HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

24 January 2019

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Award to Authority Member

Brian Jones (absent) was congratulated on his receipt of a British Citizen Award.

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

A number of legislative updates were provided in the Chief Executive's report, namely:

- Veterinary Regulation 2019/6: This will come into effect on 28 January 2019 and will apply from 28 January 2022.
- Medicinal Products (Control of Prescription and Control of Supply) (Amendment) Regulations 2018 (SI 530 of 2018) and Medical Products (Control of Placing on the Market) (Amendment) Regulations 2018 (SI 529 of 2018), as amended: Both enable the roll out of termination of pregnancy services.

4 Chief Executive's Report

The Chief Executive provided an update on the following:

- Medicines authorised for termination of pregnancy: To ensure continued supply, the HPRA is engaging with suppliers and wholesalers.
- The implementation of the safety feature requirements under the Falsified Medicines Directive was highlighted. The provision which is a medicines anti-counterfeit measure is due to come into effect on 9 February. The introduction is reliant on complex IT and scanning systems which operate at national and EU levels. Transitional measures may be required to ensure the smooth introduction of the new systems.
- The HPRA will co-host and assist in the coordination of The Organisation of Professional Regulatory Affairs (TOPRA) 2019 Symposium taking place in Dublin from 30 September to 2 October. The symposium includes human and veterinary medicines and medical devices as its focus. The theme: Europe at the forefront of global healthcare regulation – Driving innovation through convergent approaches in medicines, devices and veterinary regulatory affairs.
- The members noted the increased level of human medicines allocations for European work in 2018. It was clarified that additional resources had been assigned in respect of both human and veterinary medicines in 2018. Further recruitment is planned in 2019 to ensure delivery of this additional work which reflects the HPRA's Brexit strategy of increasing our European footprint.

- The CE noted that Dr Joan Gilvarry announced her intention to retire as of the end of May 2019 after 25 years of service to the HPRA. The Authority congratulated Dr Gilvarry on her service and thanked her for her significant contribution to the organisation.
- Succession plans for the Management Committee and other senior management roles across the organisation are in place and will prove useful in the recruitment process for a new Director for Human Products Monitoring.

5 ICT Update

The Chief Executive provided an update on Eolas and noted the gradual progress being made in respect of the outstanding issues.

Work on the development of the IT Strategy has commenced. Following a tender process, IBM has been appointed as the service provider. The strategy will determine the organisation's needs and focus from an ICT perspective for the next three to five years.

6 Authority Calendar 2019

The layout and terminology within the Authority calendar has been updated. Each of the business units is now reflected. Executive Directors will be invited to present to the Authority in rotation. Dr Joan Gilvarry will be invited to attend the March meeting.

7 Succession planning

Marian Bergin presented on the outcome of the Authority succession planning review. Authority members were thanked for their valuable input into the work. The resulting succession matrix will assist the Chair and Authority members to ensure that the Authority has the necessary skills and competencies to perform its functions as an Authority. The plan will also form part of the induction process for new Authority members and inform future thematic discussions. The Chair commended Ms Bergin and the Secretary for the calibre of the work completed which will have significant positive future impact.

8 Medical Devices Update

This item covered two topics:

8.1 Reorganisation of the Department

The Director of Human Resources and Change and the Deputy Director of Medical Devices provided an update on the organisation's change management programme for the Medical Devices Department. The key focus was the presentation of the Department's 'to be' structure and associated resourcing requirements.

The Authority also commented on the inclusive manner in which the change programme had been conducted highlighting the value of including all colleagues in the workshops. It was suggested that this model can be used as a case study / model for others areas of the business in future.

8.2 Product updates

Additional points highlighted during the discussion included the increase in user reports for implanted devices.

While media focus on medical devices is expected to continue, the Medical Devices Regulation will help to improve the regulatory framework. The Deputy Director also highlighted the importance developing awareness among the media of the different product types and classes. The public expectation for 'no risk' treatment options needs to be addressed through clear and open communication.

9 Brexit

The Deputy Chief Executive presented an update on HPRA preparedness planning.

The key priority remains ensuring the continued supply of medicines and medical devices. The HPRA has always believed that pragmatic regulatory solutions may be required to allow companies complete their pathway to full regulatory compliance in the event of a "no deal" Brexit. A key focus for the coming weeks will be identifying areas where there is a risk of non-compliance, assessing the impact and proposing solutions.

The HPRA will work with all stakeholders to ensure that there is a continued focus on the supply of medicines and medical devices and to ensure that companies are working towards regulatory compliance.

The HPRA is also working collaboratively with the Department of Health, the HSE and other health stakeholders as part of the whole of Government preparedness approach.

The HPRA Brexit stakeholder event will take place on 1 February in the Crown Plaza, Santry with up to 400 attendees expected. This was noted by the members of the Authority who were invited to attend.

10 Standing orders (8(8) of the IMB Act)

The Authority adopted the updated Standing Orders as amended.

11 Statutory Review of the Committees

An update on the progress of the statutory review of the scientific advisory committees was provided to the Authority. Meetings are planned with the department management teams and a new questionnaire will also be issued to staff. The review will be finalised by mid-2019 with a view to sharing the proposal with the Department of Health after the June meeting of the Authority.

14 Performance Review Committee

The Chair reported on a positive meeting with the Chief Executive and congratulated her on three years in the role. Priorities for 2019 were presented and agreed. It was noted that 2018 objectives had been successfully met.

15 Finance

The management accounts were noted and are due for formal review by the Audit and Risk Committee at the next meeting.

16 Licensing Activities

The tables of licenses approved by the Management Committee during the period 07/12/2018 to 18/01/2019 were noted by the Authority.

17 Authority Meeting Dates 2019

The next meeting of the Authority is scheduled for Thursday, 14 March 2019. It was agreed the Secretary would send a reminder to all members.