HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

28 January 2021, 2:00 pm (meeting held remotely)

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

None noted.

2 Matters Arising

None noted.

Chairperson
As the appointment of a new Chairperson was still in progress, it was agreed that Prof Keane would Chair the meeting.

Proposal for Facilities upgrade
A proposal for the refurbishment of bathroom facilities in Kevin O'Malley House was discussed. The proposal was in accordance with the 2021 capital budget, which was approved at the December 2020 Authority meeting. The Authority considered both the need for and the importance of improving hygiene facilities in the present pandemic.

HPRA Updates (such as changes to legislation, competencies and terms of reference)
None noted.

3 Chief Executive's Report

The Chairperson asked the Chief Executive to outline key issues and invited comments and queries from the Authority members. The following matters were discussed:

Public Health – Vaccine Authorisation and Roll-out

As noted in the paper, on 21 December the European Commission approved the conditional marketing authorisation (CMA) of the Pfizer/BioNTech Covid-19 vaccine (Comirnaty). The Authority was updated on the rapidly evolving landscape of vaccine authorisation; on 7 January the Moderna vaccine was granted a CMA in Europe. The European Medicines Agency (EMA) has received an application for a CMA for the AstraZeneca/Oxford vaccine, with authorisation expected by 29 January.

The Authority discussed the vaccine authorisations to date, the impact on national rollout and emphasised the importance of regulatory rigour. It is anticipated that the AstraZeneca/Oxford vaccine will be indicated for use in persons above 18 years of age. It requires only standard cold storage, which suits mass roll-out in community settings and this may commence from 4 February. It was noted that Germany and Norway have indicated, in advance of the EMA decision that they do not intend to use this vaccine for older people as there is limited data available on its use in older populations.

The Authority noted that although the AstraZeneca/Oxford vaccine is easier to manage in GP settings, use of the mRNA vaccines would be feasible with some adjustments.

The HPRA is acting as co-rapporteur for two monoclonal antibody therapies.

Public Health - Vaccine Safety

The HPRA has received a total of 500 safety reports associated with the use of Comirnaty. The number of reports received reflects the increase in the number of vaccinations. It is generally consistent with levels of reporting that other international regulators are experiencing. As the volume of reports received grows, this will significantly increase the workload of the Human Products Monitoring (HPM) department. Additional resources are being deployed to HPM from within the organisation to help meet this increased workload.

Safety outcomes are reported weekly to NPHET.

The Chair thanked the Chief Executive and all HPRA staff involved in this important work at this time.

4 Brexit Update

The Chief Executive provided an update on Brexit. On 24 December 2020, as part of its withdrawal from the EU, the UK agreed a "The Trade and Cooperation Agreement (TCA)". Its implications for medicines and other health products were discussed.

In addition to the TCA, the Commission issued a communication in late December providing four derogations to compliance for smaller markets including Ireland, Malta, Cyprus and Iceland. The derogations related to medicinal products are limited to one year and relate to: UK Batch release, UK batch testing, and the unique identifier under the Falsified Medicines Directive (FMD). The HPRA is working through the rules and have published an explanation and a form for applying the exemptions.

There remain a number of companies that have not yet completed the regulatory changes required in light of Brexit. As some products are covered under the derogations, the companies have an extra year to complete necessary changes.

The HPRA is also aware that some of the Qualified Person for Pharmacovigilance (QPPVs) have not yet made the required move from the EU to the UK.

Clarity was sought on the impact on movement of products between the UK and Ireland. There have been some initial delays in the movement of products through customs related to procedural issues which have been substantially resolved. The HPRA and relevant stakeholders have managed the import of critical medicines closely to reduce/avoid the delays at ports with the result that patients have not been adversely impacted. Stockholdings built up pre year-end has meant that medicines supply has not been affected by Brexit.

Key staff within the organisation are continuing to attend daily Brexit Review Incident Team meetings which have taken place since 31 December.

The Chair thanked all HPRA staff involved in work, particularly those working over the Christmas holiday break.

5 Authority Matters

March meeting date
To be agreed post meeting. The Secretary will send a reminder to the Authority.

Public Appointments Update
The appointment process for a new Chairperson and two Authority members is expected to conclude in February 2021.

Board Calendar for 2021
Deferred – to be agreed with new Chairperson.

6 Finance

The Management Accounts for November 2020 were noted.

7 Committees

ITEM	**Statutory Committee**	**Last Meeting Date**	**Updates**
7.1	Audit and Risk Committee (ARC)	01/12/2020	– 2020 ARC Report was noted. – 2020 September ARC signed minutes were noted. – There remains two Authority members on ARC. As the quorum is two, the next meeting will take place in March.
7.2	Advisory Committee for Veterinary Medicines (ACVM)	16/09/2020	– Dr Joe Collins has been appointed ACVM Chairman. – The newly appointed ACVM Committee will meet in March.
7.3	Advisory Committee for Medical Devices (ACMD)	23/11/2020	– Prof Richard Reilly remains as Chairman of the ACMD. – New appointments to the ACMD are expected soon.
7.4	Advisory Committee for Human Medicines (ACHM)	03/12/2020	– Dr Diarmuid Quinlan's letter of appointment as Chair is expected. – New appointments to the ACHM are expected soon.
7.5	Performance Review Committee	June 2020	– Next meeting deferred, pending appointment of new Authority Chairperson and new Authority members.

8 Licensing Activities

The Authority noted the tables of licenses approved by the Management Committee during the period 27/11/2020 to 15/01/2021.

9 AOB

The Authority considered two items under AOB, which were raised by an Authority member:

- Designation of antimicrobials as being reserved for human use,
  The role of the HPRA and other high-level stakeholders under the 'One Health' model, particularly regarding the HPRA remit for both veterinary and human medicines was discussed. In the context of classes of antimicrobials to be preserved for human use, the European Commission (EC) is conducting a consultation on this item, the principle is set out in the new Vet Regulation and the delegated Act is the mechanism used to generate the list of preserved classes.
- Succession planning
  In supporting the role of the Authority, and identifying key skills and requirements, the Authority engaged in a comprehensive succession planning exercise in recent years, and the skills required form the base criteria for new member vacancy profiles.

At the close of meeting, the Chief Executive expressed her appreciation to Prof Keane for acting as Chairperson for the January 2021 meeting.