

14 June 2018

## Authority Meeting Report

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### 1 Declarations of Interest

There were no interests declared.

### 2 Chief Executive's Report

The Chief Executive provided a briefing on the following key issues and, on invitation from the Chair, responded to questions and comments from the Authority members:

- *Mutual recognition agreement:* In relation to the mutual recognition agreement (MRA) of GMP inspections between the EU and US, Ireland was included on the list of recognised member states on 1 June 2018. It was confirmed that the FDA will begin to use inspection reports from the HPRA inspectorate from the MRA reference date of 20 March 2018. A press release will be issued in the coming weeks. Both HPRA and IDA Ireland will highlight the outcome on social media and mainstream media.
- *Sodium valproate:* There have been a number of meetings with the Department of Health and HSE in recent weeks to prepare for a targeted outreach from the HSE to both prescribers and patients impacted by this issue. The HSE are the lead agency relating to these clinical care aspects.

The importance of involving pharmacists was reiterated. The Chief Executive highlighted that the outreach the HPRA had conducted with healthcare professionals on valproate had included pharmacists who are viewed as a key stakeholder group. The situation in Europe regarding use of valproate in pregnancy was discussed including the prevalence of this issue in the UK, Ireland and France.

- *Crisis management:* The Management Committee is conducting a review of the HPRA's approach to crisis management. Previous examples of where crisis management principles were utilised will be reviewed and used as case studies to ensure optimum processes are in place.
- *Medical devices fees:* The response to the consultation was positive overall. Benchmarking against other member states will be considered for future reviews.
- *HPAR Director:* The recently recruited Director of HPAR, Grainne Power, will commence employment on 16 July. Ms Power will formally meet the Authority at the September meeting.
- *Repeal of the Eight Amendment:* The impacts on the HPRA, in terms of the availability of medicines for termination of pregnancy were discussed.

Work is underway to identify products authorised within the European network that could potentially be authorised in Ireland pending submission of an application and subsequent assessment of the product(s).

### **3 Eolas Update**

The second phase (wave 2) covering the implementation for human medicines has been completed. An additional round of testing is scheduled for the end of June in advance of go live in August. End user training has been completed. The second phase clinical trials development is progressing well and go live is scheduled for August.

### **4 Review of the Service Plan Quarterly Progress Report**

The outturn for Quarter 1 2018 vis-à-vis the service plan was discussed based on the paper provided. It was generally considered that progress is on track and no concerns were noted. A number of strategic organisational initiatives to minimise the impact of Brexit were highlighted.

### **5 HR Strategy Presentation**

A midterm review of the HR Strategy was provided at the May meeting. This was complemented by a formal presentation from the Director of Human Resources and Change on the achievements under the strategy to date, based on key indicators. It also included an evaluation of the impact and effectiveness of these.

It was agreed that the ongoing monitoring of the strategy and related outcomes was particularly useful in informing the organisation's performance delivery agreement with the Department of Health.

It was proposed that greater use of social media should be considered to encourage scientific experts to engage with the HPRA as well as for recruitment. The Director of Human Resources and Change clarified that education outreach sits outside of her team, but greater cross-organisational focus on this is an important consideration.

Other issues raised included mechanisms to generally enhance cross-organisation communications such as greater use of blogs and town-hall sessions. Focus on achieving other awards within the public sector for excellence across a number of key areas was also raised particularly given the quality of the strategy and the breadth of issues it addresses.

The Chair commended the Human Resources and Change team on the work completed to date, the involvement of all team members and noted that results from this are visible through change management project outcomes.

### **6 Succession Planning Update**

The Chair provided a verbal update on succession planning and also requested that the Human Resources and Change Director, in conjunction with a HR consultant, prepare a proposal on this matter. The related programme is expected to include surveys, one-to-one meetings and 360 review by Board and Management Committee members to identify the most appropriate succession plan to inform future development areas and appointments as required.

### **7 Board Evaluation**

The annual Board (Authority) evaluation will be initiated over the summer months. A survey will be circulated to all members and will be based on the Code of Practice for the Governance of State Bodies template. The Audit and Risk Committee may also carry out a similar exercise.

## **8 ICDRA Update**

The Chief Executive provided an update on ICDRA conference preparations. The Deputy Chief Executive held a meeting with WHO representatives to discuss ICDRA following the World Health Assembly side meeting and they welcomed the progress to date. Registrations are going well and the WHO consider that the numbers at this point are strong. It is still a possibility that the Director-General of the WHO may open the conference. The agenda is developed and will be available on the website in the coming weeks. The AV and design tenders are complete. There is interest from the pharmaceutical press and a communications programme has been developed. Unlike most events of this size, all the conference arrangements, registration and staffing will be delivered directly by HPRA staff with a daily and evening rotation.

## **9 Committees**

### *Audit and Risk Committee*

The Chair of the Audit and Risk Committee provided an update from the meeting held earlier in the day.

## **10 Finance**

### *Management Accounts*

The Audit and Risk Committee reviewed and noted the most recent accounts. There were no additional comments.

## **11 Licensing Activities**

The tables of licenses approved by the Management Committee during the period 17/05/2018 to 08/06/2018 were noted by the Authority.

## **12 Authority Meeting Dates 2018**

The next meeting of the Authority is scheduled for Wednesday, 19 September at 2:00 pm. It was agreed the Secretary would send a reminder to all members.