HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of reference of the
HPRA Patient Forum

MGT-P0044-2
10 OCTOBER 2024

1 PURPOSE

1.1 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 improvements in the regulation of health products.

1.2 The objectives of the forum are:

- 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.

1.3 Matters discussed within the forum do not include any ongoing evaluations related to a HPRA decision or advice on a specific medicine or medical device. The HPRA will not disclose information that relates to individual patients or data subjects or is commercially confidential.

2 MEMBERSHIP

2.1 The forum contains a mix of patients (or carers, patient advocates) and patient organisations, which provides a balanced and wide range of experiences and perspectives.

2.2 In so far as possible, the forum will work to ensure representation from across a wide range of diseases and conditions, especially the main disease areas affecting many patients in Ireland, or where treatment depends on high demand or long-term use of medicines or medical devices. Where possible, the voices of underrepresented patient cohorts will be sought.

2.3 Membership is open to any patient or patient organisation that wishes to join and meets the criteria below. If necessary, numbers of attendees will be managed to ensure meetings remain effective.

Patients, carers and patient advocates eligible to be members of the forum:

- Have an interest in medicines and medical devices and the role they play in improving health and increasing quality of life
- Have a particular interest in the regulation of medicines or medical devices
- Declare any potential conflicts of interest for consideration. The member should not be employed by an industry regulated by the HPRA.

Patient organisations eligible to be members of the forum:

- Are registered in Ireland as a charity
- Have a clear mission and objectives
- Have a special interest in medicines and/or medical devices
- Have appropriate governance structures that are representative of the membership
- Issue statements and opinions which are representative of members
- Have a code of conduct governing independence from sponsors

- Provide information on sources of funding from any industry regulated by the HPRA

The member representing the patient organisation must declare any potential conflicts of interest for consideration, and should not be employed by an industry regulated by the HPRA.

2.4 Individual patient members can draw on their experiences as a consumer of medicines or medical devices and share how their experiences may apply more generally to the wider patient group.

2.5 Members appointed by patient organisations, whether staff of the organisation or volunteers, act as their representatives for the purpose of the forum activities and not in their own individual capacity. They are responsible for liaising with their organisation in order to provide the organisation's position on the topics to be addressed, and should report to their organisation on the activities of the forum.

2.6 Other external persons may be invited from time to time depending on the topic.

2.7 HPRA staff are in attendance at meetings but are not members of the forum.

3 PRINCIPLES

3.1 The forum is based on mutual respect between members and the HPRA as demonstrated by:

- Equality of voice
- Respect for diverse views
- Open, collaborative engagement
- Commitment to the principles of patient and public engagement and involvement
- Respect for boundaries and confidentiality

- Constructive contributions to discussions

3.2 The HPRA and forum members recognise the importance of diversity and inclusion and aspire to achieve the broadest possible representation of the patient community. The HPRA will make every reasonable effort to arrange necessary supports and provide accommodation to ensure all forum members can fully and equitably participate.

3.3 The HPRA commits to working transparently with the forum to seek mutually acceptable outcomes. All proposals will be considered and where something is not possible or practical to achieve, an explanation will be given.

3.4 The names of the forum members and a summary of topics discussed at meetings are published on the HPRA's website.

4 MEETINGS

4.1 Meetings are held quarterly, primarily by videoconference and are chaired by a person appointed by the HPRA.

4.2 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.

4.3 Based on the work plan and topical issues which may arise from time to time, the agenda of each meeting is established by the chairperson, in consultation with the members of the forum and the staff of the HPRA.

4.4 The objectives and expected outcomes for each agenda item are clearly indicated.

4.5 The Terms of Reference will be reviewed at least annually and will be updated, as appropriate.

4.6 The forum will conduct an evaluation within two years of the outcomes and benefits for patients and propose changes to the operation of meetings as appropriate.

4.7 An annual report to the Authority of the HPRA will be drafted by the HPRA and agreed with the forum.