HPRA Patient Forum Meeting Record

Tuesday 13 December 2022, Virtual meeting (Microsoft Teams)

Chair: Dr. Paula Kilbane

1 Welcome & Introductions

The Chair welcomed the members to the meeting.

2 Declarations of Interest (DoI)

There were no DoI's declared.

3 Adoption of the agenda

The agenda was adopted.

4 Record of the last meeting

The record of the meeting held on 20 September was agreed.

5 Matters arising/issues of Interest

Matters arising from the last meeting were discussed. Members were updated on the status of workplan actions. A request for additional volunteers to participate in the pilot patient speaker programme was made.

6 Workplan 2022, Package leaflets

A presentation was given on the package leaflet, which is a document for patients which is provided with a medicine. The presentation included a

summary of the regulatory framework, the requirements for content and structure of the package leaflet, as well as how patient feedback is incorporated into the regulatory approval process to help ensure the information is understandable and readable. Ongoing work within the EU to develop electronic package leaflets was presented and members noted the potential benefits in particular for accessibility (see links to the EMA website here detailing further information on electronic Product Information pilot project and key principles here including benefits for public health). Members discussed the topic in breakout groups and provided their experience and views on package leaflets. Feedback included the importance of the information to medicine users, and members also reflected on the need to provide complete information but to do so as simply as possible for the reader. Challenges in this regard were also discussed. The HPRA thanked members for their valuable comments and would update the forum, as necessary, on future regulatory developments concerning package leaflets.

7 Workplan 2023 proposal

The HPRA presented a draft workplan for 2023 following member feedback and consideration of the forum's terms of reference. Themes identified from member feedback included an interest in regulatory communications, in continued learning on the development and regulation of medicines and medical devices, on deepening the understanding of the role of HPRA within the broader healthcare system, and diversity and inclusiveness of forum membership. Feedback from members was sought on the draft workplan, including, the number and priority of topics, areas of focus, in addition to the length and timing of

meetings. Forum members supported the proposed workplan and identified medicines shortages as an important additional topic for further consideration. The HPRA thanked the members for their valuable feedback and noted an updated proposed workplan will be circulated for any final comments prior to adoption.

8 Meeting Dates

Forum members were informed that future meeting dates for 2023 are under review and will be finalised in Q1 2023.