HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

29 April 2021, 2:00 pm (meeting held remotely)

Authority meeting record

1 Declarations of Interest / Conflicts of Interest

There were no interests to declare.

2 Matters Arising

New Authority Appointments

The Minister for Health has notified the HPRA of the appointment of Mr Michael M. Donnelly as Chairperson. Mr Donnelly will attend the June Authority meeting.

3 Minutes

The meeting record of the meeting of 28 January 2021 were agreed.

4 HPRA Updates (such as changes to legislation, competencies and terms of reference)

Changes to legislation were noted by the members. There were no further items to report.

5 Chief Executive's Report

Specific points discussed included:

Public health: Sodium Valproate inquiry

The Minister has requested the HPRA to engage in the planned review of sodium valproate. The HPRA is compiling and scanning all files relating to valproate, which cover multiple products and date back to the early 1970s. The HPRA is committed to supporting the inquiry and the Authority will continue to be updated on progress.

Public health: BIA ALCL

The Authority was briefed on the expert subgroup established by the Advisory Committee for Medical Devices (ACMD) to consider the risk of BIA ALCL and textured breast implants. The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) published a draft Scientific Opinion on the safety of breast implants in relation to anaplastic large cell lymphoma in late April 2021 and this will be considered by the expert subgroup.

Future of work and implications for HPRA

The Authority was updated on the review of the future of working arrangements (including remote working), noting that Mercer had completed an analysis of views across the organisation including the Management Committee, Section Managers and employees. The leadership view highlighted that remote working: "fundamentally works for the HPRA and that our work is suited to the approach". The update included a number of "watch-outs" to manage challenges with remote working and to ensure benefits remain positive overall for the organisation and staff. This analysis will inform the next steps in relation to developing policies and reviewing accommodation requirements going forward.

HPRA business: Succession planning for Management Committee

There is an ongoing focus on succession planning for the Management Committee due to planned retirements and the need to reflect on the future organisational needs, ensuring the organisation has the appropriate processes in place to meet those needs. The HPRA has engaged with the Department of Health in relation to seeking agreement to backfill the roles in question.

It was noted that the Director of Human Resources and Change (HR&C), Ms Lynsey Perdisatt, is leaving the HPRA at the end of May to pursue a new career opportunity after 15 years of excellent service to the organisation. Arrangements are in place to progress recruitment for this key position.

The Authority extended thanks to Ms Perdisatt acknowledging her role in driving the HR&C strategy.

HPRA business: Brexit

As noted previously, the European Commission provided temporary exemptions for medicines in relation to UK batch release, batch testing and decommissioning/reaffixing the unique identifier under the Falsified Medicines Directive (FMD) for countries with small markets including Ireland, Northern Ireland, Malta and Cyprus. The HPRA has granted a number of exemptions but is monitoring and engaging with companies with the expectation that the products will be regulatory compliant by year-end. As there is no exemption for a small number of products with a UK Marketing Authorisation Holder (MAH), the future of these is uncertain. Overall, the supply of medicines to the Irish market remains positive.

The Chair thanked all HPRA staff involved in this important work at this time.

6 COVID-19: Vaccines, therapies, rapid antigen tests and safety monitoring

*Mr Brian Jones joined the meeting.

As previously noted, the AstraZeneca vaccine (Vaxzevria) received a conditional marketing authorisation (CMA) on 9 January 2021 and the Johnson & Johnson vaccine received a CMA for its single dose vaccine (Janssen COVID-19 Vaccine) on 11 March.

The discussion focused on vaccine safety monitoring. The Authority was updated on reports of suspected side effects from the vaccines on the EU market. The most commonly reported side effects include dizziness, headache, muscle pain, general pain, nausea, tiredness, chills and fever. Rare instances of clotting combined with low platelets following vaccination with viral vector vaccines were also discussed. The EMA's human medicines committee (CHMP) has concluded an Article 5(3) review of Vaxzevria. The outcome is that the benefits of vaccination continue to outweigh the risks, but the product information will be updated to include a warning on unusual blood clots combined with low blood platelets. Similar warnings will also be included in respect of the Janssen vaccine. The National Immunisation Advisory Committee (NIAC) is now reviewing how these vaccines will be rolled out nationally in light of this conclusion.

Resourcing requirements for vaccine safety monitoring activities

It was noted that there had been a significant increase in the number of suspected side effect reports received including those from the general public. In the first quarter of 2021, 8,000 adverse reaction reports were received which is the equivalent of the typical reporting rate in a full year.

The vast majority of these reports related to COVID-19 vaccines. Actions taken to address this high level of reporting have included recruitment of new staff and redeployment of a small number of staff from across the organisation to support case processing work. Additional efficiencies and automation have been implemented as a matter of priority to maximise utilisation of the available resources. The Authority acknowledged the ongoing work of the Human Products Monitoring department, and all staff involved at this busy time for the organisation.

7 Patient Forum Update

An update was provided on the progress of the Patient Forum. There have been three meetings to date and the next meeting will take place in early May 2021. The Forum was started as a pilot, with the view of developing it into an established forum based on the experience of the first year. The upcoming meeting will focus on establishing terms of reference (ToR) and a programme of work for the Forum. Topics for consideration include current issues, regulatory developments and other more general topics. The outcome of the next few meetings will assist the HPRA in establishing a patient forum that works for both patients and the HPRA.

The Authority welcomed the progress made and emphasised the importance of the forum. The future consideration of an initiative to support the use of veterinary medicines was raised.

8 ICT Update: Cyber Security

The Director of ICT and Business Services presented an update on the digital transformation strategy, including strategy delivery in 2020/21, priority areas and strategic alignment. The Authority thanked the director for the presentation and raised a number of points including staff retention, cyber-security and moving to a cloud-based solution. It was noted that the HPRA is engaging with similar agencies to share experiences, cloud based storage was under review and that staff retention is well managed and addressed within the strategy. In terms of cyber-security, the systems are being fully reviewed.

The Authority members expressed their thanks for an excellent presentation and overview.

9 Risk Management – Risk Register

*The Director of Quality, Scientific Affairs and Communications joined the meeting for Items 9, 10, 11 and 12.

A document was presented on a proposal to change the format of the risk register in order to have a more focused register for ongoing management of the risk profile of the HPRA. The updated risk register will be presented to the Audit and Risk Committee (ARC) in September 2021.

An overview was provided of the current risk register, including the downgrading of risks on the availability of medicines as a result of Brexit and COVID-19 as medicines' supply has been maintained. The risk related to the Eolas workflow system has been removed as the project stage has been completed. A new risk has been added in respect the overall physical ICT infrastructure. Changes have also been made to the prioritisation of other lower priority risks.

The Authority agreed with the proposed changes and approved the risk register as presented.

10 Service Plan – Final 2020 Report

The Authority was briefed on the outturn for the 2020 Service Plan. The COVID-19 pandemic impact was noted from late Q1 2020. Nevertheless, the overall outturn for the year was positive with more activities completed or on target than initially projected, and higher outputs when compared to 2019. In terms of total service volume numbers, the output was 12% over projected numbers for the year.

The Authority and Chief Executive complimented the overview and the clear presentation of metrics.

11 Strategic Plan 2016 to 2020 – Summary of Achievements

A high-level summary of the overall achievements against the goals, objectives and actions in the Strategic Plan 2016-2020 was provided. The strategic plan for 2016-2020 included 5 goals, 17 objectives and 47 actions with a range of outcomes and indicators set for each objective.
The Authority acknowledged the achievements of the HPRA against the plan over its duration, complimenting the Chief Executive and Management Committee in delivering on the goals and objectives set out.

12 Review of HPRA use of Experts

The Authority was briefed by the Scientific Affairs Manager on the proposal to refine and improve engagement with experts who provide advice to the HPRA. Initial recommendations were made to the Authority in September 2019. Work is ongoing to implement the recommendations including: establishment of an internal database; developing electronic declaration of interest forms; and investigating new mechanisms for identifying experts, including approaches to other agencies.

The proposed next steps were welcomed by Authority.

13 ICT & Veterinary Sciences: New Veterinary Regulation / Union Database

The Authority was given an update on the ongoing development of the EU Union Product Database (UPD) which will be a database containing all veterinary medicinal products that are authorised in each Member State (MS).

The UPD is extensive and complex. The details are outlined in Article 55(2) of the New Veterinary Regulation (NVR), and will contain detailed information on each veterinary medicinal product. Article 155 of NVR requires MSs to submit electronically, information on all the veterinary medicinal products on their markets in the required format before 28 January 2022. The challenge for the HPRA is to ensure that its IT systems and databases are capable of integrating with the UPD, in circumstances where the EMA has not completed development of the database. A second challenge is ensuring that the HPRA data is in a format compatible with the UPD. This is an ambitious, complex and challenging project with a short deadline for completion.

The Authority approved the request for additional budget to deliver on the project.

14 Finance

Management Accounts: December 2020, January and February 2021
The accounts were noted by the members.

15 Committees

Item	Statutory Committee	Last Meeting Date	Updates
15.1	Audit and Risk Committee (ARC)	25/03/2021	Prof Keane provided an update on the recent meeting of ARC. The System of Internal Controls statement 2020 had been reviewed by the ARC and the members recommended the document to the Authority. Under a written procedure held in advance of the meeting, the Authority approved and agreed that the controls in place were considered appropriate and sufficient. An update was provided on the risk register, the corporate procurement plan and the 2020 audit by the C&AG.
15.2	Advisory Committee for Veterinary Medicines (ACVM)	24/03/2021	The ACVM Chair updated on the recent meeting of the ACVM. Highlights included: the New Veterinary Regulation; the status of the HPRA's Report on antiparasitic veterinary medicinal products; and the Oireachtas Committee meeting. The Chair thanked all involved for their support
15.3	Advisory Committee for Medical Devices (ACMD)	None since last meeting	It was noted that the Minister of Health has appointed the members of the ACMD for the period 2021 – 2025.
15.4	Advisory Committee for Human Medicines (ACHM)	None since last meeting	It was noted that the Minister for Health has appointed the members of the ACHM for the period 2021 – 2025.
15.5	Performance Review Committee	None since last meeting.	Nothing to report.

16 Licensing Activities

The Authority noted the tables of licenses approved by the Management Committee during the period 22/01/2021 to 16/04/2021.

17 AOB

2021 – 2025 Strategic Plan

A press release to announce the launch of the new Strategic Plan will issue shortly.