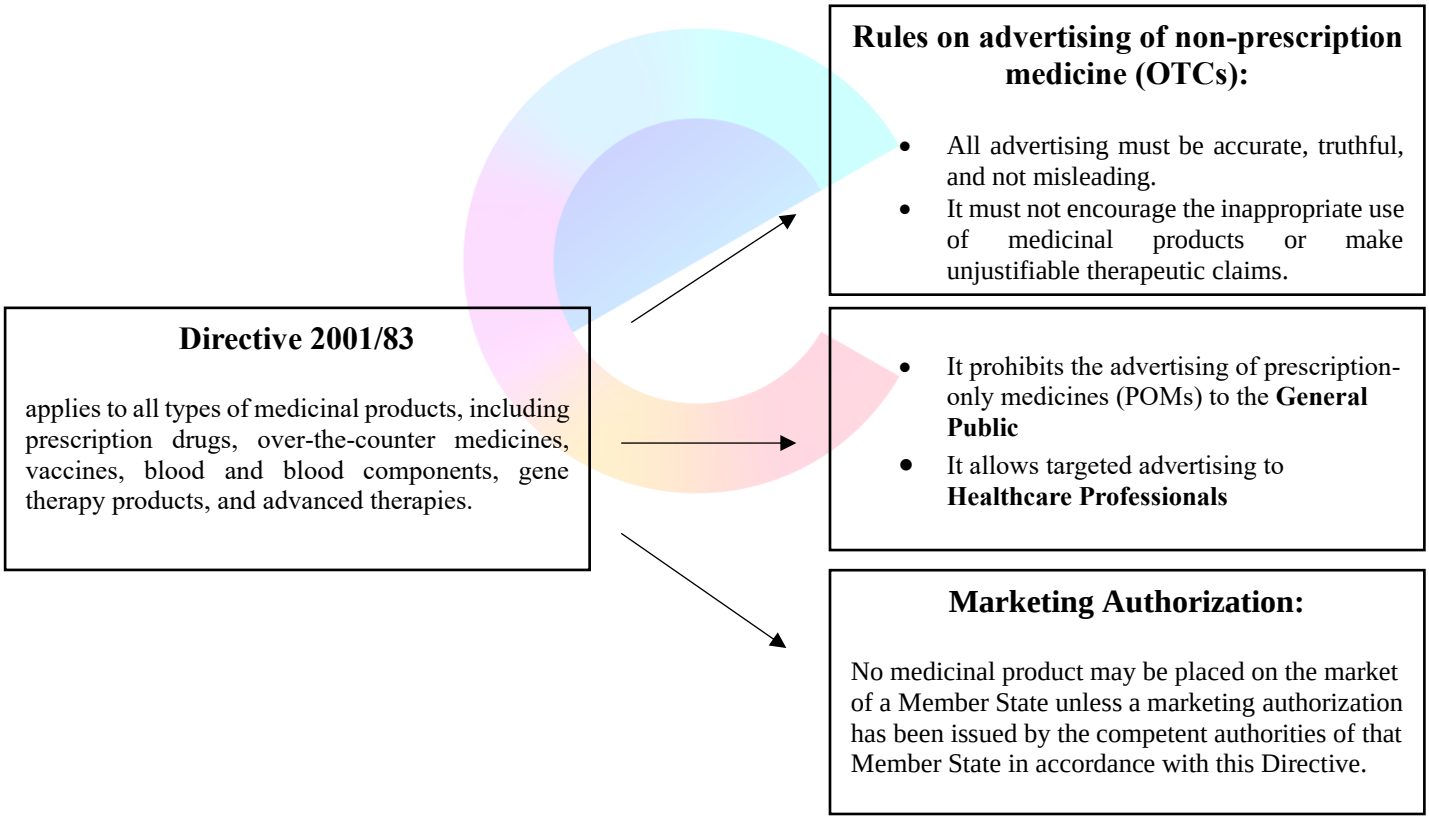
EACA Policy Brief: Pharmaceutical Advertising

Drug advertising is heavily regulated at both the EU and national level, with the aim of ensuring that medicines are used appropriately based on reliable and comprehensive information. In this Brief, we are going to outline which laws are applying to advertising of medicinal products by laying out the European regulatory framework (I) before presenting specific Member State regulation (II), focusing, in particular, on two distinct mechanisms for advertising depending on whether the intended audience is the **General Public** (i) or **Healthcare Professionals (HCPs)** (ii).

a) What is the regulatory context for pharmaceutical advertising in Europe?

The European Union's regulatory framework, outlined in **Directive 2001/83**, focuses on medicinal products for human use and includes provisions dedicated to advertising and promotional activities related to these products.



Pharmaceutical advertising is required to undergo thorough and sufficient monitoring.
The Regulation further mandates that the company commercialising Marketing Authorization Holder (MAH) should establish a scientific service responsible for medicinal product information and ensure that regulatory decisions related to advertising monitoring are adhered to. The Regulation further mandates that the company commercialising a medical product (Marketing Authorization Holder) should establish a scientific service responsible for medicinal product information and ensure that regulatory decisions related to advertising monitoring are adhered to.

However, the Directive does not provide specific guidelines for pharmaceutical advertising control, leaving Member States with some discretion in their monitoring implementation.

b) What are the specific advertising laws and requirements for different Member States?

The Directive has been incorporated transposed into national laws and regulations of each country, and as a result, Member States have implemented their own specific measures for pharmaceutical advertising. Depending on the country, the monitoring and control of pharmaceutical promotion may be carried out by governmental or national competent authorities, or through self-regulation.[1]

I) U.K

Part 14 of the Human Medicines Regulations 2012/1916, as amended (Regulations) provides the general legal framework for the advertising of medicines in the UK.

Definition of advertising: "anything designed to promote the prescription, supply sale or use of that product".

The Regulations are applicable to any person, Marketing Authorization Holder ("**MAH**") or any third party such as a journalist or public relations agency.
The Medicines and Healthcare Products Regulatory Agency (**MHRA**) supervises the advertising of medicinal products on behalf of the licensing authority. MHRA publishes supplemental guidelines to the Regulations, currently in the form of the Advertising and Promotion of Medicines in the UK (2020) (the **Blue Guide**) and general guidance on the MHRA website.[2]

i. Legal Framework**: Promotion and Advertising to the **General Public

It is prohibited to publish an advertisement for a medicinal product unless there is a relevant marketing authorization in place. This authorization can be issued through different channels including the European Medicines Agency (EMEA), the European Commission (EC), and competent authorities of Member States. In the UK, the authorization can be granted by the Medicines and Healthcare product Regulatory Agency (MHRA) acting on behalf of the UK licensing authority.

Additionally, any advertisement for a medicinal product must adhere to certain requirements:

- comply with the Summary of Product Characteristics (SmPC); which is a framework describing the properties and the officially approved conditions of use of a medicine;

[1] Self-regulation involves the delegation of monitoring and control responsibilities to entities such as national associations of pharmaceutical industries, multi-stakeholder groups, or the advertising company itself in the absence of identified national competent authorities. These associations and organizations create their own codes and have the authority to assess and approve advertisements.

[2] In addition to the legal regulations and guidelines that govern the advertising of medicinal products, there are also industry codes of practice that companies may follow as members of trade associations or on a voluntary basis. These codes supplement and sometimes go beyond the statutory provisions.
For example, the Association of the British Pharmaceutical Industry (**ABPI**) Code of Practice applies to advertising of medicines to healthcare professionals and decision-makers. Companies that are members of the ABPI are required to follow the ABPI Code, while non-members can voluntarily agree to follow it.
Similarly, the Proprietary Association of Great Britain (**PAGB**) has Professional and Consumer Codes that set rules for advertising over-the-counter medicines. These codes reflect and expand upon the statutory provisions outlined in the law.

- comply with the Summary of Product Characteristics (SmPC); which is a framework of product characteristics that any medicine needs to comply with in order;
- encourage rational use of the product by presenting it objectively and without exaggerating its properties; and
- not be misleading.

ii) ***Legal Framework****: Promotion and Advertising to* ***Healthcare Professionals (HCPs)***

Advertisements aimed at healthcare professionals for pharmaceuticals must comply with the general regulations that apply to all medicine advertisements. Additionally, there are specific regulations for advertisements targeting healthcare professionals who are considered "persons qualified to prescribe or supply" (PQPS).
According to the general regulations, advertising of unlicensed medicines[3] is prohibited.
In exceptional circumstances, some factual information can be disseminated before a license for a medicine is granted. Manufacturers and suppliers of unlicensed medicines ("specials") can send price lists to healthcare professionals to whom the price of specials may be relevant. However, the price list must only contain factual information related to the active ingredient, dosage form, strength, etc. and must not contain any product claims.
Despite the prohibition on advertising unlicensed medicines, healthcare professionals may provide a factual answer to an unsolicited question about an unlicensed medicine.

II) GERMANY

The advertising of medicinal products in Germany is governed by the German Act on Advertising of Medicinal Products.

Definition of advertising: the German Act does not provide a legal definition of advertising. However, the Community Code (Directive 2001/83/EC) defines the concept of advertising as "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products" and provides specific examples for such advertising.

It applies to the advertising of pharmaceuticals, medical devices, as well as other means, procedures, treatments and objects in case the advertising claims refer to the detection, elimination or alleviation of diseases..

i. ***Legal Framework****: Promotion and Advertising to the* ***General Public***

According to German law, advertising of prescription-only medicines is limited to qualified healthcare professionals such as physicians, pharmacists, and authorized traders. It is prohibited to advertise prescription-only medicines to less-qualified healthcare professionals like nurses or to the general public.

- Only non-prescription medicines can be advertised to the general public;

[3] Products for which no-one holds a UK Marketing Authorization are unlicensed.

- All advertising activities of medicinal products, whether prescription-only or non-prescription, must comply with general advertising principles as set forth in the German Act against Unfair Competition. Additionally, any claims made in promotional material about the therapeutic efficacy or effects of medicinal products must be substantiated with clinical data, and advertisements must not be misleading.

ii) ***Legal Framework****: Promotion and Advertising to* ***Healthcare Professionals*** *(HCPs)*

Under German law, all advertising for medicinal products, regardless of the target audience, must contain mandatory information, with few exceptions. This includes information to be provided in pharmaceutical advertising to the general public, as detailed in the previous section.
Furthermore, any advertising directed at healthcare professionals that refers to scientific or medical publications must include:

- the names of the authors;
- the publication date and;
- the correctly quoted reference.

However, there is no mandatory content required for advertising aimed at healthcare professionals beyond these obligations. For instance, German law does not mandate that advertising includes the price of the medicine.

III) FRANCE

In France, the legal framework governing advertising for medicinal products for human use is mainly based on the Public Health Code[4].

> **Definition of advertising**: "any form of information, including that derived from canvassing, prospecting or inducement, designed to promote the prescription, dispensation, sale or consumption of medicinal products, except for information provided by hospital pharmacists".

i. ***Legal Framework****:Promotion and Advertising to the* ***General Public***

Advertising and promotion of medicinal products to the general public are permitted if the medicinal product:

- is not subject to medical prescription;
- is not reimbursed by the French health insurance scheme; and
- is not held back by a prohibition or restriction on advertising to the public due to a possible risk to public health mentioned in the marketing authorization or registration.

However, as an exemption from the above conditions, disregarding their prescription-only or reimbursement status, advertising for vaccines is allowed under specific conditions, along with smoking cessation products, for public health purposes.

[4] In France, the legal framework governing advertising for medicinal products for human use is mainly based on the Public Health Code.
The applicable provisions are partly set out in legislation (Articles L.5122-1 to L.5122-16) and partly in regulations (Articles R.5122-1 to R.5122-17).

ii) ***Legal Framework***: *Promotion and Advertising to* ***Healthcare Professionals*** *(HCPs)*

Advertising targeted at healthcare professionals must contain accurate, verifiable, up-to-date, and comprehensive information that enables them to develop a personal understanding of the medicinal product's therapeutic value.
Advertising medicinal products to healthcare professionals (referred to as "PM") is not restricted based on the product's prescription or reimbursement status. However, it does require prior approval from the Guidelines of the French Medicines Agency (ANSM) in the form of a "Visa PM".
Unlike advertising to the general public, it is permissible to provide HCPs with free samples of medicinal products, subject to compliance with specific legal requirements.

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