HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA Patient Forum Annual Report 2024

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1 BACKGROUND

The HPRA Patient Forum is a platform for dialogue and exchange with patients on issues relevant to regulating medicines and medical devices. It also gives patients in Ireland a voice in the regulatory process. The terms of reference for the forum provide that an annual report is submitted to the Authority. This is the third annual report since establishing the forum in 2022. The report describes the meetings and work activities of the forum throughout 2024.

2 MEETINGS

There were four hybrid meetings of the forum held in 2024. The number of forum members attending remained relatively constant throughout the year, with nine members attending in March, four in June, seven in September, and five in December. The members agreed on an agenda for each meeting, covering topics from the forum's work plan, standing items, and matters arising. A record of all forum meetings held in 2024 was published on the HPRA website.

3 WORK PLAN

Forum members and the HPRA collaboratively developed a work plan for 2024 that reflected areas of common interest and was aligned with the forum's purpose.

The forum focused on deepening the engagement between the HPRA and members by developing a mutual understanding of perspectives concerning a

range of regulatory topics, outlined below. Members also discussed how to raise public awareness of the availability of educational materials for specific medicines, and how patient organisations could support this activity.

3.1 Guide to Reporting Suspected Safety Issues

As part of efforts to promote awareness of reporting suspected safety issues, the HPRA developed a guide in collaboration with the forum. Since its launch in September 2023, the guide has been well-received across social media platforms. Members discussed its value as a resource and highlighted the importance of utilising multiple communication channels to engage a broad audience. The HPRA will continue to promote the guide through its social media platforms. At the same time, forum members agreed to support awareness-raising efforts through their respective networks.

3.2 Information sessions

A series of information sessions was held throughout the year, covering key topics such as the HPRA's role in supporting the development of innovative medical devices, considerations surrounding the online sale of medicines, and the opportunities and challenges within Ireland's current clinical trial landscape for medicines. These sessions facilitated a deeper mutual understanding between the HPRA and forum members. Forum members provided beneficial insights during subsequent discussions following presentations on each topic throughout the year.

3.3 Review of the Terms of Reference

The HPRA is dedicated to being an organisation that acknowledges and values diversity and inclusion, which is embedded in the organisation's values, culture, and activities. And this commitment to diversity and inclusion extends to the Patient Forum.

In 2023, focused discussions took place on the forum's terms of reference, with members highlighting the need to consider underrepresented groups and ensure that HPRA information is clear, accessible, and inclusive. As a result, the terms of reference were updated in 2024 to reflect a shared commitment to diversity and inclusion.

3.4 Patient Speaker Programme

Co-developed with the Patient Forum and initially run in 2023, the Patient Speaker Programme allows HPRA staff to hear patients' experiences and perspectives directly from them. This programme reinforces the organisation's commitment to being patient-focused and contributes to staff training by deepening awareness of the real-world impact of regulatory decisions.

On 22nd October, Cancer Trials Ireland's Patient Consultants Committee members joined HPRA staff for the second Patient Speaker Programme event. The Patient Consultants Committee brings together people affected by cancer to influence and contribute to a patient-centred perspective on clinical trial activity in Ireland. The event provided an overview of patient involvement in

clinical trials, including the role of a dedicated patient committee in shaping research. The event also featured a panel discussion, during which patient representatives shared their personal experiences of participating in clinical trials. Discussions highlighted patients' challenges, the importance of accessible information, and the need for continued collaboration between patients, researchers, and regulators.

This programme continues to strengthen the HPRA's commitment to patient-centred approaches, ensuring that patient needs and insights remain central to the work of its staff.

4 TRANSPARENCY

Key information about membership and forum activities continues to be published on the HPRA's patient forum webpage. In addition to general information, this includes the terms of reference, meeting summary reports, an updated list of forum members and a policy for managing potential conflicts of interest.

5 CONCLUSION

The HPRA Patient Forum continues to serve as a valuable platform for dialogue and collaboration on regulatory issues affecting patients. Throughout 2024, members provided meaningful insights and feedback across key focus areas, including regulatory communications, discussions on patient engagement in clinical trials, and accessibility of HPRA information.

Notable achievements this year include the continued promotion of the Guide to Reporting Suspected Safety Issues, updates to the forum's terms of reference to reflect a stronger commitment to diversity and inclusion and the ongoing success of the Patient Speaker Programme in enhancing awareness of the patient experience among HPRA staff.

The forum remains committed to strengthening patient involvement in regulatory processes, and discussions will continue in 2025 to build on the progress made to date.

The HPRA wishes to thank all members for their contributions, dedication, and engagement and looks forward to continuing this important work in the year ahead.