HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

5 December 2019

Authority Meeting Report

1 Declarations of Interest / Conflicts of Interest

There were no interests declared.

2 Sad News

It was with regret that the recent death of Michael Hayes, the previous Chair of the Authority, was noted. The Chair will write to Michael's family on behalf of the Authority members to pass on their condolences.

3 Health and Safety

There were no issues to report.

4 Risk Management

There were no issues to report.

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

The Authority noted proposed changes to the Terms of Reference and had no additional comments. This document will be circulated when finalised.

6 Chief Executive's Report

The Chief Executive updated the Authority on key matters arising since the previous meeting and invited comments and queries from the members of the Authority. Specific points discussed included:

Valproate: The proposed meeting of the Organisation for Anti-Convulsant Syndrome with the Minister for Health was noted. This continues to be an issue of high focus for the organisation.

Nitrosamines: The matter was discussed at length. An overview of issues of contamination of medicines with nitrosamines that have identified to date was given. Colleagues from across the organisation have been working on these issues, to include defect investigation and subsequent recalls, and the coordination of activities with industry and the European and international regulatory networks. Management of these recalls has involved extensive outward communication and engagement with impacted groups including healthcare professionals and patient associations.

An emerging issue relates to trace amounts of a nitrosamine impurity found in a small number of metformin containing diabetes medicines outside of Ireland and the EU.

The Chief Executive noted that next steps focus on continued work with the EMA and the European network of competent authorities on the review of this matter and investing in the testing programme. As a matter of precaution, marketing authorisation holders for human medicines containing chemically synthesised active substances have been requested to review their medicines for the possible presence of nitrosamines and test all products at risk.

Cannabis for medical use: The HPRA has received applications for products to be included under the access programme. Overall, the number of applicants has been small and one of those withdrew recently due to quality issues. Three products have been recommended by the HPRA for inclusion in the legislation. The Department of Health has amended the legislation to permit two of these to be prescribed under the access programme. A further amendment to include the third is expected shortly. Product should be available for supply under the programme in early 2020.

Legal cases: The Chief Executive highlighted two legal cases, Pandemrix and Arthropharm. These were discussed by the Authority.

Additional updates: The Chair noted Ms Mary O'Grady's appointment by the EMA's Committee for Medicinal Products for Veterinary Use (CVMP) as a Co-opted Member on Quality.

The contribution of Mr Hugo Bonnar, retired Enforcement Manager, was recognised. The Chair will send a letter to Mr Bonar post meeting. The establishment and success of the enforcement team and its continued contribution to the public health protection was acknowledged.

The performance and outturn across all business areas during 2019 was noted by the Chair and Authority members.

7 Brexit

The Chief Executive provided an update based on the content of the paper provided. The Chair commended the agency staff involved in the significant amount of work completed and the high degree of preparedness, which was achieved for the October deadline. The significance of the UK election outcome and its impact on the nature of the UK's exit at the end of January 2020 was acknowledged.

8 Review of the Statutory Committees

A paper outlining the HPRA's proposal for progressing the review of the statutory committees was tabled under this item. All members agreed to the approach as outlined and commended the selection of the Director of Quality, Scientific Affairs and Communications (QSAC) as lead.

The Authority approved the proposal.

9 Eolas

The Head of IT updated the Authority in respect of the current Eolas project. The members acknowledged the extensive work that had been conducted.

10 Strategic Plan – Next Steps

The QSAC director joined the meeting. In line with the tabled paper, an update was provided on progress to date, including the general and targeted consultation with a range of external stakeholders. An update was also provided on the roll-out of the internal consultation with staff across the organisation, which includes a number of initiatives. The targeted consultation, which includes face to face discussion with stakeholders, is providing valuable input.

A subgroup of the Authority and management committee has been established to provide support to the development plan. A workshop with the subgroup is planned for the end January.

The QSAC director also presented the progress with the establishment of a patient forum. A further update will be provided at the January meeting.

11 Authority Matters

11.1. Board Calendar 2019

It was considered that all items have been completed in line with the Code of Practice for the Governance of State Bodies.

11.2. Meeting Dates 2020

The meeting dates for 2020 were agreed.

11.3. Board Calendar 2020

The Chair and Chief Executive will review the calendar in advance of the January meeting and will present the updated calendar at that time.

12 IBTS Annual Report

The 22nd annual report to the Minister for Health by the HPRA in relation to the Irish Blood Transfusion Service (IBTS) was tabled.

The Chief Executive provided an overview of the oversight of the IBTS that had been conducted in 2018. Based on the inspections carried out, and the corrective actions identified, it was concluded that the blood establishment activities of the IBTS were considered to be in general compliance with the key requirements of the relevant EU directives and national legislation.

The annual report was approved by the Authority and will be shared with the Minister for Health.

The Chair expressed thanks to Director of Compliance and the compliance department for the work involved.

13 Finance, Corporate and International – Department Update

An update on the activities of her department was provided by the Deputy Chief Executive.

14 2020 Budget

The Deputy Chief Executive presented the 2020 budget, which was recommended to the Authority by the Audit and Risk Committee. The budget was approved.

15 Publication of Authority Report

The report for June 2019 was agreed for publication.

16 Reflection

Mr Pat Brangan and Mr Wilf Higgins reflected on their respective terms as members of the Authority and thanked the Chair, fellow members and the Chief Executive for their support throughout.

17 Committees

17.1 Audit and Risk Committee – 03/12/19

The Chair of the Committee noted the positive outcome of the Mazars internal audit. The 2020 budget was recommended to the Authority.

17.2 Advisory Committee Veterinary Medicines (ACVM) – 23/10/19

The Chair presented on the Report of the Task Force on Method and Supply of Antiparasitic Veterinary Medicinal Products. A presentation was provided. The report was approved by the Authority and it was agreed that a consultation period with stakeholders will follow.

18 Finance

Management Accounts – October 2019

The Audit and Risk Committee recommended the accounts, which were approved by the Authority.

19 Licensing Activities

The tables of licenses approved by the Management Committee during the period 15/09/2019 to 29/11/2019 were noted by the Authority.

20 Authority Meeting Dates 2020

The next meeting of the Authority is scheduled for Thursday, 23 January 2020. It was agreed the Secretary would send a reminder to all members.

21 AOB

Declaration of interest and Ethics in public office forms: It was noted that forms will be circulated in January. Any questions should be directed to the Secretary or Scientific Affairs Manager.