HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thursday, 30 September 2021, 2:00 pm (meeting held remotely)

Authority meeting report

1 Introductions

The Authority and Chief Executive welcomed Dr P. Kilbane and Prof S. O'Kane to their first meeting as recent appointees. Both were invited to give a brief overview of their careers to date, and they both indicated that they were looking forward to working with the Authority during their terms.

2 Declarations of interest/Conflicts of Interest

Prof S. O'Kane noted her conflicts as per the annual declarations received and abstained from attending related parts of the meeting.

3 Chief Executive's Report update

Specific points discussed included:

Public health: Sodium Valproate Inquiry

It was noted that confirmation is awaited from the Department of Health (DoH) in relation to the proposed sodium valproate inquiry and how this may proceed. The HPRA is preparing to support the inquiry and significant work has been undertaken on collating necessary supporting documents. The Authority discussed the matter and noted that it will be resource intensive.

Future of Work

The Authority were updated on the future of work project which is underway, with every department represented in the four project work streams. The focus areas for the project are model design, training needs and supports, ICT and buildings and communications. Key developments include establishing a number of guiding principles that the organisation will adopt in the immediate to medium term, which have been shared across the organisation through a series of all-staff communications.

From January 2022, a hybrid model of working (i.e. a combination of remote and office based work) will be formally integrated based on three days office and two days remote working per week. The approach will be reviewed in quarter four 2022. A hot-desking approach was considered under the future of work project, but it will not form part of the initial stage. To properly address all of the issues arising as a result of hot desking, and to redesign to a modern office space that facilitates the continued growth of the organisation, would require significant refurbishment and investment and is outside of the scope of the current project.

It was agreed that the future of work will be a key focus and a discussion topic at the Authority away day.

Succession Planning for Management Committee

The Authority were briefed on the reorganisation of functions and department restructuring in preparation for the retirement of the Director of Quality, Scientific Affairs and Communications (QSAC). Specifically, there is now an opportunity to recruit a new Director of Operational Excellence and Quality (OEQ), and the establishment of a new department focusing on these two

areas. The Quality team will be incorporated into the new OEQ Department and its remit will be extended to incorporate the business and strategic planning functions, while Scientific Affairs and Communications will be incorporated into the Finance, Corporate and International Department and Chief Executive's Office, respectively. Following approval from the DoH/DPER to progress with recruitment the position will be advertised in October.

4 COVID-19 Update

The Authority considered the update to be very valuable and will welcome future updates, where necessary, as the situation develops.

The authorisation of monoclonal antibodies was discussed and, in particular, the conditional marketing authorisation for the Renegeron combination product which had been granted in the UK. The situation nationally and the timeline for potential authorisation in the EU were discussed.

The introduction of a multifaceted approach (process redesign and enhanced resource supports) to manage the high volume of pharmacovigilance case assessment work over the summer months was discussed. This has been very impactful and all serious reports are now submitted to Eudravigilance.

Close monitoring of the safety of COVID-19 vaccines continues, incorporating the assessment of available data on new signals and any associated potential risks. The Human Products Monitoring (HPM) department continued to contribute to the EU coordinated reviews of monthly safety data as well as ad-hoc signal assessment reports. Arising from these reviews, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recently made recommendations on a number of important safety issues, including updates to the product information to add warnings on myocarditis and pericarditis (associated with Comirnaty® and Spikevax®) and Guillain-Barré syndrome (associated with Vaxzevria® and COVID-19 Vaccine Janssen®). The intensified monitoring through monthly reports is expected to continue for the present, with routine six-monthly periodic safety update reports (PSURs) also now due for submission.

5 Medical Devices Department Update

*Prof. S O'Kane left the meeting due to noted conflict of interest

The Director of Medical Devices presented an overview of the HPRA perspective on the current status on implementation and effective operation of the regulatory system for medical devices in Europe. Key challenges and priorities were identified, in addition to the proposed approach of the HPRA to help ensure the system continues to benefit patient safety while also supporting innovation. In addition, some proposed future approaches to the regulatory framework were discussed. The Authority supported the position that the HPRA should further enhance its focus at national and EU levels on advocating for continued development of the system and regulatory network.

It was agreed that this topic be further discussed at the November meeting and potentially at the away day in December.

6 ICT: Digital Signatures

*Prof. S O'Kane re-joined the meeting.

The Chief Executive briefed the Authority on the current and future approach to electronic signatures. Specifically, it was outlined that the HPRA currently uses simple e-signatures on a number of documents, and, while sufficient, an advanced e-signature using an authorised trusted service will provide greater assurance of the integrity of the signature. In the coming months, the HPRA intend to enter into an agreement with a trusted service provider to establish the required capabilities and operational process to allow the application of advanced e-signatures on authorisations issued.

The Authority supported the proposal.

7 Open Board Meeting update

The HPRA had previously considered the scheduling of a pilot open Authority meeting. Plans were deferred in 2020 due to the pandemic. The Authority agreed that further review and consideration was required prior to progressing. An update will be provided at the November 2021 meeting.

8 Risk Management: Review of Risk Register

The Risk Register was reviewed by the Audit and Risk Committee (ARC) at its meeting on 23 September. Updates included an overall reduction in the number of risks from 50 to 20 based on the current maturity of the organisation and planned future development. Updates to the description of existing risks to increase specificity were noted, along with changes to the scoring of some risks. The updates reflect best practice and aims to track changes and act as a dynamic document to progress actions. There were a small number of other changes suggested and noted. The Authority approved the risk register as presented.

9 Service Plan for 2021

The service plan update for January to June 2021 was noted by the Authority. Currently, 70% of deliverables are in line with target and delivery against the plan at this stage of the year is in-line with performance in previous years.

10 Business Planning 2022

The service plan for 2022 is being developed to align activities to the strategic plan goals. Planning work will be completed soon and a final detailed plan will be presented to the Authority in December.

The Authority congratulated Dr Caitríona Fisher, the Director of Quality, Scientific Affairs and Communications (QSAC), on her forthcoming retirement and thanked her for her significant and highly valued contribution to the development of the organisation.

11 Authority Matters

Authority Annual Self-Evaluation Questionnaire

The questionnaire will issue after the 18 November 2021 meeting.

Training Updates/Requirements

Both code of conduct and finance for non-finance people training is proposed for January 2022.

12 Authority Terms of Reference

The Authority agreed a minor amendment to the Authority Terms of Reference.

13 Finance

Management accounts: The accounts for July and August 2021 were noted by the members.

Final signed financial statements 2020: The final signed financial statements for year ended 31 December 2020 were included in the meeting pack for reference.

14 Committees

Item	**Statutory Committee**	**Last Meeting Date**	**Updates**
14.1	Audit and Risk Committee (ARC)	27/08/2021 23/09/2021	The ARC Chair provided an update on the recent meeting of the ARC, including the ICT Cyber Security report and HPRA investment strategy. Mr Brian Jones was proposed and endorsed as an ARC member.
14.2	Advisory Committee Veterinary Medicines (ACVM)	None since last meeting.	Nothing to report.
14.3	Advisory Committee Medical Devices (ACMD)	20/09/2021	The Authority noted the meeting update from the ACMD Chair.
14.4	Advisory Committee Human Medicines (ACHM)	None since last meeting	Nothing to report.

15 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 11/06/2021 to 17/09/2021.