HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Work Plan 2023

# HPRA Patient Forum

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## INTRODUCTION

The Patient Forum was established in 2022 as a platform for dialogue and exchange on topics relevant to the public regarding the regulation of medicines and medical devices. It was established by the HPRA to give Irish patients a voice in the regulatory process, especially in areas of patient safety, licensing and use, and in how the Authority communicates with wider society. The forum is based on a partnership approach to empowering patients so their experience and perspectives are heard, acknowledged and actioned to bring about positive improvements in the regulation of health products.

The terms of reference for the forum sets out that, together with the HPRA, the forum will prepare a work plan, which includes areas of common interest to patients and the HPRA, and which is aligned with the purpose and objectives of the forum. These include;

- To provide a mechanism for exchange of information on issues of interest and facilitate engagement with patients in regulatory activities

- To listen to, and understand, patients and representative organisations' views and consult them in the development of relevant policies, plans and activities

- To incorporate the values and perspectives of patients into HPRA activities wherever possible and into the wider EU network

- To help optimise dialogue, communication and information exchange on health products and regulatory activities between the HPRA, patients and the public and vice versa

The HPRAs remit does not extend to the provision of healthcare, as such, matters related to clinical practice are not within the scope of the forum.

Matters discussed also do not include ongoing evaluations related to a HPRA decision or advice on a specific medicine or medical device.

## Overview of 2023 workplan

In 2023, the forum will continue to focus on deepening the engagement between the HPRA and forum members and on further developing a mutual understanding of perspectives on regulatory topics.

The workplan for 2023 includes topics for which work with the forum is ongoing, as well as a number of new topics. The forum members were consulted on new areas of interest at the September 2022 meeting. Feedback given by the members included the following;

- Regulatory communications for the public; general awareness of communications as well as understandability and readability of content

- Continued learning on how health products are developed and regulated, in particular in the areas of medical devices and generic medicines

- Understanding how the HPRA fits within the broader health system, including the respective roles and interface between health product regulation versus the use of health products in the delivery of clinical care and health services

- Diversity and inclusiveness of the forum membership

Areas of interest to the forum members have been incorporated into the workplan, as applicable.

Standing items are included such as a review of the terms of reference and preparation of annual report to the Authority of the HPRA.

## WORKPLAN TOPICS

The proposed work plan for 2023 was discussed by the HPRA and members of the forum at a meeting on the 13 December and agreed at a meeting on 28 March 2023.

1. Prepare an annual report to the Authority on the work of the patient forum since its establishment in 2022.

2. Undertake a review of the forum's terms of reference, as described in the ToR section 4.5. As part of the review, further consideration is to be given to membership, including the diversity and inclusivity of representation.

3. Continue engagement on development of a HPRA induction module on the importance of being patient focused for HPRA employees.

4. Co-develop a pilot of the forum's patient speaker programme for HPRA employees.

5. Continue engagement on matters related to the reporting of safety issues by members of the public to the HPRA, including progressing collaborative approaches with patient organisations.

6. Continue engagement on matters related to medicines shortages.

7. Hold informational session for members on the regulation of medical devices and the role of the HPRA.

8. Hold informational sessions for members on how medicines are developed and regulated including generics.

9. Hold information session on quality defect reporting and management by the HPRA.

10. In relation to HPRA communications, the forum will be consulted on the proposed redevelopment of the HPRA website.