

# Rolling Work Plan 2022

## HPRA Patient Forum

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## **BACKGROUND**

The Patient Forum is a platform for dialogue and exchange on topics relevant to patients regarding the regulation of medicines and medical devices. It was established by the Health Products Regulatory Authority (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 rolling work plan, which includes areas of common interest to patients and the HPRA, and which is aligned with the purpose of the forum.

The work plan will be regularly reviewed, including progress against agreed actions, and updated as necessary.

This work plan for 2022 was discussed by the HPRA and members of the forum at a meeting on 14 December 2021.

## **TOPICS**

As the inaugural year of the forum following establishment, the focus for 2022 is to deepen the engagement between HPRA and forum members, as well as to explore topics identified as being a priority.

The forum agreed to focus on work related to HPRA culture and values and adverse event reporting as core topics for 2022. In addition, if feasible, topics related to the online sale of health products and coordination of the management of shortages will be further explored, possibly by way of separate workshops. Further details on each of these topics are provided below.

## Core topic: HPRA culture and values

The HPRA launched its strategic plan in 2021, including a refreshed mission statement and organisational values. A key value is that the HPRA *'put the interests of those who use health products first'*. As part of this topic for the work plan, the perspectives of members on the approaches the HPRA could take to deepen understanding within the organisation of the importance of this value, and how best to foster a patient focused culture, will be explored.

In addition to exploring the perspectives of members on this topic, direct input to the following activities will be sought:

- The HPRA is introducing, as part of employee corporate induction, a session on the importance and meaning of the 'patient focused' value. Members will be involved in the design of this session, including provision of content and key messages. It is planned that the corporate induction training session will be rolled out to all HPRA staff by the end of 2022, and will form part of the induction curriculum for all new starters thereafter.
- The HPRA is considering establishing a patient speaker program, through which patient representatives will be invited to speak to the HPRA's staff on their disease area. It is envisaged that through the patient speaker program, HPRA staff will have an opportunity to hear of the real experiences and challenges that face patients in relation to managing their disease, which will support staff in having a deeper appreciation of a patient's perspective and in maintaining an outward focus in their work. The HPRA will work with members to explore how such a patient speaker program could be established, and how best to identify speakers and a schedule.

In working collaboratively with patients in this way, together with the forum, the HPRA aims to enhance understanding and highlight the importance of its 'patient focused' value across all facets of the organisation. By strengthening this core value, the HPRA reinforces a culture that will aid in the delivery of the organisation's mission.

## **Core topic: Reporting adverse experiences to the HPRA, involvement of patient organisations in raising awareness**

Members have highlighted the importance of public awareness that a patient, carer or consumer of health products can report adverse experiences to the HPRA.

During 2021, the role of the HPRA system for reporting suspected side effects to medicines was a focus of public attention through the roll out of the COVID-19 vaccination program, with widespread media coverage, as well as information provided to those vaccinated in HSE literature on 'how to report'. It remains to be seen if this may serve to increase public awareness more generally on reporting adverse experiences associated with different types of health products. The HPRA also participates annually in a WHO led social media campaign to raise awareness around reporting, with members also involved in 2021 in advocating the key messages.

As part of the 2022 work plan, it is proposed that through this topic, the perspectives of the members on how the forum could further contribute to efforts to increase public awareness of the role of the HPRA and to encourage reporting of adverse experiences with health products will be explored. The types of activities that could be considered, for example, include signposting to the HPRA reporting webpage via patient organisation websites, and encouraging patient organisations beyond those represented as members to do similar. The views of the members on other interventions that could be impactful in terms of increasing awareness will also be sought.

The HPRA also plans to undertake specific work on its reporting systems for medical devices and medicines in 2022. The HPRA recognises that patients, carers and members of the public give valuable insight to the health products that they use and the difficulties and adverse events that can be encountered using these products. Contributions from members of the forum will be an important input to this area of work.

## **Optional exploratory topic: HPRA approach to coordinating the management of shortages**

Since 2018, the HPRA has worked with stakeholders to develop and implement a multi-stakeholder approach to tackling medicine shortages. The HPRA has recently performed a two-year review of shortages in Ireland. This review is the first time data on shortages in Ireland has been collected in such a comprehensive and quantifiable manner.

With this in mind, the HPRA is seeking to engage with stakeholder groups regarding the review. This includes engaging with the forum to seek input on the following topics:

Experiences of patients/groups:

- How are shortages perceived in general?
- What information would patients like to have about shortages?
- Who would patients like the information from?
- What are drivers for patients' desire to stockpile medicines in certain situations?

Where contact with groups is needed:

- How is the contact best made, typically, by phone, email, to whom?
- What information would be required from the HPRA and level of detail?
- How quickly can requests from the HPRA be responded to?
- Who would be involved in responding to the HPRA?

In general:

- Do patients look at the shortages section of the HPRA website, do they ring their association, talk to their pharmacist?
- Do patient groups keep an eye on the HPRA website?
- Within the limitations of the current website, is there anything the HPRA can do to make the information more accessible, or is it better to work through patient groups?

The insights gained will provide vital information to guide future strategies to optimise the approach to shortages, their prevention, and mitigating the impact on patients.

### **Optional exploratory topic: Online sale of health products - public awareness**

The sale of health products and provision of related services online has increased significantly over recent years. While online sales provide potential benefits and convenience, sales of this nature also have specific regulatory challenges to ensure reliable supply of safe health products.

The HPRA is seeking to explore this topic with members to learn about their perspective and any experience they have, in particular on the following aspects:

- benefits and merits of buying health products online
- experiences with purchasing health products online, if any
- perspective on the safety and reliability of online sales
- perspective on the ability of online sales to enable access to health products

The views of members will also be sought on information currently on the HPRA website and available in a leaflet, including any additional information considered of value to highlight, in particular, the controls around the online market and what that may mean for the safety of health products obtained from these sources.

The insights gained will provide a greater understanding of patient perspectives and experiences with online sales of health products and support identification of any potential areas of improvement for future HPRA communications.