European Federation of Pharmaceutical Industries and Associations

Working Together with Patient Groups

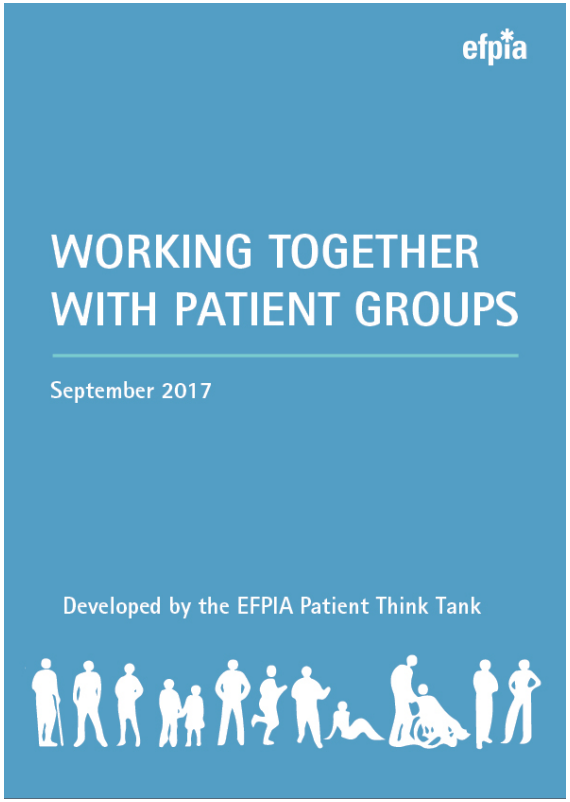
Presentation – EFPIA E&CC Patients Interactions Working Group







Working together with patient groups



- This document, endorsed by EFPIA Board in September 2017 and EPF Board, is intended to support patient organisations, companies, associations and external stakeholders that are considering collaborative efforts to improve the lives of patients.
- This document, which is the first one of this kind in Europe, was co-created by representatives of Patient Organisations and the research-based pharmaceutical industry through the EFPIA Patient Think Tank with support from EFPIA's Ethics and Compliance Committee.
- The *EFPIA Ethical Principles* have been a key driver for the development of this paper.

Aim of this document

- Underlining the rationale for interactions between the pharmaceutical industry and Patient Organisations
- Suggesting the principles, deriving from EFPIA Ethical Principles, on which these interactions should be based
- Outlining the points of collaboration through the life cycle of a medicine
- Discussing some of the challenges and potential solutions to interact
- Providing a list of resources to support meaningful/appropriate collaboration

How does it fit in with EFPIA PO Code?

Since the EFPIA Code on Relationships between the Pharmaceutical Industry and Patient Organisation (PO Code) was developed, there has been a **significant shift in the world and encouragement to do so for more collaboration between consumers, patients and the industry.**

This paper is **an additional point of reference** to guide these interactions, and to **complement the PO code**. It is not binding and does not overrule more restrictive law and regulations.

This document is not intended to be an exhaustive document but rather a useful reference point.

Who should use this document?

- **All partners in the healthcare equation who would like to understand the rational for collaboration**
- **Representatives of the pharmaceutical industry in Europe who are looking to collaborate with POs in different phases of medicines development**
- **Patient Organisation Representatives who are working on collaborative projects with industry or looking to collaborate**

Rationale for the interactions: WHY

- Listening to patient experiences, patient challenges and exchanging insights can shape future of medical research and disease management to more adequately address the unmet needs of patients. And it is only through open and transparent dialogue between patient organisations and industry that we can ensure that the patient perspective becomes an integral part of how medicines are researched, developed and delivered to patients. Appropriate inclusion has the potential to co-create and co-develop better health care management and patient outcomes, delivering greater efficiencies in healthcare utilization.

Rationale for the interactions: WHY

Each Company, Patient Group, National Industry Association, can complement with their own experience of **WHY** this interaction is important.

Principles for engagement: HOW

Clarity of purpose

Legitimate need identified in advance/Being clear on the purpose but also the desired outcome

Transparency

Aims & objectives/Financial relationship

Independence

In all aspects/To ensure credibility/Funding from multiple sources

Respect

Mutual respect/prioritizing long term commitment/valuing each other's contribution

Non-Interference

In the HCP/patient relationship

Principles for engagement: HOW

Each Company, Patient Group, National Industry Association, can complement with their own experience on **HOW** they interact with patient groups, based on concrete examples and policies/procedures.

Engagement across the life-cycle of a medicine: WHAT

- **Patient engagement happens at each step of the cycle of a medicine**
- **It can be:**
  - Direct engagement between companies and patient groups
    - **For example when contributing to study design in the context of clinical trial**
  - Exchange of information between companies and patient groups to build understanding, but the direct engagement is between patient group and regulator or HTA bodies
    - **For example at the initiative of Regulatory Authorities in the context of Marketing Authorization, participation of patients in scientific/protocol assistance procedures**

Engagement across the life-cycle of a medicine: WHAT

Each Company, Patient Group, National Industry Association, can complement with their own examples to illustrate **WHAT** types of engagement have been implemented.

The EFPIA 2017 Health Collaboration Guide is a good source of examples.

Potential hurdles and proposed solutions

- The Working Together with Patient Groups document is meant to be used and give guidance all around Europe.
- In the same time, the Patient Think Tank has recognised that different countries and regions might face some specific challenges.
- These specific challenges can be identified through national round-tables, to discuss potential solutions and share best practice examples among the relevant stakeholders (representatives of national patient organisations and from the national industry associations and companies).

Potential hurdles and proposed solutions

- Feedback and conclusions from the roundtables will be brought back to the Patient Think Tank.

- If necessary this can lead to adding some regional or country- specific recommendations to the paper “Working together with patient groups”.

→ Companies, Patient Groups, National Industry Associations to contact the EFPIA Patient Think Tank at communications@efpia.eu if they wish to organise national round-table.

Foreword

The evolution in patient engagement is matched by the rapid progression of the science that underpins research and development of medicines.

This progress allows for more personalised medicines that target individual patient needs.

In order to support this transition, **all stakeholders must explore new models of engagement between patients, healthcare providers and industry.**

→ Based on the ethical considerations of this document "Working together with Patient Groups"