

Work Plan 2024

HPRA Patient Forum



INTRODUCTION

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

The terms of reference (ToR) for the forum set 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 is aligned with the purpose and objectives of the forum. These include:

- To provide a mechanism for the exchange of information on issues of interest and facilitate engagement with patients on regulatory activities.
- To listen to, and understand, the views of patients and representative organisations and consult them on 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.

The HPRA's remit does not extend to healthcare provision; as such, matters relating to clinical practice are not within the scope of the forum.

Furthermore, matters discussed do not include ongoing evaluations relating to HPRA decisions or the provision of advice on a specific medicine or medical device.

OVERVIEW OF THE 2024 WORKPLAN

In 2024, the forum will continue to focus on the engagement between the HPRA and forum members and on further developing a mutual understanding of perspectives on regulatory topics.

In developing the work plan, members were surveyed on a range of potential topics, which were then discussed at a meeting in December 2023. Topics identified as of interest from this meeting are included within the work plan. In addition, topics that remain ongoing from 2023 are included.

Standing items such as reviewing the terms of reference and preparing an annual report to the Authority of the HPRA are included.

WORKPLAN TOPICS

The proposed work plan topics are:

1. Prepare an annual report to the Authority on the work of the patient forum in 2023.
2. Continue the review as per section 4.5 of the terms of reference concerning membership, including the diversity and inclusivity of representation of the forum. Relevant entities will be consulted to strengthen an inclusive approach within the forum.
3. Explore approaches to better enable forum members access to meeting information (e.g. slides presented).
4. Hold a patient speaker programme event for HPRA employees, building upon the success of the first event held in 2023. In this initiative, representatives of the patient community are welcomed to speak to HPRA employees and share first hand accounts of their experiences and challenges. It ensures that the views and values of patients in Ireland are central to the HPRA's regulatory work.

5. Hold information sessions with forum members covering the following areas:
 - How does the HPRA support the development of innovative medical devices, and,
 - The current clinical trial landscape for medicines in Ireland - opportunities and challenges,
 - Considerations in relation to the online sale of medicines.
6. Discuss with members how to raise public awareness of the availability of educational materials for specific medicines and seek feedback on how patient organisations could support this activity. Educational materials are additional risk minimisation measures relevant to the safe use of medicines for patients and healthcare professionals. They complement the approved product information of the Summary of Product Characteristics and Package Leaflet.
7. Consult the forum on the redevelopment of the HPRA website, including, for example, new content relating to reporting safety issues, ease of use, and accessibility of reporting portals.

Any emerging issues of interest and relevance to the forum over the course of 2024 will also be considered for inclusion at meetings.