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HPRA Authority Meeting Report 4 November 2020 (meeting held remotely)

Item Type	Report
Authors	Health Products Regulatory Authority (HPRA)
Publisher	Health Products Regulatory Authority (HPRA)
Download date	2026-05-20 23:02:02
Link to Item	https://hdl.handle.net/10147/640843

4 November 2020 (meeting held remotely)

Authority Meeting Report

It was noted that the November meeting of the Authority was an extra meeting, deemed necessary in view of the volume of work to be covered by the Authority before the year-end. This has been an exceptionally busy year, due to the COVID pandemic and BREXIT in particular.

1 Declarations of Interest / Conflicts of Interest

None noted.

New Authority Member

The Chairperson welcomed Dr Joe Collins to his first board meeting. Dr Collins introduced himself and gave a brief overview of his career to date and his interest in the work of the HPRA.

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

Changes to Code of Practice, Diversity and Inclusion

The Authority were updated on recent changes to the Code of Practice, with the Annex on Gender Balance, and Diversity and Inclusion, effective from September 2020. It was highlighted that State Board appointee terms should now be between three and five years, which may be renewed once to a maximum of eight years.

New National Legislation

Medicinal Products (Prescription and Control of Supply) (Amendment) (No 5) Regulations 2020 (SI 401/2020): The Chief Executive advised that the purpose of these Regulations, in light of the pandemic, is to allow for vaccinations to be administered by pharmacists in places other than retail pharmacy premises.

3 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:

Public Health - IMMDS Review - Independent Medicines and Medical Devices Safety Review

The Authority re-emphasised the importance of strengthening engagements between health stakeholders to consider regulatory issues and clinical practice implications in a more systematic way where related to potential patient safety issues linked to health products.

Public Health - Anaplastic Large Cell Lymphoma (BIA-ALCL)

The Chair of the Advisory Committee for Medical Devices (ACMD) updated the Authority on the establishment of an expert sub-group tasked with independently examining the issue of BIA-ALCL in an Irish context. Input from the sub-group is expected by year-end, and this will be shared with the Authority.

HPRA Business - Brexit

The Authority noted the HPRA's plans and areas of focus for year-end, with specific reference to continued supply of medicines and medical devices. The plan also includes work on reviewing

and addressing areas where non-compliance remains an issue. It was noted there are currently no significant concerns in relation to the compliance status for medical devices and clinical trials.

HPRA Business – Remote working

The Authority members welcomed the proposal to seek external advisory support to assist in performing an organisational analysis of considerations for the future of working, and asked to be updated on progress once the work commences.

The Authority members noted the range of communication methodologies and initiatives that had been undertaken to maintain staff connectedness. Staff morale was noted as being positive in general and a key area of focus for the Management Committee. A further pulse survey is being carried out and will give a more thorough insight. An update will be provided at the December meeting.

HPRA Business - International

The Chairperson expressed her opinion that the Authority would benefit from a focussed discussion on the considerable and impressive level of work of the HPRA at international level. The Chief Executive undertook to organise a presentation on this work for early 2021.

4 HPAR Department Update: COVID-19 Priorities

A presentation was given by the Director of Human Products Authorisation and Registration (HPAR) which set out key considerations for the HPAR department in light of COVID-19 activities. Specific issues included collaboration with the European medicines regulatory networks in the authorising of a vaccine and continuing involvement with the Immunisation Strategy Group (ISG) in relation to deployment.

The HPRA is working within a highly expert network at European level, where work is allocated by the EMA to Member States with sufficient capacity and expertise. It was emphasised that the HPRA has built expertise among our staff, in addition to diligent capacity planning. It is recognised that there is always potential for loss of expertise to industry. However, we have a good track-record of staff retention while operating in this environment. Through consistent engagement, succession planning and communicating supports and values of the organisation, the HPRA has exceptionally committed staff who are enthusiastic at being at the forefront of ground-breaking work.

Distribution and logistics is a GDP matter for the HPRA Compliance department, who will have responsibility to ensure that procedures are in place to support vaccines that are on the Irish market. Further details on distribution logistics will depend on the vaccine authorised. It is anticipated that certain vaccine candidates might receive regulatory approval in mid to late December, where more details will become available concerning distribution requirements.

Several vaccine candidates are undergoing efficacy study at present. While Ireland is part of the Commission's Advance Purchase Agreement (APA) and has opted-in on some contracts, the independence between the Government purchase contract and any regulatory decisions were again emphasised.

Several companies with vaccines in late-stage phase 3 clinical trials have included individuals over 65 to ensure sufficient representation in that cohort.

The Authority members acknowledged the importance of the considerable work undertaken by the HPAR department, and extended their thanks for an excellent presentation and to all working in the department.

5 Progress of Digital Transformation Strategy and Other Projects

A paper on the progress of the Digital Transformation Strategy was noted by the Authority. The paper outlined the status of the project and progression to finalisation. It is expected that a final strategy paper will be presented at the December meeting for adoption.

6 HPRA Strategic Plan, 2021 to 2025 – Update

Two overview documents were presented covering the plan itself and the HPRA’s Mission, Vision and Values. A number of points related to strengthening the emphasis on animal health protection and the principle of One Health was noted. The Authority agreed the Strategic Plan was ready to be submitted to the Department of Health and remains on track for final agreement at the December meeting.

The Authority expressed thanks for the considerable work on the strategy to date.

7 Board External Evaluation – Verbal Update

The Chairperson advised that an evaluation report is awaited from Board Excellence. The Secretary will follow up with Board Excellence.

8 Review of Authority Meeting Schedule

Upcoming meetings of the Authority were noted. Suggested meeting dates for quarter one 2021 will be circulated by the Secretary.

9 Committees

ITEM	Statutory Committee	Last Meeting Date	Updates
9.1	Audit and Risk Committee (ARC)	23/09/2020	The minutes of March 2020 and May 2020 were noted by the Authority
9.2	Advisory Committee for Veterinary Medicines (ACVM)	16/09/2020	Met on 16 September 2020 chaired by Acting-Chair. The Chair’s report was noted by the Authority.
9.3	Advisory Committee for Medical Devices (ACMD)	30/09/2020	Met on 30 September 2020. The Chair’s report was noted by the Authority. The next ACMD meeting is scheduled for 23 November 2020
9.4	Advisory Committee for Human Medicines (ACHM)		None since last meeting. The next ACHM meeting is scheduled to take place on 3 December 2020

Advisory Committee Terms

It was noted that the present Advisory Committee member terms are up for renewal from 31 December 2020, including the position of Chair for the ACHM and the ACVM, respectively. The HPRA will write to the Minister for Health on the matter.

10 Finance

10.1 Management Accounts: September 2020

The accounts were noted by the members.

11 Licensing Activities

The tables of licenses approved by the Management Committee during the period 18/09/2020 to 23/10/2020 were noted by the Authority.