efpia
European Federation of Pharmaceutical Industries and Associations

ETHICAL GUIDELINES APPLICABLE TO SOLUTIONS PROVIDED TO PATIENTS

The pharmaceutical industry recognises the importance of interacting with patient organisations and patients to understand their experiences, knowledge to help shape and develop medicinal products and define the outcomes that give the most benefit to patients.
Patients and patient organisations play a pivotal role by contributing their deep understanding of patient conditions. Their insights are instrumental for the pharmaceutical industry. The real-world perspective on patient conditions guides the development of treatments and solutions that are truly beneficial for those they are meant to serve.

Patient solutions[1] are essential to enhance patient outcomes, and are initiatives implemented in addition to the healthcare systems.
Patient solutions are recognised and legitimate pathway activities designed to support patients by improving their experience, providing them with necessary information and supporting a better management of their disease.

The EFPIA members recognize the value of such activities and, therefore, introduce these guidelines to ensure they keep adding value while also committing to high ethical standards.
This commitment means that EFPIA members must comply with the provisions of the EFPIA Code as transposed in the national codes. In the event of a conflict between the provisions of the national codes, the more restrictive of the conflicting provisions apply.

In addition to this commitment, EFPIA members must also comply with laws and regulations applicable to the pharmaceutical sector such as pharmaceutical, medical device regulations, competition, intellectual property, and data protection laws as well as anti-bribery, anti-corruption and environmental, corporate and sustainable reporting legislation.

The purpose of this document is to provide common understanding of patient solutions and guiding principles for providing patient solutions in the countries in scope of the EFPIA Code.

1. Scope of the patient solutions covered by this document

The patient solutions covered are any types of solutions aiming to benefit any actual or potential individual patient.
They may or may not be connected to a medicinal product but must be connected to the therapeutic management area of the Member Company.
They may include supporting the screening and diagnostics of targeted population, helping the healthcare professional ("HCP") independently identify the most appropriate option for treatment and/or helping the individual patients in their disease management.

These patient solutions are designed, implemented or commissioned by, or on behalf of the Member Company.

[1] **Patient Solution:** any types of services/programs/solutions aiming to benefit any actual or potential individual patient including Patient Support Programs.

2. Principles applicable to patient solutions

a. Based on the Directive 2001/83/EU, Member Companies must ensure that the patient solution does not promote the prescription, supply, sale or consumption of medicinal products to the general public, including patients and does not include any type of inducement for HCPs to prescribe any Medicinal Product.
b. The patient solution must be based and properly documented on patient's medical need.
c. The patient solution must not interfere with the HCP-patient relationship. Any component or part of patient solution must not compromise independent treatment choices or the medical decision of HCPs. If the patient solution is related to a medicinal product's instruction/administration already prescribed to the patient, then inclusion of a patient into the solution should be established through an HCP, not directly with the patient. For patient solution related to a Prescribed Only Medicine, information about its existence should always be directed to the HCP. Once the patient has been informed by the HCP, information can be provided (through traditional or digital communication).
d. Member Companies must verify if any component of a patient solution qualifies as a medical device, in such a case, they must follow the applicable medical device regulation.
e. Patient solutions for medicinal products used off-label are prohibited. Therefore, these patient solutions must be designed for the marketing authorisation indications.
f. The Member Company staff (or the Third Party) involved in the patient solution should be adequately trained to be able to provide precise and complete information in an ethical and professional manner.
g. Member Company should ensure the existence of clear, objective and documented patient inclusion criteria for the patient solution. Those criteria should be communicated to HCPs and relevant stakeholders for the duration of the solution.
h. Member Company is not allowed to offer a remuneration or any personal benefit for the patient nor to provide payment or incentive to the HCP for introducing or enrolling a patient in a solution. Patient solution must not serve to cover routine costs of HCPs and patients.
i. The design of the patient solution could be done with the support of a Third Party (HCP[2] – HCO - PO – other) that can be remunerated for this support in accordance with a written agreement. When interacting through a Third Party, the same principles remain.
j. Member Companies can collaborate[3] with stakeholders including HCOs in relation to a patient solution.
k. The overall cost of the patient solution should be reasonable and appropriate in relation to the delivered solution.
l. The patient solution should be transparent and should include information about the support provided by a Member Company to the patient.
m. Data protection laws and regulations, such as GDPR and relevant Member State laws apply. Member Companies must ensure that all privacy principles, including data minimisation, transparency, purpose limitation and secondary use, and security, are considered and complied with during the design, implementation, execution, and close-out phase of patient solutions.
n. The patient solution duration should be limited to its objectives, predetermined, and justified by the identified patient need. This duration should be communicated to all stakeholders at the beginning of the solution. In case of early termination by the Member Company, the stakeholders engaged should be informed and an exit strategy should be offered.

[2] Including nurses when they are qualified as HCPs in the country concerned
[3] Cf. document on partnership collaboration guidance:
https://efpia.box.com/s/iec201wyanwa2xrgv1wn4tny2u4kucej

o. Member Companies must ensure that pharmacovigilance requirements are followed within the patient solutions.
p. Regarding disclosure requirements, when relevant, payment or transfers of value made directly or indirectly (e.g., through a third party) to HCPs must be disclosed when the HCP can be identified. Transfers of value made for the benefits of HCOs or POs must be disclosed as well.
q. The patient solution should be properly monitored and any extension, renewal or closure should be reviewed to ensure patient medical needs are at the centre.
r. Patient solutions may be offered provided that they are not fully reimbursed by local health insurance providers or payors within the patient's geographic area or country.

3. Non-exhaustive examples of a patient solution as defined in this guidance

A solution is intended to:

- Provide education and support for patients in using their medicines, in the context of the approved and up-to-dated information of the SmPC and the package leaflet, e.g., nurses educating patients on how to self-inject.
- Provide informational materials and solutions in the context of compliance with treatment, such as reminder programmes for taking the medicine.
- When possible, facilitate delivery of a medicinal product, or patient transport to HCO.
- Provide support for home care, such as providing solutions for patients.
- If not totally covered by the national healthcare system, the provision of test kits and/or diagnostic solutions in order to help identify the most appropriate option for treatment.
- Support to manage related aspects of the disease including related adverse events, such as mental health, diet and nutrition, physical exercises.

Non-exhaustive examples of solutions that are not in scope of this document

- Compassionate use, disease awareness communication (not included as part of a broader patient solution), institutional programs especially programs part of a tender/package deal are out of the scope of this document.
- Sale discounts, coverage of co-payments, reimbursement of a Medicinal Product or any other patient access program.
- Any information related to reimbursement.
- Activities organized and implemented by third parties acting independently from the company, where a Member Company has provided funding through a Grant, Donation and/or Sponsorship.
- Information provided without personalisation, two way communication or an organised activity (e.g., leaflets on how to manage the disease left at a doctors' office).
- Any clinical research or development program or post-marketing studies or health economic studies, including any non-interventional studies.
- Pre-approval access programs, expanded use programs, post-trial access and continued access
- Industry-Government or public-private partnership initiatives where patients receive supports but they are not directly mandated, executed, implemented, controlled or run by a Member Company.

REFERENCES

- **Directive 2001/83/EC** of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF
- The **EFPIA Code**: https://www.efpia.eu/media/676434/220718-efpia-code.pdf
- The **National Codes**: https://www.efpia.eu/relationships-code/national-codes/
- EFPIA document developed with the EFPIA Patient Think Tank: **Working together with Patient Groups**: https://www.efpia.eu/media/288492/working-together-with-patient-groups-23102017.pdf
- **IFPMA Note for Guidance** on Patient and Patient Organization Interactions: https://www.ifpma.org/publications/ifpma-note-for-guidance-on-patient-and-patient-organization-interactions/
- **EMA Guideline** on good pharmacovigilance practices (GPV) - Module 6: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf
- **ICH** E2D Post-approval safety data management – Scientific guideline: https://www.ema.europa.eu/en/ich-e2d-post-approval-safety-data-management-scientific-guideline