approach taken to simplify the variation framework under the New Veterinary Legislation may be a very helpful starting point for further discussion and revision of the variation framework as it applies to human medicinal products. Indeed, some of the learnings on the veterinary side which have been gained through the development of the ‘variations not requiring assessment (VNRA)’ concept and the implementation of the Union Product database should be taken into consideration by the ROG and within industry as we look to co-create a more efficient framework for variation management.  |
| Make use of features to improve harmonisation of product information in Europe, e.g. mandatory worksharing, ePI (see also action points theme 3) | [Ref. IATF letter appendix] |
| 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. | EFPIA welcomes discussions with CMDh on optimisation of procedures by deleting administrative/unnecessary procedures / procedural steps.  |
| Make use of new telematics features to facilitate the handling of applications. (see also tasks of the ROG) | A key ask from EFPIA is to ensure broad adoption of ISO IDMP and SPOR across all CMDh/HMA members. * What is needed to achieve this, is a network-wide agreed timeline and commitment to a common goal of using and sharing IDMP data.
* Then through clear governance and leadership, shared by EMA and HMA, timelines, roadmaps, and pilots must consequently be built with the involvement and commitment of National Competent Authorities (NCAs) and industry. As part of the network-wide adoption, clear actions need to be taken to prepare for SPOR through data mapping.
* Today only a limited number of NCAs have started this process, and only 11 NCAs are actually engaged through the UNICOM project with IDMP in some form. DADI will be a first step to introduce web-based forms as a means to exchange structured data with the regulatory authorities, but it has to be expanded beyond the scope of regulatory procedures: all types of data submissions, the ones requiring regulatory assessment as well as the ones not requiring assessment, should be enabled by this mechanism. Also, it will be paramount to prioritise the enablement of system-to-system communication using HL7 FHIR to fully realise the Target Operating Model and to achieve high efficiency and data quality, as the information is fed through the “data supply chain”. Introducing ePI in legislation could be a catalyst to prioritise FHIR data communication with industry.
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Specific comments: Optimisation of communication/relationship/meetings with Interested Parties and stakeholders

| Action points | Comment and rationale; proposed changes |
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| Improve interaction with IPs and provide efficient, targeted and timely information in a proactive manner | EFPIA supports improved interactions |
| Explore possibility of separate meetings with e.g., one trade association and CMDh or CMDh WG. | EFPIA supports possibility for separate meetings |
| Include IPs in ongoing CMDh projects as needed | EFPIA welcomes to be involved in future/ongoing CMDh projects |
| To continue/further improve bi-directional communication between:• CMDh and CMDv• CMDh and EMA• CMDh and European Commission• CMDh and HMA• CMDh and NtACMDh and telematics WGs | The Network has recently introduced new ways of working with regard to an agile governance for IT network strategy and execution. There is a clear need to establish a dialog, inclusive of all stakeholders, not only the directly involved ones like the EMA IT teams and product owners, but also the industry users, the agency’s business as well as the national authorities’ IT and business functions. The CMDh has a key role to play to ensure long-term success and adoption across the network.  |

1. https://doi.org/10.1007/s43441-022-00383-3 [↑](#footnote-ref-1)