HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Wednesday, 23 March 2022, 2:00 pm (hybrid meeting)
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**, Mr B. Jones
In attendance	Dr L. Nolan, Chief Executive (CE), Ms. R. Purcell*, Deputy Chief Executive, Ms. S. Curran*, Director Human Products Monitoring, Dr. C. Fisher*, Planning Support, Ms. A. Barsch Diest*, Quality Manager, D. Balding*, In-house Lawyer
Apologies	
Minutes	Ms. A, McGowan, Corporate Affairs Manager (Acting)

*attended for part of meeting
**attended remotely

1 Declarations of interest/ Conflicts of Interest
Prof S. O'Kane and Dr J. Collins noted their conflicts as per the annual declarations received and abstained from attending related parts of the meeting.

2 Matters arising
There was nothing to report.

3 Authority Report
The report of the meeting of 26 January 2022 was adopted.

4 Health and Safety Update
There was nothing to report.

5 European Medicine Agency (EMA)'s Management Board Chair
The Authority were updated on the Chief Executive's successful appointment to the role of Chair of the EMA Management Board.

6 HPRA updates (Changes to legislation, competencies, ToR, Code of Conduct etc.)

European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 (SI 36 of 2022):
The coming into effect of national legislation implementing the new European Regulation for veterinary medicines was noted. The national legislation includes new provisions for an appeals mechanism for the HPRA's Advisory Committee for Veterinary Medicines (ACVM). The implications of the national legislation on the HPRA's role in the legal classification of a veterinary medicinal products was discussed. The need for DAFM to immediately address this through further legal measures was agreed.

European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (SI 99/2022)

European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022 (SI 41/2022):
The coming into effect of national legislation to implement the new EU Clinical Trials Regulation, and the establishment of the National Research Ethics Committees were noted.

A number of amendments to the Medicinal Products Prescription and Control of Supply Regulations to take account of additional vaccinations that can be administered in pharmacy settings were noted (SIs 32, 57 and 84 of 2022)

7 Chief Executive update
Specific points discussed included:

Low Dose Codeine Preparations
An update was provided on the sale of Low dose codeine preparations as combined analgesic products, which are permitted to be available without prescription through retail pharmacy businesses only where there is the personal supervision of a pharmacist. The matter was considered by the HPRA and the ACHM in 2019 and based on evidence available at that time, it was recommended to be kept under review. The HPRA were included in a communication from a healthcare professional directed to the Chief Medical Officer (DoH), which reported a public health concern regarding an ibuprofen low dose codeine combination and dependency syndrome. The HPRA subsequently directly received a number of cases which describe adults with serious health consequences arising from prolonged misuse in the context of codeine addiction. A cumulative review of available evidence is being undertaken by the HPRA. A discussion was had on the regulation of codeine containing products in countries including New Zealand and Australia, including considerations for primary care needs. The HPRA will continue to engage with the DoH, the PSI and other health stakeholders for the purposes of collectively considering this matter in full.

Haemostatic Agents
An overview was provided of the evaluation of a possible association between haemostatic agents used during routine surgical procedures with a small number of patients with rare complications.

Patient Forum
An update was provided from the recent Patient Forum meeting. This was the first meeting of the Fourm since its establishment on a permanent footing under the Chairmanship of Dr Paula Kilbane. Its focus related to the establishment of the Forum's work programme. The meeting was considered insightful with regard to suggested approaches that the organisation could take in relation to its staff training programmes involving patients.

The Future of Work
HPRA staff started the phased return to work on March 21. The full Future of work model will be 3 days on site and 2 days remote working, or the equivalent of 60% of working hours across a month. The preparations for the return to office including the establishment of new meeting rooms and installation of technology to enable hybrid meetings were highlighted. A query was raised regarding other national competent authorities which key

differences across the network noted. Pulse surveys will be conducted and the review of the Future of Work model will be data driven. The Authority congratulated all those involved in the return to work preparations. The equity in the approach that had been taken by the organisation with regard to the capacity of all staff to avail of hybrid working to same extent, was highlighted as a strength in the approach.

8 COVID-19 update

An update was provided in relation to the national booster vaccination campaign and the paediatric vaccination programme. An overview of the additional COVID-19 vaccine candidates and therapeutics and the ongoing status of their evaluations was provided.

9 Update on medical supply due to situation in Ukraine and Russia

The HPRA, in coordination with the EMA are monitoring the supply of medicines in light of the situation in Ukraine. No resulting supply issues had been identified to date. A discussion was had on any public health concerns arising from the situation and resulting movement of people including Covid-19 vaccination rates.

10 Appeal to change HPRA policy on method of supply of spot-on anti-parasitic products for companion animals

An application from Chanelle Pharmaceuticals was recieved regarding spot-on products containing fipronil and s-methoprene to change the route of supply classification from licensed merchant (LM) to companion animal medicine [seller] (CAM). The Advisory committee for Veterinary medicines (ACVM) reviewed the application during the March 2nd meeting and recommended the changed of supply route to CAM. The ACVM also agreed that this decision is in principle applicable to other spot-on products containing fipronil, fipronil and s-methoprene as well as other active substances that have a well-recognised efficacy and an exemplary safety profile (over more than five years) and which do not have a claim for flea allergic dermatitis.

A discussion was had on the potential implications of the change of the route of supply classification including any environmental implications. The Authority approved the change of route of supply classification from licensed merchant (LM) to companion animal medicine [seller] (CAM).

The Authority also noted its approval for the revision of the related HPRA policy with a second addendum to indicate the following. Spot-on adulticidal flea and tick products containing fipronil, fipronil and (s)-methoprene or other active substances may be considered for sale/supply as CAM products, upon submission of an appropriate application and approval by the HPRA, where they have a well-recognised efficacy and an exemplary safety profile (more than 5 years), and which do not have an indication for flea allergic dermatitis.

11 Service Plan 2021 Outturn

*C. Fisher and A. Barsch Diest joined the meeting.

An overview of the outturn of the 2021 service plan was presented. Overall 2021 had a very high outturn in spite of the significant impact of the pandemic. Feedback was sought on

the new reporting format, which the Authority noted made it clearer and easier to identity progress and any reasons for delay. A query was raised in relation to the current focus with regard to Brexit. It was clarified that work is still ongoing within the Commission to establish a legal framework to protect the continued supply of medicines to Ireland, Malta and Cyprus until the end of 2024. Additional exemptions are being developed for Northern Ireland.

*C. Fisher and A. Barsch Diest left the meeting.

12 Risk Register Review

The Audit and Risk Committee (ARC) reviewed the Risk register and recommended the register for review by the Authority. An overview of the current risk register was presented. It was noted that significant revisions were made during 2021 to the risk register and as such there were no further recommendations for changes to the risks listed. The Authority approved the risk register.

13 Overview Year 1 HPRA Strategic Plan 2021-2025

*C. Fisher and A. Barsch Diest joined the meeting.

The first review of the HPRA Strategic Plan 2021-2025 was presented. It was noted the strategic plan currently closely reflects the service plan. Given that 2021 was the first year of the new strategy that is to be expected and there may be more divergence in subsequent years. The Authority approved the overview of the first year of the Strategic Plan.

*C. Fisher and A. Barsch Diest left the meeting.

14 Human Products Monitoring Department Priorities

*S. Curran joined the meeting

An overview of the Human Products Monitoring (HPM) Department and its role was presented. A case study of the pharmacovigilance associated with potential adverse reactions related to Covid-19 vaccinations was presented, noting the emphasis placed on communication to patients, the public and healthcare providers. The Authority thanked the HPM for their ongoing work especially noting the increased workload associated with the national Covid-19 vaccination campaign.

*S. Curran left the meeting

15 Authority Matters

There was nothing to report.

16 HPRA : Energy and Sustainability Committee Update

*D. Balding joined the meeting

An overview of the work carried out by the HPRA Energy and Sustainability Committee (ENSUS) was provided noting the legal requirements of the HPRA. The awareness campaigns and improvements made by the HPRA Facilities teams were highlighted. The HPRA has reduced energy consumption by 62.4% since 2015, including substantial savings

during 2020 and 2021 with very low building usage. The Authority congratulate the ENSUS team on their work to date and looked forward to future initiatives.

*D. Balding left the meeting

17 Finance

Management Accounts: November, December 2021 and January 2022 – were noted by the members.

18 Committees

Item	Statutory Committee	Last Meeting Date	Updates
18.1	Audit and Risk Committee (ARC)	**23 March**	The ARC Chair provided an update on the recent meeting of the ARC including an update on the risk register which was noted under item 12. It was noted that the external Audit provider has been appointed. The ARC reviewed and recommended the Statement of Internal Controls for 2021 for the Authority to review. The Authority will review the Statement via written procedure by March 31 2022.
18.2	Advisory Committee Veterinary Medicines (ACVM)	**2 March**	The ACVM Chair provided an update on the recent meeting of the ACVM.
18.3	Advisory Committee Human Medicines (ACHM)	**9 March**	The ACHM Chair provided an update on the recent meeting of the ACHM, highlighting the discussion on low codeine dependency under item 7.
18.4	Advisory Committee Medical Devices (ACMD)	None since last meeting	Nothing to report.

19 Update Authority Vacancies 2022

An update was provided on the status of the ongoing recruitment process.

20 Update Meeting DoH Secretary General

A meeting has been arranged for April. The Authority discussed potential topics to add to the agenda.

21 Licensing activities

The Authority noted the tables specifying the authorisations approved by the Management Committee during the period 21/01/2021 to 11/03/2022.