27 November 2015

Submission of comments on CMDh Strategy to 2020  
(CMDh/335/2015, Draft)

Comments from: EFPIA

| Name of organisation or individual |
| --- |
| EFPIA – Pär Tellner (par.tellner@efpia.eu) |

*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*

*When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).*

**Introduction**

EFPIA commends the Coordination group for Mutual recognition and Decentralised procedure for human medicinal products (CMDh) for its laudable efforts to establish and progress an enduring strategy. Accordingly, EFPIA is pleased to offer comments on the Consultation draft of the CMDh Strategy to 2020 (CMDh/335/2015, Draft) and trusts that these remarks will be useful as the strategy is finalised and implemented.

EFPIA brings together 33 European national pharmaceutical industry associations as well as 40 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use. In its Strategy to 2020, CMDh mentions that the “strategy is in line with EMA/HMA strategy to 2020”[[1]](#footnote-1) for which EFPIA previously had the opportunity to offer comment. While the comments included at this time are tailored towards the CMDh’s strategic plan, EFPIA does propose several similar themes to those formerly presented in our response to EMA/HMA’s 5-year strategy document. Practically, within these comments, EFPIA does not list each of the many aspects of the Strategy to 2020 that we fully support.

EFPIA member companies fully endorse the overall goal stated in the Strategy to 2020 which is “to ensure availability of safe and effective medicines that promote and protect public health across the network”1. We believe that a well-constructed strategy, collaborative stakeholder engagement along the way, and frequent tracking of progress will, in the end, enable the EU mutual recognition (MRP) and decentralised procedures (DCP) to achieve this aspiration. EFPIA and its member companies stand ready to partner with CMDh and other stakeholders to realize this collective goal.

1. General comments

| General comment |
| --- |
| **Achieving enhanced harmonisation**  Importantly, in the introductory section, CMDh puts forth its principal mission to “achieve harmonisation”. There are few EU organisations that must coordinate, collaborate, network and harmonise to the same elevated level as CMDh in order to meet its regulatory objectives.  In fact, in acknowledgement of this aspect of its activities, CMDh prominently mentions the words ‘harmonise’ and ‘harmonisation’ a total of 15 times within its Strategy. For example, CMDh states its “(aim) to achieve harmonisation when appropriate in all Member States and aim to increase consensus opinion amongst the Member States, where possible when voting is required”1. Also, mentioned is CMDh’s plans to “continue to contribute to global harmonisation initiatives”1. Indeed, there are repeated references to ‘collaboration’, ‘coordination’ and ‘harmonisation’ between Member States and stakeholders, however there is minimal clarification on stakeholders of focus or the proposed actions to achieve this.  The CMDh reiterates its desire to promote work-sharing to ensure best use of resources. However, greater clarity is needed on mechanisms to facilitate greater information sharing. The idea of ‘efficiency’ and ‘timely processes’ is emphasised; it would be helpful if the Strategy further explained how it plans to engage stakeholders to facilitate this.  EFPIA considers that the CMDh’s efforts to harmonise and streamline regulatory practices for MRP/DCP is paramount for reducing the administrative burden for National Competent Authorities (NCAs) and industry, and therefore, the availability of new medicines for patients. While noting the progress CMDh has achieved in this regard, EFPIA suggests that there are some areas that could benefit from even greater harmonisation. There is a need to seek further harmonisation also between CMDh/NCAs and EMA, specifically concerning interpretation of Directives and Regulations and subsequent implementation.  Further, the single process for submission delivery should be prioritised. EFPIA also believes that greater transparency between the NCAs and the applicants on progress of their applications (MRP/DCP pre and post-MA applications, including cause of any delays) should be harmonised and standard practice. This could be encouraged and facilitated by the CMDh. |
| **Prioritising and Resourcing**  We welcome that the strategy has clear messages on the CMDh’s proposed activities through 2020. However, in order to be the most efficient and effective, it may be useful for the strategy to prioritise objectives and provide expected timelines. It is necessary to understand how the CMDh, NCAs, HMA and other stakeholders will divide and coordinate activities to achieve these strategic objectives. Prioritisation, resourcing, and new initiatives should be fully communicated and established through consultation with stakeholders. We presume that the CMDh intends to develop task prioritisation, resource allocations, and project plans necessary for realising this strategy.  It would be most helpful for the CMDh to address the cases of old products with multiple national licences across the European Union, where regulatory maintenance is difficult to harmonise. It may be beneficial to consider the development of a straightforward mutual recognition / decentralised procedure ‘umbrella’ mechanism over existing National procedures.  As another priority, we also believe that the Strategy to 2020 should address the repeat-use procedure as the current procedure is unnecessarily burdensome.  Finally, it is important that implementation of the individual initiatives in the Strategy to 2020 does not delay patient access to new treatment options through MRP/DCP nor increase the burden on Regulators or on industry. As helpful, industry would be interested in being involved and providing input during these next stages of implementation. |
| **Communicating Progress**  EFPIA proposes that CMDh develop a full communication strategy to ensure that all of the concerned stakeholders remain informed on the progress. As one aspect of this plan, perhaps, CMDh’s Strategy to 2020 could be a standing agenda topic during the biannual Interested Party meetings for which industry participates. If so, updates on the CMDh’s current priority activities, resourcing issues and opportunities for further collaboration would be welcomed.  CMDh notes that the “strategy will be complemented by annual work plans which will set up more detailed activities to take forward the high level strategy”1. While EFPIA appreciates that these work plans may not be directly posted, as much as possible, the general work plans and progress made within the work plans should be shared with stakeholders. |

1. Specific comments on text

| Line number(s) of the relevant text | Comment and rationale; proposed changes |
| --- | --- |
| Page 4 | In its Strategy to 2020, the potential interactions with Healthcare Technology Assessment (HTA) bodies are not mentioned. It would be helpful to suggest where interactions including HTA bodies may occur. |
| Page 5 | CMDh states its regulatory priority of “(ensuring) clear, practical, implementable and understandable product information is communicated to patients and healthcare professionals in a timely manner”. EFPIA concurs that this is a critical activity of CMDh for MRP/DCP products.  The product information is able to contribute to enhancing overall patient health literacy levels. Therefore, the regulated product information must become a useful and trusted reference for informing prescribers and patients about medicines. While there is mention of the need to improve the efficiency of new information reaching patients and healthcare professionals, in terms of communications and use of digital media, the primary focus seems to be on business and regulatory needs. It would be useful for the Strategy to further address how the proposals would be expected to beneficially impact patients.  The strategy paper would also benefit by including reflections on the development in the fields of e-health. From a product information context perspective, there is a need to further streamline the dissemination of the product information. As the EU network is still lacking an up-to-date integrated database containing the product information of all the approved medicines in Europe. Further, CMDh’s support and involvement in the concept of progressing the possibility of electronic package inserts would be welcomed by industry and help achieve this stated goal. |
| Page 5 | Another CMDh priority is to “(s)treamline processes and further reduce administrative burden for all Member States and industry and make best use of the resources available in the Member States and avoid duplication of work” (pg. 5)1. Regarding reduction of the administrative burden, it would be useful to consider the issue of additional national requirements. While significant progress has been made on this aspect, continued attention is warranted (*e.g.,* CESP). |
| Page 5 | EFPIA believes that the objective ‘to streamline’ could benefit from enhanced tracking for the applicant to check the status of their submission(s) and the ability to make available pre-established calendars (as is done by EMA). |
| Page 5 | Also for harmonisation, CMDh could consider posting on its website the priorities and challenges identified by the Working Parties of the CMDh.  It is recognised that further integration in topic discussions with EMA (*e.g.,* stakeholder meetings) would be welcomed in order to achieve harmonisation and further development of network. |
| Page 5 | The role of the Reference Member State (RMS) should be further defined. Several initiatives have begun already. However, over the long-term, the RMS’s role should be further reinforced regarding decision making in order to avoid any kind of arbitration between the RMS & one or more of the Concerned Member States (CMS). |
| Page 5 & 10 | CMDh recognises the pivotal role that IT tools and systems will play in achieving enhancements in 2020 and beyond. “Support the implementation and development of new IT tools and processes (telematics), in the Member States”. While progress has been achieved, there is a need to have comprehensive IT discussions with all stakeholders.  Since there is a high level of ongoing telematics development work on EudraVigilance, the PSUR repository, and EU Clinical Trials Database and Portal, EFPIA will continue to engage in dialogue with EU regulators and other stakeholders as it awaits efficient functionality of these pending systems.  CMDh could strengthen its statement on the need for the most efficient connection between the National and the EU IT systems as well as for a gradual convergence of National systems. Also, CMDh could reinforce the objective of electronic submissions through one single portal - avoiding shipments of DVDs to agencies for ALL procedures (not only submissions of new MAA or variations). |
| Page 6 | CMDh plans to “(f)urther develop and enhance the collaboration between the CMDh and the US Food and Drug Administration (FDA), the World Health Organisation (WHO) & the International Conference on Harmonisation (ICH)”. As medicine development truly is a global venture, EFPIA strongly supports CMDh in engaging with other regulatory agencies to foster greater compatibility and assist some in developing their capabilities. We encourage CMDh to further define the level and type of collaboration within the scope of their core competencies (*e.g.,* ASMF, generics applications, and mutual recognition framework). |
| Page 7 | In its strategy, CMDh acknowledges that “(s)ome steps of these procedures, like validation/granting the national license after the MRP/DCP has been finalised, may need further improvement. Further ideas need to be explored together with trade associations”. EFPIA appreciates the suggested opportunity to participate in consideration of ideas for further improvement. EFPIA agrees with this objective and would prioritise it over many of the other stated objectives in order to reduce administrative burden and facilitate availability of medicines to patients.  In its coordination role, CMDh could work to ensure that the NCAs release National authorisations within an expedient time (*i.e.,* 1 month). Not only should the CMDh investigate other, more efficient ways in which to obtain a marketing authorisation in a Member State (where a medicinal product is not already authorised), but the CMDh should also consider simplifying the existing repeat-use procedure (RUP).  One approach is to adopt a simplified, administrative procedure similar to the Day 0 RUP introduced by Cyprus or a shortened procedure similar to the simplified CADREAC procedure. A simplified approach would be particularly helpful where a national licence is held by a NCA that wants to join an existing MRP.  Finally, it should also be clarified that this objective includes the translation review process. |
| Page 7 | EFPIA considers CMDh’s mention of the “possibility for an applicant to ask scientific/regulatory advice from CMDh before submission of the application” most essential.  Published regulatory agency data demonstrate that early and ongoing dialogue with regulators leads to a higher likelihood of a positive regulatory outcome. Therefore, EFPIA would welcome the timely initiation of this option. |
| Page 8 | While the sharing of DCP assessment reports with agencies outside Europe has already been piloted and is currently being considered for expansion, it is important that the receiving regulatory agencies maintain the assessment reports in strict confidentiality and do not further share them with third parties (*e.g.*, another regulatory agency, non-governmental organisation). A confidentiality agreement between the sending and receiving regulatory agencies should be established *a priori*. Also, there should be a notification to MAH in case of sharing of an assessment report.  Finally, there needs to be visibility of the impact of the sharing of assessment reports within EU. For example, communication of the specific advantages, since it currently seems that there is still a full assessment conducted by the receiving parties even in light of sharing of the assessment reports. |
| Page 8 | CMDh has noted its intention to “(d)iscuss the possibility of accepting reference products in (e.g.) bioequivalence studies from outside the EU”. EFPIA considers that this should be approached with an appropriate level of caution and, as such, should first be discussed with interested stakeholders including the innovative industry. |
| Page 8 | CMDh includes its plans to further develop guidance for implementing post-marketing referrals. EFPIA would welcome additional regulatory guidance in this area as well as the insurance of consistency with EMA/PRAC’s approach to referrals. |
| Page 8 | Mention is made of an initial focus for work-sharing on ‘Risk Management Planning’ for MRP/DCP products; however, it is not clear if this means RMPs or risk management planning in a more general sense.  It would be helpful if the Strategy clarified whether the mention of work-sharing is in reference to RMPs, or risk management planning in a more general sense. It may also be useful to suggest how work-sharing may be of benefit. |
| Page 9 | CMDh mentions that it will “develop measures to assure the product supply chain for essential EU medicines”. Further detail would be appreciated on the high level approach and the role of CMDh in optimizing this process. |
| Page 10 | Regarding telematics EFPIA proposes to crosslink the telematics topics with the EU telematics strategy 2015-2017 as published by EMA and HMA.  The CMDh should also continue the work on simplifying and unifying IT solutions for stakeholders by further EU harmonisation and a decrease in different National requirements. The strategy should include collaboration to reach an acceptance by all NCAs of fully electronic submissions without the need for any handling of paper (*e.g.,* compliance and update of the eSubmission Roadmap 1.0 141107). |
| Page 11 | Again, here we propose crosslinking of the telematics topics with the EU telematics strategy 2015-2017 as published by EMA and HMA.  The CMDh should promote the telematics work on common standards (e.g. potential use of ISO-IDMP standards across the EU Network) and guidance documents (e.g. SPOR project) to ensure well-structured dossiers that facilitate the scientific assessment. The CMDh should be involved in evaluating any new standards and guidance documents that affect the scientific work before they are adopted. |

1. CMDh Strategy to 2020 (CMDh/335/2015, Draft) [↑](#footnote-ref-1)