

Work Plan 2025

HPRA Patient Forum



INTRODUCTION

The Patient Forum was established in 2022 by the Health Products Regulatory Authority (HPRA) as a platform for dialogue and exchange on topics relevant to the public regarding regulating medicines and medical devices. The forum aims to give patients in Ireland a voice in the regulatory process, particularly in patient safety, medicine licensing and use, and how the Authority communicates with broader 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 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 exchanging 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 developing 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 2025 WORK PLAN

In addition to a continued focus on engagement between the HPRA and forum members to develop a mutual understanding of perspectives on regulatory topics, the forum will also broaden its focus in 2025 to investigate some of the organisation's interfaces with other key stakeholders across the health system.

In developing the work plan, members were surveyed on a range of potential topics, which were then discussed at a meeting in December 2024. Topics

identified as of interest from this meeting are included within the work plan. In addition, topics that remain ongoing from 2024 are included.

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

WORK PLAN TOPICS

The proposed work plan topics are:

1. Prepare an annual report to the Authority on the work of the patient forum in 2024.
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 previous events. Through this initiative, patient community representatives are invited 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. The Pharmaceutical Society of Ireland (PSI) will deliver a dedicated meeting to introduce its role as the regulator for the pharmacy profession in Ireland, its interface with the HPRA, and its strategy for engaging with patients.
6. Discuss the challenges and opportunities of emerging digital health technologies and the role of the HPRA with forum members.
7. Provide members with an overview of interchangeable medicines (often referred to as generic substitution) in Ireland and the HPRA's role in establishing lists of interchangeable medicines.

Any emerging issues of interest and relevance to the forum over the course of 2025 will also be considered for inclusion at meetings and relevant updates on previous topics discussed.