Wednesday, 26 January 2022, 2:00 pm (meeting held remotely)
Report of the Authority

Chair	Mr M. Donnelly
Present	Prof E. Keane, Dr P. Kilbane, Prof S. O'Kane, Prof R. Reilly, Dr J. Collins, Mr D. Holohan, Dr D. Quinlan
In attendance	Dr L. Nolan, Chief Executive (CE), Dr. J.G. Beechinor*, Director of Veterinary Sciences, Ms G. Power*, Director of Human Products Authorisation and Registration
Apologies	Mr B. Jones
Secretary	Ms. A. McGowan, Corporate Affairs Manager (Acting)

*attended for part of meeting

1 Declarations of interest/ Conflicts of Interest

Prof S. O'Kane and Joe Collins noted their conflicts as per the annual declarations received.

2 Matters arising

Face-to-face Meetings

Due to the revised public health advice, the next Authority meeting in March may be an in person meeting.

3 Authority Report

The report of the meeting of 9 December 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.)

- Medical Devices (Registration) Regulations 2021 (SI 691/2021): *Provide for registration requirements in relation to medical devices, and other devices, placed on the market in the State.*

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 14) Regulations 2021 (SI 692/2021*): Amend the relevant schedules in relation to the Comirnaty and Spikevax COVID-19 vaccines to take account of updated advice in relation to booster and additional doses.*

- Medicinal Products (Prescription and Control of Supply) (Amendment) (No 15) Regulations 2021 (SI 718/2021) : *Update the relevant schedules in relation to the COVID-19 vaccines, by taking account of the extension of the vaccination programme to include children aged 5 to 11 years being administered Comirnaty. COVID-19 Vaccine, Paediatric Formulation, as per NIAC recommendations of 7 December 2021, and to provide for boosters in accordance with NIAC recommendations of 13 December 2021.*

- Health Products Regulatory Authority (Fees) Regulations 2021 (SI 744/202): *Provide for the revision of fees payable to the Health Products Regulatory Authority pursuant to Section 13 of the Irish Medicines Board Act 1995. They also revoke the Health Products Regulatory Authority (Fees) Regulations 2020 (SI 654/2020).*

6 Chief Executive update

Specific points discussed included:

Sodium Valproate

The Department of Health have confirmed the intention to progress with the non-statutory public enquiry commencing in Q2 2022. The enquiry's terms of reference are expected to be in Q1 2022. An internal group has been established within the HPRA to prepare for the enquiry. The document retention periods within the HPRA were discussed.

The HPRA are due to publish a dedicated drug safety newsletter (DSN) regarding the use during pregnancy of several well established antiepileptic drugs. A pre-publication version of the DSN was distributed to key stakeholders, including HSE clinical leads in epilepsy and psychiatry, as well as to ICGP and relevant patient organisations. It was noted that there was limited feedback received in relation to the dedicated DSN.

Succession Planning

An update was provided on the competition for the position of Director for Operational Excellence & Quality. The position has not been filled. In collaboration with the leadership team, alternative resourcing options to enhance the focus on operational excellence are now being explored. Secondment was proposed as a potential alternative.

Future of Work

Following the revised public health advice, HPRA staff will be returning to the office on a phased basis from 21st March. The upcoming proposed new legislation on the right to request remote working was discussed.

Network Discussion on the Functioning of the Regulatory Network

A series of European workshops were held in January on the functioning of the regulatory networks for medicines and medical devices and future proofing both systems in light of the changing environment. This takes into account both future needs and the learnings from the pandemic. The workshops have been independently arranged and facilitated by the European Medicines Regulatory Network (EMRN (EMA & HMA)), and the Competent Authority for Medical Devices (CAMD), respectively. Within the HMA a tactical group will be organised to consider the next steps from the learnings from this exercise. The HPRA will conduct a similar exercise on the HPRA's experience during Covid-19.

Medical Devices

The CAMD facilitated an exchange of views on the functioning of the European medical device regulatory system and key developments required within the next five year timeframe and considerations beyond that. The first meeting of the "core group of heads of agencies" who have responsibility for the regulation of medical devices was held.

The core group have agreed to focus on three main priorities related to strengthening network coordination; the investigation of safety issues, certification capacity and innovation support.

7 COVID-19 update

An update was provided in relation to the national booster vaccination campaign and the paediatric vaccination programme.

Omicron

The International Coalition of Medicines Regulatory Authorities (ICMRA) hosted a technical meeting to agree on the clinical data requirements for approval of vaccines targeted against variants. Further analysis of the epidemiology of the Omicron variant is warranted prior to a public health decision being made on the need to update vaccines or the approach that should be taken.

Use of COVID mRNA Vaccines in Pregnancy

The EMA's COVID-19 task force (ETF) recently conducted a detailed review on the safety and effectiveness of COVID-19 vaccine use during pregnancy. Following review of several studies, it was concluded that mRNA COVID-19 vaccines reduced the risk of hospitalisation or death during pregnancy. Moreover, there was no evidence of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects on the baby following mRNA COVID-19 vaccination.

The EMA's human medicines committee (CHMP) will consider the latest data on the use of COVID-19 vaccines during pregnancy with a view to updating the recommendations in the product information for the vaccines, where applicable. The HPRA has liaised with the Department of Health and will share all updated regulatory information that may support uptake of vaccinations in pregnant women.

Therapeutics and Vaccines

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

Vaccine Safety Monitoring

The Human Products Monitoring (HPM) Department continue to closely monitor the safety of COVID-19 vaccines both nationally and in coordination with the European regulatory network. The EMA have offered support to Member States and are processing a number of non-serious case reports on behalf of the HPRA. This has ensured there is no backlog in processing case reports. The Authority congratulated the HPM department for all their work during the pandemic.

8 Genrui Biotech Rapid Antigen Test Recall

Since January 2022, the HPRA has received in excess of 1,350 medical device reports from members of the public, reporting false positive results when using the Genrui SARS-CoV-2 Rapid Antigen Self-Test. It was noted that the CE mark only applies to the instructions for use as a self-test only, not to the performance of the diagnostic itself.

The HPRA worked with the distributors who voluntarily withdrew the product from sale pending investigation. Subsequent investigation by Genrui Biotech has identified an issue with two specific lots relating to contamination of the sample diluent. A field safety corrective action was issued by the Genrui Biotech, withdrawing these two lots from the market across Europe. The investigation and evaluation is ongoing. As the EU Representative for the manufacturer is based in the Netherlands, the Dutch Competent

Authority are the lead competent authority for this issue and will action any ongoing considerations or outcomes. This rapid antigen test has been certified as a self-test by the notified body based in Poland.

9 Conflicts of Interest Management

It was agreed that the Chair will review proposed agenda topics alongside HPRA staff and agree whether any redactions are required in line with the conflicts as per the annual declarations received.

10 Authority Vacancies 2022

The recruitment process for the upcoming Authority Vacancies has commenced. The Authority Chair will be consulted as part of the recruitment process. It was noted that the dynamic of organisation has changed substantially in recent years which is important to reflect in the composition of the Authority. A discussion took place on the areas of expertise which may be beneficial to have on the Authority.

11 Update on Clinical Trial Regulation Implementation

*GP joined the meeting.

An update on the new Clinical Trial Regulation due for implementation from January 31st was provided. The implications for stakeholders involved nationally was highlighted. The national legislation does not introduce additional requirements than those outlined in the existing Clinical Trial Regulation. THE HPRA ran a series of webinars in November 2021 which attracted significant interest in with 300 attendees daily. The standardised timelines for authorisations and implications for the network's workload were discussed.

A query was raised on the implications of Brexit on clinical trials. Medicines from the United Kingdom are now considered as third party imports which adds a level of complexity. Investigative medicinal products coming from the UK are included in the Commission proposed derogations and may still be used in clinical trials carried out in Ireland until end 2024.

*GP left the meeting.

12 Update on Veterinary Medicinal Product Regulation Implementation

*JGB joined the meeting

An update on the new Veterinary Medicinal Product Regulation due for implementation from January 28th was provided. The HPRA actions to communicate the legislative changes were highlighted. The European Commission (EC) have provided an interpretation of the regulation in relation to the time line for the regulation applying to the labels and leaflets of products currently on the market from January 2022. The HPRA and HMA disagrees with this interpretation and has commenced communication with the EC.
It was noted that new national legislation will be issued in relation to the implementation of the new regulations.

* JGB left the meeting

13 Proposal for HPRA to Host 2022 ICMRA Summit Meeting

A proposal was made for the HPRA to submit a bid to host the International Coalition of Medicines Regulatory Authorities (ICMRA) Summit Meeting in Q4 2022. In addition to the normal work of ICMRA, the summit usually takes one day to discuss matters of regulatory scientific interest with an associated dinner. The Authority approved the proposal for the HPRA to host the 2022 ICMRA Summit Meeting.

14 Authority Reports for Publication – November 2021

The Authority approved the publication of the Authority reports for November and December 2021 on the HPRA website.

15 Authority matters

i. Internal Authority Evaluation
The findings of the internal Authority Evaluation survey were completed. It was noted that the answers were generally consistent.

ii. Board Calendar
The draft Authority Calendar for 2022 was discussed.

iii. Declarations of Interest/Ethics in Public Office
The Authority members were thanked for returning their completed Declarations of Interest and Ethics in Public Office declarations promptly ahead of the deadlines outlined.

16 Finance

Management Accounts: November 2021 – were noted by the members.

17 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 10/12/2021 to 20/01/2022.

18 AOB

Kerry Child and Adolescent Mental Health Services Report
The HPRA will review the Kerry Child and Adolescent Mental Health Services Report to see if there are any regulatory issues raised.