

27 January 2016

Authority Meeting Report

1 Appointment of the Chair

The Chair provided an overview of the recruitment process for the new Chair of the Authority. As part of that process, she was requested to attend a meeting of the Oireachtas Joint Committee on Health on 21 January 2016 to provide an overview of her career to date and her vision for the organisation going forward. Subsequently her appointment was officially ratified by the Oireachtas Committee.

2 Training and Evaluation for the Authority

It was agreed that a training and evaluation session for the Authority take place at the June meeting with the Chief Executive and Secretary also present.

3 Introduction of new Chief Executive

The Chief Executive thanked the Chair for her warm wishes and said that she was delighted and proud to have been appointed to the role of Chief Executive of the HPRA. She is looking forward to working closely with the Authority members.

4 Declarations of Interest

There were no conflicts of interest declared.

5 Health and Safety

There were no health and safety items to report.

6 Risk Management

There was nothing to report.

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

There was nothing to report.

8 Chief Executive's Report

The Chief Executive provided an overview of the main highlights of her report which were noted by the Authority:

- The HPRA has been asked by the Department of Health to lead on dealing with medicines shortages and is currently in discussions with the Department on the need for financial and staffing support to progress this matter.

- The HPRA has developed a register for those entitled to purchase emergency medicines as required by the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015.
- The Zambia contract is progressing with a fact finding mission having been completed in December 2015. An invitation has been extended to the head of the Zambian agency to visit the HPRA. It was noted that the Chief Executive and Deputy Chief Executive are to meet with the lead for medicines regulation at the WHO and with the Gates Foundation in relation to regulatory development in Africa.
- The Gardasil High Court action seeking the withdrawal of the authorisation for Gardasil and the cessation of the roll out of the Human Papilloma Virus (HPV) vaccine among teenage girls in schools is ongoing. However, the simultaneous Article 20 EMA review of the HPV vaccine has confirmed that the evidence does not support a causal link between the vaccines (Cervarix, Gardasil/Silgard and Gardasil-9) and development of Complex Regional Pain Syndrome (CRPS) and Postural Orthostatic Tachycardia Syndrome (POTS).
- The HPRA was asked to make a written presentation to the Oireachtas Joint Committee on Health in relation to (1) the De Puy hip recall 2012/2013 and (2) the medicinal use of cannabis.
- The medical devices legislation recast is progressing as is the matter of fees, with the submission of a fee proposal to the Department of Health.
- The roll out of the HPRA Brand Awareness campaign in 2016 was outlined. In relation to the BT Young Scientist and Technology Exhibition 2016, it was the HPRA's seventh year of participation in an event that provides a great opportunity to raise awareness of the HPRA's role among students. The HPRA Special Award went to three students in Ardscoil Phádraig in Granard, Co. Longford, for their project on the *Awareness of Parasites in Cattle and on-Farm Practices to Sustain Herd Health*.

9 Audit Committee – Meeting of 3 December 2015

The draft minutes of the above meeting were noted by the Authority.

10 Advisory Committee for Medical Devices (ACMD) – Meeting of 30 November 2015

The Chair's Report for the above meeting was noted by the Authority.

11 National Standards Authority of Ireland (NSAI) Redesignation

The redesignation of the NSAI for a five year period was noted by the Authority.

12 Letter of Non-Capital Expenditure from Department of Health

The Authority noted the above.

13 Board Vacancies 2016-2020

It was noted that the Department of Health is currently considering nominations to the Authority of the HPRA. It is expected that the two remaining positions will be filled via the Public Appointments Service (PAS).

14 Financial

The Authority approved the proposed list of banks with whom the HPRA can place deposits while the management accounts for November 2015 were noted by the members.

15 Licensing Activities

The tables of licences approved by the Management Committee during the period 27/11/15 to 15/01/16 were noted by the Authority.

16 Authority Meeting Dates 2016

The Authority noted the meeting dates for 2016.