HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Monday, 15 November 2021, 2:00 pm (meeting held remotely)

Authority meeting report

Chair	Mr M. Donnelly
Present	Mr B. Jones, Prof E. Keane, Dr P. Kilbane, Prof S. O'Kane*, Prof R. Reilly, Dr J. Collins
In attendance	Dr L. Nolan, Chief Executive (CE), Dr N. MacAleenan, Director of Medical Devices*, Dr D. Scully, Senior Assessor Shortages*.
Apologies	Mr D. Holohan, Dr D. Quinlan
Secretary	Ms. A. McGowan, Corporate Affairs Manager (Acting)

*attended for part of meeting

1 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.

It was noted Ms. A. McGowan will be the secretary for this meeting.

2 *Updates from previous meetings*

European Medicine Agency (EMA) fees - *Update*

The Authority were briefed that there has been no further update since the September Authority meeting. The European Commission are still completing the consultation process. An update is expected following the completion of the consultation. It is expected to be presented to the European Council in early Q1 2022.

3 Authority Report – *For adoption*

The report of the meeting of 30 September 2021 was adopted.

4 Health and Safety - Update

There was nothing to report.

5 HPRA updates (Changes to legislation, competencies, ToR, Code of Conduct etc.) – *For Information*

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 9) Regulations 2021 (SI 492/2021): *Allows for additional or booster/subsequent doses of mRNA COVID-19 vaccines to be supplied and administered to certain persons.*

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 10) Regulations 2021 (SI 511/2021): *Allows COVID-19 vaccinators to administer the seasonal influenza vaccines.*

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 11) Regulations 2021 (SI 558/2021): *Allows booster/subsequent does of Cominarty COVID-19 vaccine to be supplied and administered to certain persons.*

- Medical Devices (Amendment) Regulations 2021 (SI 510/2021): *Excludes Switzerland from the definition of "member state" and make various other minor changes.*

- Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) (Amendment) Regulations 2021 (SI 557/2021): *An update to list certain cannabis products or preparations for medical use as being eligible for under the cannabis access programme.*

6 Chief Executive update

Specific points discussed included:

Public health: Sodium valproate inquiry Confirmation is awaited from the Department of Health (DOH) in relation to the proposed national inquiry on Sodium Valproate and whether the inquiry will be on a Statutory or non-Statutory basis. The level of HPRA resourcing that might be required to support the inquiry was discussed. The learnings from other international reviews including the recent UK inquiry will be relevant.

HPRA business: Future of work

The Authority were briefed on the progression of arrangements for the return to work in 2022. The HPRA highlighted the application of a 3:2 working week, incorporating three days in the office and two days working from home, as a key focus. It was noted that infrastructure arrangements have been made in order to prepare for the return to the offices. The Authority were briefed on the generally positive feedback from the HPRA section manager meeting. The return to work arrangements will be implemented in a phased basis from January 17th with full implementation expected in March 2022, contingent on any changes to the current public health advice.

A query was raised in relation to health and safety considerations in the preparations for return to the office, specifically first aid officers and fire marshals. It was clarified that rostering will be a key feature of the return to work.

A discussion was had in relation to mental health supports for HPRA employees ahead of the return to work. The Chief Executive highlighted the Employee Access Programme (EAP) which provides a comprehensive support package to employees and relatives and noted health and wellbeing has been a primary focus for the organisation, particularly throughout the pandemic.

HPRA business: Succession planning for Management Committee

The Authority were updated on the ongoing recruitment for vacant positions on the HPRA Management Committee (MC). It was noted that the Director of Compliance vacancy has now been filled with an internal candidate appointed. The recruitment process for the Director of Human Products Authorisation and Registration (HPAR) was organised and completed since the September Authority meeting. A candidate has been appointed and will start in March 2022. The recruitment for the Director for Operational Excellence and Quality (OEQ) position is ongoing and interviews have been scheduled. The modification to reporting lines arising from the structural department change have been completed. The Authority commended the MC on the success of these recruitment competitions and ensuring the HPRA is an attractive place to work.

Action: HPRA secretary to circulate revised organisation structure to Authority members.

HPRA business: Diversity and Inclusion
The Authority extended their congratulations to the MC and the HPRA Diversity and Inclusion Committee on achieving the Investors in Diversity Silver Award, an accreditation from the Irish Centre for Diversity.

7 COVID-19 update

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

It was noted that the rolling reviews for Regeneron (Ronapreve [Casirivimab / Imdevimab]) and Regdanvimab have concluded and the products have been approved.

An update was provided on additional COVID-19 vaccine candidates and the ongoing status of their evaluations.

It was noted that the Pfizer BioNTech COVID-19 vaccine (Comirnaty) has recently been granted Emergency Use Authorisation by the FDA for paediatric indication in 5-12 year olds. The EMA is evaluating a similar application for use in this cohort.

The Human Products Monitoring (HPM) Department continues to closely monitor the safety of COVID-19 vaccines, through contributions to EU coordinated reviews of monthly safety update reports submitted by the licence holders, as well as *ad-hoc* signal assessment reports. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) continues to focus on the assessment of available data to further characterise the risk of myocarditis and pericarditis following vaccination with mRNA vaccines Comrinaty and Spikevax.

An update was provided in relation to the EMA's Committee for Medicinal Products for Human Use (CHMP) conclusion that a 30 and 25 µg booster dose of Comirnaty and Spikevax, respectively, may be considered in adults aged 18 years and older at least six months after the second dose of the primary sequence. It was noted that the National Immunisation Advisory Committee (NIAC) have provided recommendations regarding selection, dose and timing of booster doses of COVID-19 vaccines in Ireland.

A discussion was had on the availability of information regarding COVID-19 vaccinations during pregnancy. It was noted that some Irish maternity hospitals are participating in international clinical trials. The HPRA noted that nationally, vaccination during pregnancy has been a focus for communications in recent weeks by the HSE, National Taskforce, general practitioners (GPs) and the Royal College of Physicians of Ireland. A query was raised on the vaccination rate among pregnant women as vaccine hesitancy during pregnancy was reported in the British Medical Journal. It was noted that the HSE, through its provision of maternity services, would be responsible for monitoring this data. The Chief Executive agreed to circulate information relating to the communications focusing on COVID-19 vaccinations during pregnancy.

8 Open Authority Meetings

A discussion took place regarding the need to identify the clear potential benefits of hosting an open meeting. The Authority noted the Patient Forum is a structured engagement with one of the potential audiences for the open Authority meetings. It was proposed that the Patient Forum might be consulted on the transparency needs of that group. Openness and transparency remain key objectives and the HPRA is currently publishing a vast amount of information on the HPRA

website. The website redesign project will further help achieve these objectives by making information easier to access by the public. The Authority noted the increase in public awareness of the HPRA as a brand as a result of the work during the Covid-19 pandemic. It was noted that this additional awareness has resulted in a significant increase in the number of Freedom of Information requests received by the HPRA in 2021. Increasing transparency across the organisation remains as a key HPRA goal for the future.

Decision: The Authority agreed to pause the discussion of hosting open Authority meetings for now, and allow for further evaluation on both whether there is a need and what the value add would be. An update on the on-going evaluation would be given at an Authority meeting in 2022.

9 Away Day Proposal

A proposal had been made to schedule the December Authority meeting over two days to allow additional time for discussions. In light of the current public health advice, the decision not to travel was taken and the meeting would be hosted in the HPRA offices instead. The proposed dinner with Authority members and the MC was cancelled.

Decision: The board agreed to compress the meeting into a full single day meeting on December 9, contingent on public health advice changing. A tour of the HPRA premises will be scheduled ahead of the Authority meeting.

The prevailing public health situation was highlighted and will be kept under consideration in the next weeks, with regard to the feasibility of meeting in person.

Action: Summary email to be sent by the HPRA Secretary outlining the new arrangements.

10 Medical Devices Regulatory System Strategic Discussion

Following on from the presentation during the September Authority meeting, the Director of Medical Devices presented an update on the status of implementation and practical operation of the new regulatory system for medical devices at national and EU level. The priorities and proposed future approaches to the regulatory framework were outlined. A discussion was had on the resource requirements of these proposed future approaches. It was noted that legislative clarity could encourage medical device companies to innovate and run clinical investigations in Ireland. It was highlighted that there is no legislation currently for the use of medical devices in veterinary medicine in Ireland. Collaboration between Competent Authorities and Health attachés was highlighted as a key area of importance. It may be helpful for the Authority to reflect on how it might influence nationally across government departments and agencies.

The Authority supported the proposed approach.

Action: Chair to meet with the Director of Medical Devices and the chair of the Advisory Committee for Medical Devices (ACMD) to discuss practical next steps.

11 Management of Medicines Shortages

The HPRA provided a presentation on its on-going review of the organisation's approach to medicines shortages management which also includes consideration of various European and international strategies to better address this area.

The positive benefits of the HPRA's investment in this area have been illustrated by its capacity to manage the significant challenges posed by both Brexit and the Covid-19 pandemic. A discussion was had on the impact and lessons learned from these issues.

A query was raised on the implications for the veterinary medicines sector. It was clarified that the shortages project is funded by the Department of Health and as such focuses solely on human medicines. It was noted that the HPRA shares the responsibility for regulating the supply chain of veterinary medicines with the Department of Agriculture, Food and the Marine (DAFM). It was noted that an EU level Taskforce on Shortages exists and includes veterinary medicines, although Ireland has not received any notifications to date. The model for human medicines could be applicable to veterinary medicines in the future.

The Authority sought clarification on the proposed publication of the ongoing review. The HPRA outlined the planned publication, both on the HPRA website, highlighting the collective work of stakeholders, and in academic journals, in terms of information from a European perspective. The next steps for the project were outlined by the HPRA and were supported by the Authority.

12 IBTS Annual Report 2020

An overview of the inspection programme of the IBTS and findings during 2022 was provided. This is reported annually to the Minister for Health. The IBTS operation was considered to comply with European and national requirements for collection, processing, and traceability. It was noted that the report was approved by the Advisory Committee for Human Medicines (ACHM) via written procedure prior to the Authority meeting.

For adoption: The report was adopted by the Authority.

13 Authority Matters

Online publication of HPRA Annual Report

It was noted that media engagement planning is ongoing in advance of the publication of the 2020 Annual Report. This will seek to build on the recent increase in brand awareness.

2022 Authority Meeting Dates

Proposed dates for the Authority Meetings in 2022 have been circulated. Confirmation of the dates will be circulated once all responses are received. The next meeting will be scheduled for January 26.

Housekeeping Issues {SharePoint; Email Use}

Consideration to be given to the procurement of individual iPads for Authority members. A tutorial on the use of IT equipment was requested to be scheduled during the December Authority meeting. An update was provided on the potential use of SharePoint and HPRA email addresses for Authority members.

Authority evaluation questionnaire
The questionnaire is proposed for issue after the November Authority meeting.

14 Finance

Management Accounts: September 2021 – were noted by the members.
Finance for non-finance people training is proposed for January 2022. A revised version of the management accounts report was proposed going forward.

15 Committees

Item	**Statutory Committee**	**Last Meeting Date**	**Updates**
15.1	Audit and Risk Committee (ARC)	None since last meeting	Nothing to report.
15.2	Advisory Committee Veterinary Medicines (ACVM)	20/10/2021	The ACVM Chair provided an update on the recent meeting of the ACVM, including an overview of a technical discussion on virus vaccines.
15.3	Advisory Committee Human Medicines (ACHM)	None since last meeting	Nothing to report.
15.4	Advisory Committee Medical Devices (ACMD)	None since last meeting	Nothing to report.
15.5	Performance Review Committee (PRC)	05/10/2021	Recognition of the Chief Executive's contribution to the organisation was noted. The Chair highlighted the exceptional workload during the pandemic.

16 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 18/09/2021 to 05/11/2021.

17 AOB

Climate Action Bill
A query was raised on the implications of the Climate Action Bill for the HPRA in terms of workload and resources. It was noted that environmental goals are a key part of the HPRA strategic plan. A proposal within the Climate Action Bill is a requirement for organisations to report against carbon budgets and the Climate Action Plan'. It was proposed to list the environmental actions of the HPRA as a potential future agenda topic.