

21 September 2016

Authority Meeting Report

1 Declarations of Interest

Professor O'Driscoll stated that she is the Vice-Chair of Regulatory Science Ireland (RSI).

2 Payment for Authority Members

It was noted that the matter of payment for Authority members has been included in the Health (Miscellaneous Provisions) Bill which is to go before the Oireachtas in due course.

3 Health and Safety

There was nothing to report.

4 Risk Management

The Authority adopted the contents of the Risk Register and the Risk Map as recommended by the Audit Committee. It was noted that the impact of Brexit has been logged as a risk.

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

The Terms of Reference for both the Authority and the Management Committee were reviewed and approved subject to a modification in the Management Committee's Terms of Reference.

6 Chief Executive's Report

The Chief Executive had circulated her report in advance of the meeting and the members of Authority were invited to comment and ask questions:

- The Chief Executive drew the members' attention to the section of her report concerning policy issues on the medical use of cannabis.
- It was noted that a Freedom of Information request relating to SAP inspection reports was appealed to the Office of the Information Commissioner (OIC) who did not agree with the HPRA proposal to redact certain data. The HPRA is challenging the OIC decision in the High Court.
- It was agreed that the Chief Executive would table an initial paper on medical devices at the December meeting in advance of a medical devices thematic discussion early in 2017.
- The Authority complimented the Chief Executive and HPRA staff on their successful bid to host the prestigious World Health Organisation (WHO) biennial International Conference of Drug Regulatory Authorities (ICDRA) in Dublin in 2018.

7 Audit Committee Meeting – 21 September 2016

The Authority noted the agenda of the above meeting. The Chair provided an overview of the highlights of the meeting. It was noted that the internal auditors report on budget management and fixed assets was reviewed by the Committee. The HPRA Finance team was complimented on an excellent report with no recommendations from the auditor. The report provides substantial assurance in respect of the HPRA's financial systems. It was also noted that the Code of Practice for the Governance of State Bodies 2016 has been finalised and a high level review will be prepared for the next meeting of the Audit Committee. Following on from agreement by the Authority in early 2016 on the cash deposit policy of HPRA, it was noted that the Audit Committee reviewed which European banks based in Ireland would be considered appropriate for short and longer term deposits.

8 Review of External Experts

The Authority discussed the future structure of the scientific advisory committees. It was agreed that the Authority set up a small working group to consider the matter in more detail. The Chairs of the existing scientific advisory committees, internal experts and the Director of Finance, Corporate and International, are to make up the group and will report back to the Authority.

9 Regulatory Science Ireland (RSI)

(Professor O'Driscoll left the room for this item).

The Authority was updated on HPRA's involvement in RSI.

10 Outcome of Authority Training (June 2016)

The Authority was provided with an overview of the outcome of the Authority training in June 2016. It was agreed that the matter would be reviewed regularly to ensure that the outcomes are implemented as agreed.

11 Innovation – Thematic Discussion

A discussion on innovation was led by two board members. They highlighted a strong recognition of the need to put in place a functioning Innovation Office within a six month timeline based on national and international models, and that supporting innovation is one of the key objectives of the HPRA 2016-2020 Strategic Plan. It was noted that the HPRA has the capacity to achieve this within existing resources. Discussions with the newly formed HPRA Innovation Task Force shows that the HPRA is already providing valuable regulatory support to innovators across many different sectors. It is important to recognise the support the organisation currently provides to the sector and the expansion of this offering will create visibility of the HPRA among innovators and build recognition of regulatory advice as a key support on the innovation journey.

The primary change in the approach will be more proactive and targeted engagement by the HPRA with this sector through outreach and education, horizon scanning, classification, knowledge management, research and building synergies with other similar organisations in the field. The Authority noted that the Director of Finance, Corporate and International is leading the start-up phase of the project. The Authority was of the view that strong internal leadership is needed to ensure the success of this project and given that a virtual model is proposed, it is

important that a single senior member of staff is given overall responsibility for developing the Innovation Office. The Chair thanked those involved in leading the thematic discussion and complimented the work to date.

12 Business Planning

The Authority was provided with an overview of the Q2 Service Plan Report which demonstrates that the organisation is meeting 92% of its targets and this was well received. The Authority also reviewed and adopted the Key Priorities and Objectives for 2017 which is consistent with the 2016-2020 Strategic Plan.

13 Eolas

An overview was provided of the Eolas project to date. An updated plan has been agreed which will see the project roll out move from veterinary medicines to human medicines and then on to the inspection section and medical devices. The timeline for go-live for the Veterinary Sciences department is January 2017.

14 TB Vaccine Shortage

The Authority noted the global shortage of tuberculosis vaccine and that the HPRA is working to identify a suitable alternative supply for Ireland.

15 Brexit Impact

The Authority was updated on the future implications of Brexit for the HPRA. While in the short term there will be little change, in the longer term it has the potential to impact on inspections and wider product assessment activities. It was agreed that a full discussion would be held on Brexit at the March 2017 meeting.

16 Financial

The management accounts for May, June and July 2016 were noted by the members having been reviewed by the Audit Committee at its recent meeting.

17 Licensing Activities

The tables of licences approved by the Management Committee during the period 02/06/2017 to 15/09/2017 were noted by the Authority.

18 Authority Proposed Meeting Dates 2017

The Authority noted the proposed meeting dates for 2017. It was agreed that an online poll be circulated so that members could confirm their availability.