HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

2 July 2020 (meeting held remotely)

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

None noted.

2 Matters Arising

None noted.

3 Health and Safety

There were no issues to report.

4 Risk Management

There were no issues to report.

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

There were no issues to report.

6 Chief Executive's Report

The Chairperson asked the Chief Executive to highlight key points and invited comments and queries from the Authority members. Specific points discussed included:

Nitrosamine Review
The Authority was updated on the outcome of the EMA's Committee for Medicinal Products for Human Use (CHMP) opinion. The opinion provides a framework for management of incidents where nitrosamines are detected, which is predominantly based on evaluation of exposure risk using internationally accepted intake levels, balanced against the risk of availability restrictions. The Authority discussed the approach in the context of dealing with the complexity presented by metformin and potential impacts on patient care. The use of internationally accepted intake limits was welcomed by the Authority. The Authority considered a coordinated approach at EU level for implementing the opinion was important and they welcomed the role that the HPRA had played in the EU network on this issue.

The Independent Medicines and Medical Devices Safety Review (IMMDS)
The IMMDs review in the UK was discussed. The Chief Executive outlined that given the similarities between the UK and Irish systems, the findings of the review will require consideration by all parties including the HPRA, HSE and the Department of Health with a view to ensuring a coordinated response.

Pandemrix Legal Case
The Authority was updated on a significant development in relation to the current Pandemrix case whereby a Notice of Discontinuance has been received from the solicitors for the plaintiff.

This notice means that the HPRA is no longer a defendant in this Pandemrix case that is currently before the courts. The HPRA will seek similar notices in relation to other Pandemrix cases.

The Authority thanked the HPRA legal team and all contributors for their work in relation to this matter.

IPPOSI Patient Education Programme
The Authority noted the HPRA's continued involvement as a partner in IPPOSI's education programme.

Vaccine Hesitancy
The recent statements on vaccine hesitancy developed by the International Coalition of Medicines Regulatory Agencies (ICMRA) were noted, and it was agreed to circulate the links.

7 ICT Digital Transformation Presentation

A paper was provided on the approach to the Digital Transformation Strategy, including a detailed overview on remote working, Eolas and other projects.

The Authority agreed with the need for finalisation of the strategy and development of an implementation plan as being a key priority.

8 Away Day Approach

The Authority was invited to consider the best working arrangement for the away day session. The preference is to meet face-to-face. A final decision, depending on Government guidelines, will be made in August. It was noted that a remote session could be considered if it is not possible to host in person.

9 COVID Emergency – HPRA Response

The Chief Executive provided an update on the HPRA response to Covid-19 in line with the detailed paper circulated to the Authority members.

The Chairperson and Authority members expressed their thanks to the Chief Executive on the excellent business continuity efforts of senior management and all staff. The importance of the work in completing the staff survey and feedback was acknowledged.

10 Authority Succession Planning

A brief update was provided on HPRA succession planning. It was noted that in light of upcoming changes to the Authority composition, and the new 2021-2025 strategic plan, it is prudent to again reflect on both current skills and outgoing expertise due to Authority member changes while also considering the future needs of the Authority and organisation.

11 Authority Evaluation 2020

An update on the Board evaluation that is being facilitated by Board Excellence was provided.

12 HPRA Strategic Plan, 2021 – 2025 – Thematic discussion + Mission, Vision and Values

An overview of the development of new strategic plan and its high level goals and objectives was provided. There was broad agreement that the goal areas reflected the changing health and industry environment and captured the inputs from previous sessions. The importance of the goals focused on public health, innovation and stakeholder and public engagement were highlighted.

The Authority emphasised the need for the text to be concise and to resonate with all stakeholder groups. A further review will take place at the next meeting.

The Vision, Mission and Values statements and proposed revisions were also discussed.

The members expressed their thanks to the Chief Executive and management committee, in particular the Director of Quality, Scientific Affairs and Communications (QSAC), for their work on this item.

13 Authority Calendar 2020

The calendar was noted.

14 Finance

14.1 Management Accounts: April and May 2020

The accounts were noted by the members.

15 Licensing Activities

The tables of licenses approved by the Management Committee during the period 08/05/2020 to 26/06/2020 were noted by the Authority.

16 Authority Meeting Dates 2020

The 2020 meeting dates were noted. It was agreed that an additional meeting would be held in late October/November 2020. The Secretary will liaise with the Authority members to establish a suitable date. Scheduled dates are 10 September and 3 December 2020.

17 AOB

17.1 National Concert Hall (NCH) – Support letter for Health and Wellbeing programme

The Authority considered and approved support for the NCH Health and Wellbeing programme.