Ensuring Consistent and Coherent Application of EU Rules on Medicines' Advertising

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The European Patients' Forum (EPF) raises its concern about the **fragmented interpretation of the current rules on the advertising of medicines**. Reports from multiple EPF member organisations point to this inconsistency leading to unequal access to information for patients across Europe and restricting the activities of patient organisations.

Background

The current EU legal framework prohibits advertising for prescription-only medicines but not for over-the-counter medicines[1,2]. Advertising includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. This covers advertising to the public or healthcare professionals, visits by medical sales reps, supply of samples, offering inducements to prescribe or supply medicines (unless minimal in value), and sponsorship of promotional meetings or scientific congresses for those qualified to prescribe or supply medicines, including covering travel and accommodation expenses.

In some countries, different interpretations of this legal framework prevent patient organisations from providing their communities with critical information on medicinal products. In the Czech Republic, for example, patient organisations are restricted from mentioning drug names in their materials, providing information about new drugs or sharing experiences of existing treatments. In Latvia, patient organisations cannot mention prescription medicines in their newsletters, while in Italy they can only refer to the active ingredient.

Divergent interpretations also sometimes prevent patient representatives from attending medical congresses and conferences, even though health professionals have access to these events. This has led to situations where patient advocates can only record their interventions and cannot engage in discussions. This exclusion hinders their ability to contribute and benefit from shared knowledge.

A strict legal framework for advertising prescription medicines is important to protect public health, avoid misleading claims, and ensure healthcare decisions are driven by patients' needs. However, access to accurate and reliable health information is essential in empowering people to make informed choices about their care.

Patients' organisations have a responsibility and processes in place to ensure the accuracy of the information they provide to their members. Most have measures in place to ensure their independence from pharmaceutical manufacturers, which may provide financial support[3]. Patients' organisations take

[1] 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.
[2] The control of the advertising of non-prescription medicines in the EU is primarily conducted on a self-regulatory basis by industry bodies, supported by the statutory role of the national regulatory authorities in the Member States.
[3] See EPF Transparency Guidelines.

care to ensure that the advice they give is in line with current clinical evidence and best practice, and often have their material certified by medical professionals.

As the European Union revises its regulatory framework for medicines, EPF urges the EU institutions to consider the following aspects:

- **Establish a definition of "patients' organisation," shaped by patients, to formally recognise their central role.**

Patients' organisations need an official definition within the EU legal framework for medicines. This definition would recognise and strengthen their vital role in delivering fact-based, non-promotional information on authorised medicines to patients and carers. Patients' organisations, led and integrated by patients and carers, are irreplaceable stakeholders in supporting the development and authorisation of medicines. We recommend using the widely accepted definition of the European Medicines Agency (EMA)[4]: "*Patients' organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies*".

- **Clarify that patients' organisations can disseminate factual and balanced information on authorised medicines to patients, in compliance with the applicable legislation.**

The dissemination of objective and accurate information on authorised medicines by patients' organisations to inform their community about approved treatment options should not be considered advertising. This includes disseminating updates from regulatory agencies or educational material on disease management. The interpretation and application of the rules need to be harmonised to eliminate discrepancies between countries and ensure equal access to information for all patients.

Access to quality and verified information on medicines is essential in the digital age, where unverified and potentially harmful sources are prevalent. Patients' organisations have a crucial role to play in providing reliable information on existing therapies, ongoing clinical trials, and patients' experiences with treatments. During the COVID-19 pandemic, patients' organisations provided high-quality, trustworthy and clear information to patients about the situation, preventive measures and ongoing vaccination campaigns. In some cases, they were the preferred source of guidance for patients on how to manage their condition, amid widespread difficulties in accessing clear public health advice[5].

In addition, many patients are not receiving adequate information about their medicine. As treatments become increasingly complex, it is vital for patients' compliance and adherence that they fully understand their therapies. This understanding requires access to detailed information beyond what is typically provided at the time of prescription, which is often considered insufficient. Patients' organisations play a key role in making specialist, disease-specific information accessible and easy to understand for patients. They can provide comprehensive information about the benefits, potential side effects, drug interactions,

[4] European Medicines Agency (2018). Criteria to be fulfilled by patient, consumer and healthcare professional organisations involved in the European Medicines Agency (EMA) activities.
[5] See EPF Analytical report on the welfare of patients suffering from chronic diseases during the COVID-19 pandemic.

correct use, and long-term management of medicines, empowering patients to make informed decisions, building health literacy and ultimately improving treatment outcomes[6].

- **Harmonise the rules for patient experts' and healthcare professionals' attendance of industry-sponsored conferences and medical congresses in full compliance with transparency and disclosure requirements.**

Patients bring unique knowledge and expertise, as their lived experiences help tailor healthcare solutions to better address unmet needs, enhance the quality of information, improve treatment adherence, and build trust. This can ultimately result in reduced costs for both patients and healthcare systems. Despite encouragement from national and European authorities to involve patients in the research, development, and post-marketing surveillance of medicines, they are often unable to participate in industry-sponsored conferences where discussions on ongoing research and upcoming therapies take place. Major medical congresses often provide an opportunity to stay up to date on the latest research and pharmaceutical developments in a particular disease area. The primary participants from patient communities are experts and leaders of patient organisations who are well acquainted with the research environment, not lay patients. There is no reason why these representatives should not have access to these conferences, as they gather valuable information to inform their communities and ensure that the patient's voice is heard. To uphold transparency, integrity and independence, participation should be subject to clear criteria. This includes disclosing attendance, declaring any funding received, disclosing potential conflicts of interest, and ensuring that participation is not linked to the promotion of specific medicines or treatments.

We look forward to continuing to work with the EU institutions towards harmonised interpretation and application of advertising rules for medicines to ensure that patients across Europe receive consistent and comprehensive information. This alignment is essential to promote patient empowerment and improve health outcomes, as well as empower patient organisations to fulfil their public health mission.

EXAMPLES OF RESTRICTIONS AND DISCREPANCIES COLLECTED THROUGH OUR MEMBERSHIP SURVEY (JUNE 2024)

Country	**Examples**
Czech Republic	Patients and their representatives are banned from attending medical conferences. Patients and their representatives cannot receive support from pharmaceutical companies to attend events where drug names are mentioned. Patients' organisations cannot mention commercial drug names in their materials.
Germany	Whether patients are allowed to attend depends on the interpretation of corporate legal departments, compliance officers or conference organisers.

[6] See EPF Report on the added value of patient organisations

Greece	Patients' organisations cannot mention the benefits and side effects of medicines in their newsletters.
Ireland	Patients' organisations are banned from attending and speaking at pharma industry-sponsored medical conferences
Italy	Patients' organisations are restricted from discussing drugs directly in their newsletters and can only refer to the active molecule.
Latvia	Patients' organisations are not allowed to mention prescription medicines in their newsletters, they can only mention over-the-counter medicines.
Netherlands	Patients and their representatives are prohibited from attending pharma industry-sponsored conferences.
Poland	Patients' organisations are prohibited from informing their members about new drugs entering the market, such as including information about new drug approvals by the EMA in their newsletters.
Portugal	Patients and their representatives are prohibited from attending pharma industry-sponsored conferences.
Spain	Patients and their representatives are restricted in their access to pharma industry-sponsored medical congresses
Sweden	Patients and their representatives cannot receive direct information from pharmaceutical industry. Patients are not allowed to visit exhibition areas in medical congresses where the industry presents new drugs, treatments or related information.

ABOUT EPF

EPF is an umbrella organisation of patients' organisations across Europe and across disease areas. Our 79 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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