HPRA COMMENTS ON:
EMA REGULATORY SCIENCE TO 2025, STRATEGIC REFLECTION
28 June 2019

The HPRA welcomes the release of the EMA Regulatory Science to 2025: Strategic reflection document and supports the goals, recommendations and actions proposed.

With the increasing complexity of medicines and the possibilities for digitisation and automation in the manufacturing industry, it is an opportune time to consider how medicines agencies can best prepare for any regulatory challenges associated with current and future innovations. The extensive development work undertaken by the EMA to produce this reflection paper has resulted in a very comprehensive, clear and actionable document.

Translating promising research into medicines with the capacity to be much more targeted and effective will benefit patient outcomes across the EU, and worldwide. It is vital that each EU medicines agency is resourced and prepared to play a role in these developments. As an agency with a strategic goal to support innovation, the HPRA is committed to assisting researchers in innovative product and technology development and to participating in national and international efforts to adapt the regulatory system so that patients can have timely access to innovative medicines. Over the past few years, we have:

- Established an innovation office to assist researchers and small enterprises in navigating the regulatory system.
- Played a very active role in the EU-IN, leading the development of a horizon-scanning process which will benefit agencies across the EU.
- Led the ICMRA project on innovation which incorporated horizon scanning and novel approaches to licensing as key focus areas, and we will participate in the voluntary network to carry this forward.
- Become a partner agency in the Strengthening Regulatory Sciences and Supporting Regulatory Scientific Advice (STARS) project and through our encouragement, a number of Irish clinical research facilities and the 3 main health research funding agencies in Ireland will be involved in this project.
- Promoted the HPRA's and EU's supports to academia, research centres and funders, through site visits, conference lectures and involvement in educational programmes.

These supports are mirrored in similar programmes and activities across many EU national competent authorities as agencies respond to the innovation challenges and opportunities in their own countries.

In relation to the EMA's strategic reflection on regulatory science, we note the key themes of new regulatory science tools, integrative approach to regulating borderline products, collaboration with HTA and payers, network-led partnership with academia, and expertise

development. The areas outlined are wide-ranging, indicating the scale of the rapidly developing scientific and regulatory environment that medicines agencies face. The partnership approach which is highlighted throughout the document will make best use of resources to provide solutions to emerging issues. We note that a number of the recommendations and actions are not specific to the EMA but also relate to the European Regulatory Network as a whole and we agree that this report should be considered as part of the development of the next European Regulatory Network Strategy to 2025.

The HPRA considers that the EU-IN is a key vehicle for horizon-scanning across member states, sharing the outputs of individual agencies' research into innovations, and formulating potential EU responses, whether for the development of new tools, new guidance or new legislation. Linking this work to the international level through the ICMRA network should enable developments elsewhere to inform the EU position without duplication of effort. Our experience in the EU-IN and the ICMRA project suggests that there is great benefit in fostering collaboration between agencies. More medicines agencies should be invited to actively participate in the EU-IN to maximise the capacity of the group, distribute work equitably, and ensure all agencies develop an understanding of innovative products and technologies, an appreciation of the regulatory challenges and contribute to solutions.

The emphasis on developing expertise across the network is vital in creating sufficient capacity and competence among national regulatory staff who will ultimately be involved in inspection and assessment activities. Given that expert knowledge and experience in new areas is likely to be limited, creative opportunities to gain the necessary expertise among EU assessors, inspectors and committee members may be needed, examples of which are included in the document. The EU-NTC is a valuable resource for the network where it can leverage available expertise for the training of all NCAs, and the learning and development experts in the steering group and among local training champions can consider how best to address what may be fundamental gaps in expertise in key areas.

The regulatory system needs to be prepared for the future by being flexible and adaptable. Where products and technologies do not easily align with the existing legislative framework, changes to the directives/regulations may take a considerable time. A discussion with the Commission on how to achieve adaptability while continuing to ensure consistency in approach within the European regulatory network would be an important avenue to pursue.

As the document acknowledges, there is increasing convergence and combined use of health products within different regulatory frameworks, perhaps most notably with medicinal products and medical devices / in-vitro diagnostics. The new EU Medical Devices Regulation clearly provides for more interaction between medicinal product competent authorities, medical device competent authorities and notified bodies to ensure the effective and appropriate regulation of such products. As a joint medicinal product / medical devices competent authority, the HPRA believes that the implementation of this legislation and further strengthening of the interaction between the medicines and medical devices regulatory networks (for example through the joint HMA-CAMD strategic group) will be a key priority over the next 5 years.

Collaboration with other actors at national level, including notified bodies, device regulators, HTA agencies, payers, academia and research centres, will be a fundamental enabler to the

strategy. It is important that this is achieved where appropriate in association with the national medicines agencies, given their position in national health systems.

Finally the proposals quite rightly focus on communication, particularly to patients and healthcare professionals, as necessary to retaining confidence and trust in the system as it evolves to regulate very innovative products. Development of common materials to be used/adapted nationally is a good way to disseminate key messages while recognising the relationship nationally between health system users and their national competent authority.

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