HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

7 December 2017

Authority Meeting Report

1 Declarations of Interest

There were no interests declared.

2 Health and Safety

The members of the Authority were informed that the new Corporate Affairs Manager has taken over management of Health and Safety. There were no issues to report.

3 Risk management

The risk register was presented and agreed by the Authority. It was noted that this is a very comprehensive document which provides significant reassurance in respect of the Authority's risk management procedures.

A number of changes to aspects of the quality system relating to risk management were agreed. This includes consolidation of a number of relevant documents into a new risk management framework. The framework includes the policy, roles and responsibilities, the risk register, review and monitoring requirements, and the application of risk.

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

The updated terms of reference for the Authority were reviewed and adopted.

5 Chief Executive's Report

The following update was provided by the Chief Executive:

- Shortages: A senior resource has been recruited to work on the co-ordination of the multistakeholder shortages plan. The initial six months focus has been on evaluation of the current situation and has involved broad reaching stakeholder engagement.
- BEMA: The excellent result from Benchmarking of European Medicines Agencies (BEMA) was noted. It was highlighted that the outcomes will be published within the European network. The external validation reinforces the Authority's confidence in the organisation.
- Valproate: The HPRA will host a stakeholder meeting following completion of the EU referral to ensure the effective implementation of the recommendations of the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA). *Post meeting note: Due to continued consideration by the PRAC, this meeting will be held late in Q1 2018.*
- Cannabis for Medicinal Use Regulation Bill 2016: The potential implications for the HPRA were highlighted.
- Graduate recruitment: The recent campaign achieved 176 applications, resulting in two successful appointments. The appointees will bring diverse and novel experience to the organisation.

- Irish Heart Foundation: The HPRA has been awarded the Irish Heart Foundation's Gold Active@Work award, reflecting the organisations focus on promoting, developing and sustaining physical activity programmes in the workplace.

6 Medical Devices

A paper on proposals for organisational development of medical device activities was presented and supported by the Authority.

7 Strategic Plan Review - Brexit

Ahead of the 2018 interim review of the Strategic Plan, an initial analysis of the potential implications of Brexit has been completed. The Authority highlighted the importance of the review as presented.

8 HPRA Q3 Service Plan Report

A status report on progress of the 2017 Service Plan at the end of Q3 was provided to the Authority.

9 HPRA Service Plan for 2018

An overview was presented of the 2018 Service Plan. The key objectives had been presented at the June meeting. Finalising the plan will take into account the output figures at the end of the year and funding from the Department of Health. The final version will be presented to the Authority in Q1 2018 (March meeting). The Authority commended the comprehensive and detailed plan.

10 Brexit Update

An update on the work completed in preparation for Brexit was given. The HPRA Brexit task force has focussed on enhancing the HPRA's contribution to decentralised medicines assessments and inspections in addition to working to promote the HPRA's focus on public health protection and medicines availability. Each department has their own operational milestones in respect of increasing lead assessment and inspection activities. An update on the EMA's work on managing the impacts of Brexit on centralised assessments for medicines was also provided. The HPRA has put in place structured plans to meet its public health protection role and supporting the maintenance of medicinal products on the market. Protection of public health was identified as the key strategic objective for the HPRA Brexit task force.

11 Eolas Update

An update on Eolas project was presented. Key developments include completion of the roll-out for veterinary medicines.

12 Communications Update

A paper outlining a further iteration of the HPRA's public media campaign was discussed.

13 Irish Blood Transfusion Service (IBTS) Annual Report

The Director of Compliance presented on the background to the IBTS and the HPRA's regulatory role under national legislation since the 1970s and in the past twelve years under EU legislation. The HPRA's report to the Minister for Health for 2016 on its oversight role was presented. The Authority approved the report for submission to the Minister.

14 The WHO International Conference of Drug Regulatory Authorities (ICDRA)

The HPRA will host the next ICDRA on behalf of the World Health Organisation (WHO). The newly developed ICDRA website was presented. An overview of the general schedule for the conference was outlined. A more detailed agenda will be circulated to members of the Authority once available. Over the coming months, the focus will include further communications and outreach to stakeholders, including the Irish pharma sector.

15 Scientific Committees Review

An update on the on-going review of the HPRA's Scientific Committees was provided. Approaches taken by other agencies/bodies affiliated under the responsibility of the Department of Health will be reviewed. The intended outcome is the determination of an optimum model to meet HPRA's needs and the legislative impact of this. Further updates will be given to the Authority as the review progresses.

16 Buildings update

A preliminary update on an option for future office accommodation was discussed by the Authority.

17 Committees

17.1 Audit and Risk Committee – 5 December 2017

A summary of the meeting was provided:

- The Committee met with the Office of the Comptroller and Auditor General to consider a number of small findings – two low and one medium impact. The conclusion was the accounts and financial procedures and processes are well managed. The internal audit with BDO also outlined a small number of minor findings. The HPRA are in compliance and will be fully compliant next year as required by the Code of Practice for the Governance of State Bodies.
- The evaluation of the pension liability and the HPRA's future capabilities in meeting this was discussed. A meeting to discuss the liability and the need for a solution to address this is scheduled with the Department of Health for January. The Committee proposed awaiting the outcome of this meeting and then recommend that the Authority devise a strategy to ensure that the Department provides assistance to generating a solution on this matter.
- The Director of Quality Scientific Affairs and Communications presented to the Committee on the HPRA's management of protected disclosures. Specifically in terms of the Protected Disclosures Act, there are two documents: (1) The policy explains the principles and procedures associated with the legislation and is based on the Guidance from the Department of Public Expenditure and Reform; (2) The SOP explains how to

deal with protected disclosures if and when they arise. These documents were considered to be comprehensive.

17.2 Advisory Committee for Veterinary Medicines (ACVM) – 1 December 2017

A summary of the meeting was provided.

- With regards to the EMA's Committee for Veterinary Medicinal Products (CVMP) moxidectin referral, it was highlighted that moxidectin has been identified as a substance with PBT (persistent, bio-accumulative, toxic) properties. The CVMP has allowed moxidectin to continue to be used in the EU under specified conditions, including that new environmental studies be provided within five years.
- Pharmacovigilance reporting has been low. As a result, an online training module was proposed where veterinary healthcare professionals could achieve points for continued professional development. This could also be opened up to pharmacists.

17.3 Advisory Committee for Medical Devices (ACMD) – 27 November 2017

A summary of the meeting was provided.

- There was a focus on key cases in medical device vigilance relating to Medtronic insulin pumps. The Authority were also provided with an overview of a field safety corrective action relating to intraocular lenses initiated by Oculentis in September 2017. All affected customers have received the Field Safety Notice (FSNO and HPRA continues to pursue reconciliation data from the distributor. The HPRA has also raised this issue with European vigilance colleagues. A briefing paper on surgical meshes was also mentioned however this was covered by the CE earlier in the meeting.
- The new EU Regulations for notified bodies became fully applicable on 26 November 2017. The HPRA anticipate that it will receive applications for designation from three separate organisations, including the existing Irish notified body. Notified bodies are required to apply separately under each Regulation and they require separate assessments. The assessments will be complex and will need to be completed during the first quarter of 2018 to complete the first phase in an 18-month designation process.
- Subcommittee of the Advisory Committee for Medical Devices (ACMD): The establishment of a subcommittee to deal with software related issues was supported.

18 Finance

18.1 Management Accounts October 2017

The Authority adopted the Accounts based on the review by the Audit and Risk Committee.

18.2 Budget 2018

An overview of the 2018 budgets was provided following review by the Audit and Risk Committee. The budgeting process for 2018 has been challenging in light of increasing payroll costs due to restoration of elements of previous public sector pay cuts. Income is not increasing in line with the trends of previous years and this is due to reduced submissions. Brexit and associated uncertainties are contributory factors and it is likely this will continue into 2018. The Committee recommended approval of the budgets and this was supported by the Authority,

19 Licensing Activities

The tables of licenses approved by the Management Committee during the period 22/09/2017 to 01/12/2017 were noted by the Authority.

20 Authority Meeting Dates 2018

The proposed meeting dates for 2018 were agreed. The next meeting of the Authority is scheduled for Wednesday 24 January at 2:00 pm.