WHITE PAPER

PROMOTIONAL MATERIAL REVIEW

RESPONSIBLE PERSONS FOR PROMOTION OF MEDICINAL PRODUCTS IN FRANCE, GERMANY, SPAIN, ITALY & UNITED KINGDOM

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Introduction

The promotion of medicinal products is governed by different regulations and codes in the European Union (EU). In particular, the 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' establishes the European regulatory framework with articles dedicated to promotion activities and advertising of medicinal products.

Regulatory context

According to the D**irective 2001/83/EC (article 97)**, the **advertising of medicinal products** shall be sub-ject to effective and **adequate monitoring**. In **article 98**, the directive states that the Marketing Authorisa-tion Holder (MAH) shall establish a scientific service in charge of the information about medicinal products and ensure that the decisions taken by the authori-ties or bodies responsible for monitoring advertising of medicinal products are complied with. Never-theless, the Directive does not give precise rules re-garding the control of pharmaceutical advertising, leaving the Member States (MS) a certain degree of freedom in the implementation of such monitoring.

Each country has transposed the European Directive **in domestic laws** with **local adaptations** and all MS have therefore adopted further specific measures concerning the advertising of medicinal products. Thus, depending on the MS, pharmaceutical promotion can be **monitored & controlled** by the **government** or not, this approach is called "self-regulation". Within the framework of **self-regulation, monitoring and control activities** can be delegated, for example, to **national associations** of pharmaceutical industries, **multi-stakeholder groups**, or the **company responsible for the advertising** itself. Such associations and organisations develop their **own codes** and can **assess & approve** advertisements.

To comply with principles of **good promotion practices,** especially in a context of self-regulation by the company itself, we can rely on different **guides/codes**. Published by the World Health Organization (WHO) in 1988, the "Ethical Criteria for Medicinal Drug Promotion" provided a framework for developing guides and measures to ensure ethical promotional practices.

The International Federation of Pharmaceutical Manufacturers and Associations (**IFPMA)** regularly issues a **Code of Practice** which establishes a **global guidance** on pharmaceutical promotion. Section **12.3** of the **IFPMA Code of Practice 2019** states that a designated company employee with sufficient knowledge and appropriate qualifications **should be responsible** for **approving all promotional communications** (adequately qualified scientific personnel).

In parallel, the European Federation of Pharmaceutical Industries and Associations **(EFPIA)** also regularly publishes a **Code of Practice** which constitutes the collection of ethical rules for promotion of medicinal products to HealthCare Professionals (HCPs) in the EU. **Section 20.01**. of the **EFPIA Code of Practice 2019** states that each member company must establish a scientific service in charge of medicinal products information and specifies that this **scientific service must include** a **medical doctor** or a **pharmacist** who will be **responsible** for **approving any promotional material before release.**

In this regulatory context heavily dependent of MS, we present a 'Focus' on the **qualification, duties & appointment** of the **person responsible for promotion of medicinal products** in the following 5 countries: **France, Germany, Spain, Italy,** and the **United Kingdom** (UK).

France

In France, the government **regulates** and **controls pharmaceutical promotion**. Medicines advertising is therefore **defined** and **governed** by national laws and regulations, in particular the **Consumer Code** (*Code de la Consommation*) and the **Public Health Code** (*Code de la Santé Publique – CSP*).

Articles of Law **L5122-8** and **L5122-9 (CSP)** subject the advertising of medicinal products to the general public and to health professionals **to prior authorisation**, by way of an **advertising *visa***. In France, **these visa applications** must be **signed** by the **Responsible Pharmacist** 'Pharmacien Responsable' **(PhR)**.

Indeed, pursuant to article R5122-2 (CSP), companies marketing a drug ('exploitant') must have a service in charge of advertising under the control of the PhR who must ensure compliance with the provisions of the CSP (in particular those mentioned in article R4235-69).

It is important to note that, in France, the **PhR** has a statutory position (**art. R5124-36** of the **CSP**) and **has broad missions and responsibilities**. The **role and minimum attributions** of the PhR are defined by the CSP in articles **R5124-34 to R5124-37.** Article **R5124-36 (§1 and 3)** stipulates that one of the roles of the PhR is the **organization and monitoring** of the **advertising for which he/she signs visa applications.**

The duties of the PhR with regards to **promotion** are **defined in art. R4235-69** (CSP). The PhR must refrain from discrediting a colleague or a competitor (particular attention should be paid to comparative advertising). He/she is also responsible **for ensuring the accuracy of scientific, medical, and pharmaceutical information** in advertising, as well as its **fair use**. He/she ensures that the advertising of medicines is carried out **in accordance with the Consumer Code** (in particular, to be **objective** and **not misleading**).

The PhR has **personal legal responsibility. Disciplinary sanctions** may apply if he/she fails to fulfill their duties (this can be from a warning to permanent withdrawal of authorisation to practice and loss of their diploma). In the context of advertising control, the PhR also has **civil** and **criminal liability.**

NB The company shall n**otify the director general** of the National Agency for the Safety of Medicines and Health Products (**ANSM**) of the **appointment of a new PhR** within one month (**art. R5124-35** of the CSP).

A company whishing to market a drug in France **must plan in advance** to s**et up its promotional activity.** Indeed, to be **appointed PhR,** the corporate officer must:

- be a **pharmacist** (in France, **6 years** minimum)
- meet the **practice conditions** defined by the CSP (**art. R5124-16 to R5124-33**). In particular, he/she must **justify a certain professional experience,** including experience on quality insurance, PV... (from **6 months** to **2 years**, **art. R5124-16 and R5124-17**). It should be noted that e**xperience in advertising alone is not sufficient to commission a PhR** to sign visa applications. Also, sufficient knowledge of French for the excerise of his/her profession must be proven (**art.L.4222-6** of the CSP).
- be **registered with the Order of Pharmacists** and have their **diploma registered** for a **single company** (**art. R5124-20** of the CSP). The Order must decide on the acceptance of refusal of registration within **3 months** **(art. L4222-3** of the CSP). It is brought to your attention that if the Pharmacists have obtained their diploma abroad, this acceptance or refusal of registration timeframe can be **doubled**. *NB: A large number of documents shall be submitted for registration (ID, CV, proof of qualification...)*

Germany

In Germany, pharmaceutical promotion is defined and governed by **national laws**, as in particular the Law on Advertising in the Health Sector (*Heilmittelwerbegesetz* – **HWG**), the Law on the Trade in Medicinal Products (*Arzneimittelgesetz* – **AMG**) and the Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb* – **UWG**) which contains more general advertising rules. But the government does not manage the **control** of medicinal product advertising. Therefore, there is **no approval or license required and no obligation to provide** competent authorities with advertising material. The German system is rather based on a **prior self-assessment** by the company responsible for the advertising.

According to the **§74a (AMG),** any person who, **as a pharmaceutical company, that markets medicinal products, shall commission a person,** the **information officer** '*Informationdbeauftragter*' (IB), with **the expertise and reliability required** to take the responsibility for providing **scientific information about medicinal product**. In particular, the **IB** is responsible for ensuring that labeling, package insert, specialist information and advertising are **not misleading (§8 (1) No. 2 AMG)** and **comply with the Marketing Authorisation** (MA).

The IB can e**xercise another position at the same time within the company** (e.g. phase plan officer '*Stufenplanbeauftragter*' §74a) and **can be attached to various specialist departments** of the company, **except marketing**. He/she is responsible, and **personally liable**, for the **release of packaging and promotional materials** for medicinal products. It is highly recommended following the review cycle that the **IB approves the material** (possibly in a "certification step"). But **there is no explicit legal requirement for IB to sign** these materials.

In Germany, **pharmaceutical companies are allowed to commission an external IB**. In such instances, it is recommended for the company to enter into a third-party agreement with this personally liable external person. When the external IB is notified, the authorities could ask to see this contract. Thus, in Germany, it is also **allowed for an IB to be appointed by several companies.**

Since a company engaged in advertising medicinal products is liable for the conduct and activities of its employees, although there is **no "sign-off" obligation** of promotional campaigns, **recommendation for the company is to set up** Standard Operating Procedures (which can include a signature/digital signature etc.) to **control advertising materials prior to release.** This is in order to comply with the legal requirements (particularly in the context of interaction with healthcare professionals which are subject to legal risk, including criminal liability).

NB The pharmaceutical company **shall notify the competent authority (CA)** of the appointment of **IB** and of any changes **in advance (6 to 1 month before)**. In the event of an unforeseen change of the IB, notification must be made **immediately**.

Documentation to be provided for notifying the IB depends on the CA but usually contains at least an up-to-date **CV**, a **proof of eligibility** and a current police **clearance certificate** grade 0 (< 6 months old). Indeed, as stipulated in the s**ection §74a (AMG)**, the pharmaceutical company must ensure that the appointed IB has the "**expertise and reliability required**". It **must be proven** that IB has the sufficient specialist knowledge. Usually, the minimum proof of qualification is a certificate of an examination passed after completing a **university degree** in **pharmacy**, **biology**, or **medicine**. However, as this is not a prerequisite – no precise legal requirement – recommendation is to consult the authorities. A very good level of **written and spoken German and English** is required. In addition, good awareness of national case law is recommended.

A precise timeline is not stipulated but usually the notification should be completed in **less than 1 month.** The **clearance certificate** is a **critical** document as it takes **2/3 weeks** to be issued and sent to the CA by the '*Einwohnermeldeamt*' (Registration Office of the city where the IB lives).

Spain

The Spanish Medicinal Products and Medical Devices Agency, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) is the main body responsible for all technical and quality aspects of medical products for Spain. **Royal Decree 1416/1994** establishes the general framework for regulation of promotion of medicinal products and medical devices. In addition, some of the 17 **autonomous regions** which are competent for the implementation of rules on advertising of medicinal products have adopted guidelines reflecting the position of the regional authorities (e.g. in the regions of Madrid and Catalunya). In addition, **Farmaindustria**, the National Association of the Pharmaceutical Industry established in Spain issues "**Good Practices Code for pharmaceutical industry**". This code regulates promotion of medicines towards HCPs and patient associations. The latest code issued by Farmaindustria is dated January 2021.

Article 20 of the Royal Decree 1416/1994 and section 9 of the Code of Farmaindustria, state that the marketing authorisation holder **must have a scientific service** in charge of the management of the information related to the medicinal products put on the market by the company. The company or its local representative must have a scientific service **comprising a physician or a pharmacist** responsible for:

- Information on their medicinal products
- Approval of promotional material before distribution
- Ensuring the notification of the promotional materials on medicinal product to regional health authority and keeping complete records, making them available to the authority for a minimum period of 5 years
- Ensuring that medical sales representatives receive adequate training
- Ensuring submission of an annual report on promotional activities to regional health authority, including promotional materials distributed, sponsorship and participation in promotional scientific meetings and events

The person responsible for scientific service must know Spanish and is responsible for all aspects of the scientific service in the view of the Health Authority (HA). Scientific Service Responsible person s to be notified to the HA, no approval is required. Scientific Service file is not regulated by law and it is discretional for the company to decide what to include in the notification.

If the MAH is not based in Spain but is going to promote a medicine in the Territory, the MAH shall notify all 17 regions of Spain how and who is going to take the responsibilities of the Scientific Service, and they must also make notifications QUI ?of all promotional activities to all 17 regions. Whereas if the MAH has a local representative/address in Spain notification of promotional activities to the HA in the region they are located are required.

NB In Spain, in addition to the national legislation, each autonomous region adopts guidelines that pharmaceutical companies must comply with, depending on their localization.

Promotional materials dedicated to HCPs for prescription only medicines and those dedicated to general public for over-the counter (OTC) medicines are handled differently.

Advertising directed to HCPs qualified to prescribe or dispense medicinal products **does not need to be approved** in advance by an authority. **However, companies must send a copy** of the advertisement **to the regional health authority** of the region where the company is located. It is made through an **electronic notification** and includes an application form detailing promotional material information (date of first diffusion, nature, mean of distribution, addressees), copy of the final material in pdf and a signed report from the Scientific Service certifying that the material is in line with the regulation. The Ministry of Health may, in exceptional circumstances, make the advertising of a specific product subject to prior approval. Such decision must be duly justified and shall affect all products having the same composition.

For **OTC**, Personal Healthcare Association (ANEFP) has released the "Spanish code of good practices for the promotion and advertising of non-prescription medicinal products". ANEFP is a **self-regulatory association** who will review the promotional materials of its members and put the "sello ANEFP" on the approved materials.

Italy

In Italy, the national health agency is AIFA, Agenzia Italiana del Farmaco, acting under the direction and vigilance of the Ministry of Health (MoH) and in coordination with the Ministry of Economy. National regulation is t**he Italian Legislative Decree 219/2006 "Code of Medicines"** implementing directive 2001/83/EC of the EU Parliament. For promotion to consumers, companies need to comply with the provisions set forth in the Legislative Decree 206/2005 "Consumer Code". **Farmindustria** is the Italian pharmaceutical companies' trade association and Farmindustria "code of professional conduct", is the national self-regulatory code applicable in Italy. This code sets out to regulate relations not only between companies but also their relations with the scientific and healthcare sectors.

Article 16 of Decree 219/2006 states that any company in possession of a marketing authorization in Italy shall **appoint a Scientific Responsible Person** Responsabile del Servizio Scientifico (**RSS**) in charge of information on medicines put on the market. The RSS shall have a degree in medicine, pharmacy, chemistry or pharmaceutical technology. Registration of the scientific responsible person is made through AIFA portal, using the Font End forms. For registration of a new RSS, the following information are to be completed on the electronic form:

- Company name
- Name & surname
- Tax code
- Email & phone number
- Period of activity

According to article 126 of "Code of Medicines", pharmaceutical companies must have a scientific service headed by a person who ensures that the promotional materials are legally compliant. This scientific service is in charge of the information about the medicinal products that companies put on the market and must be independent of the marketing department. The scientific service shall:

- Ensure that promotional materials comply with local regulations
- Ensure that the Sales Representatives are adequately trained on performing their activity in compliance with the applicable legislation in Italian Territory
- Provide AIFA with the information and assistance if necessary
- Ensure that the decisions taken by the MoH and AIFA under the Medicines Code are immediately and fully complied with.

NB The pharmaceutical company shall notify through AIFA electronic portal any change of RSS and any change of the details givQUIen in ? the list above for a registered RSS.

In Italy, promotional materials dedicated to HCPs for prescription only medicines and the ones dedicated to general public for over-the counter (OTC) medicines are handled differently.
Promotional materials dedicated to HCPs are to be submitted to AIFA using the AIFA electronic portal. Materials can be used after 10 days after submission in the absence of objection from the Authority. For OTC, article 118 of Code of Medicines states that promotional materials dedicated to general public are to be approved by the Italian Ministry of Health before they can be used. Following submission of the application for each single advert, it is deemed approved after 45 days if no formal approval is received from MoH.

United Kingdom

In the UK, the Medicines & Healthcare products Regulatory Agency (MHRA) regulates advertising of medicinal products. The **Blue Guide** issued by MHRA on **"Advertising and Promotion of Medicines in the UK"**, third edition, third revision dated November 2020 states the primary responsibility for the content and dissemination of all advertising and promotion of a medicine lies with the licence holder. Depending on the regulatory status of the concerned medicinal product and membership of the company, different codes of practices are applicable in the UK. Member companies must follow relevant codes:

• Prescription only medicine: **Code of Practice of the Association of the British Pharmaceutical Industry (ABPI).** The Prescription Medicines Code of Practice Authority (PMCPA) is the self-regulatory body which administers the ABPI code. Current APBI Code of Practice is dated from 2019. The 2021 APBI Code was approved by ABPI members at a special General Meeting in January 2021. It will come into operation on 1 July 2021.

• OTC medicine: **Proprietary Association of Great Britain (PAGB) with PAGB Medicines Advertising Codes**. PAGB, the consumer healthcare association, represents the manufacturers of branded OTC medicines, self-care medical devices and food supplements in the UK.

Blue Guide mentioned above states that a company will normally delegate final approval of all promotional materials to qualified signatories. Although it is not a legal obligation, the appointment of **qualified signatories to certify advertising material** is a requirement of both the ABPI Code of Practice and of the PAGB Medicines Advertising Codes. Companies are also asked to **inform the MHRA** of such appointments with names and qualifications of signatories and of any subsequent changes (by email to signatories.advertising@mhra.gov.uk).

For prescription only medicines, Clause 14 of ABPI Code of Practice states that the material is to be certified by a r**egistered medical practitioner or a pharmacist registered in the UK** or alternatively, in the case of a product for dental use only, a **UK registered dentist**. The person certifying on behalf of the company must not be the person responsible for developing the material. In deciding whether a person can be a nominated signatory, account should be taken of product knowledge, relevant experience both within and beyond the industry, length of service and seniority. In addition, signatories must have an up to date, detailed knowledge of the Code.

There is no requirement in the Code relating to the actual qualifications of medical signatories. The advice usually given is that the proposed medical signatory should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge.
In addition to the declaration to MHRA, the names of those nominated as signatories, together with their qualifications, shall be notified in advance to the PMCPA. The names and qualifications of designated alternative signatories must also be given. Clause 16 of ABPI Code of Practice states that all relevant personnel including representatives and members of staff, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations. Representatives must take an examination within one year of starting such employment and pass it within two years. Due to the current context with Covid-19, **ABPI examination** is held online. PMCPA published in December 2020 explanations about the extensions to the time allowed to pass an examination. Learning manual available on exams.abpi.org.uk. The mandatory units within the certificate are:

• Structure of the NHS & Code of Practice
• Human body structure & function 1
• Human body structure & function2
• Development & use of medicines

For OTC medicines, member companies are required to n**otify PAGB of a signatory** who is responsible for ensuring that the company's advertising to persons qualified to prescribe or supply is produced in compliance with this Code (section 1.4.2 of PAGB Code). Companies should ensure that the details notified to PAGB are accurate and up to date. Companies may wish to notify PAGB of one or more deputy signatory or signatories. Deputy signatories should be appointed to cover holiday periods, etc. (section 1.4.3 of PAGB Code). Signatories are expected to have a good working knowledge of the PAGB Professional Code for Medicines (section 1.4.4 of PAGB Code).

NB In the UK, promotional materials dedicated to HCPs for prescription only medicines and the ones dedicated to general public for over-the counter (OTC) medicines are handled differently.

For prescription only medicines, in specific situations, v**etting of advertising materials by MHRA** may be required for **newly authorised product** subject to additional monitoring placed on the market and for **all new active substances.** In addition, MHRA has committed to vet advertising when previous advertising for a product has breached the Regulations. For the other prescription medicines, there is no requirement to submit promotional materials to the authorities.

The PAGB Medicines Advertising Codes apply to advertising for all OTC medicines regardless of their route to market approval (marketing authorisation or traditional herbal medicines registration). PAGB operates **a pre-publication approval system** for member companies: it is a condition of membership that all advertising aimed at consumers must be submitted to PAGB for screening and **PAGB approval must have been given prior to its release into the public domain.** PAGB organises regular trainings about their codes for its members.

Conclusion

Despite the common basis which is in the EU Directive 2001/83/EC, promotional regulation is governed **by different texts and structures** in the different EU countries and in the UK. There are **local specificities** in each country regarding the responsible person and its roles and duties for validation of promotional material for example. Pharmaceutical companies have **to fulfil many local requirements** to be in line with local regulations before promotional activities can be started at local level in EU countries and in the UK.

Throughour**OutsourcingPlatformonPromotional Material Services (OPPROS),** BlueReg experts and their network of local partners will help you by coordinating and building the regulatory promotional strategy of your products along with the fulfilment of the local requirements for the respective launch and international congress set up.

Abbreviations :

ABPI: Association of the British Pharmaceutical Industry

AEMPS: *Agencia Española de Medicamentos y Productos Sanitarios* – Spanish Agencyfor Medicines and Sanitary Products

AIFA: *Agenzia Italiana del Farmaco* – Italian Agency for Medicines

AMG: *Arzneimittelgesetz* – The German Law on the Trade in Medicinal Products

ANEFP: *Asociación para el Autocuidado de la Salud* – Spanish Personal Healthcare Association

ANSM: *Agence nationale de sécurité du médicament et des produits de santé* – French National Agency for the Safety of Medicines and Health Products

CA: Competent Authority

CSP: *Code de la Santé Publique* – French Public Health Code

EC: European Commission

EFPIA: European Federation of Pharmaceutical Industries and Associations

EU: European Union

HA: Health Authority

HCPs: HealthCare Professionals

HWG: *Heilmittelwerbegesetz* – German Law on Advertising in the Health Sector

IB: *Informationdbeauftragter* – German Information Officer

IFPMA: International Federation of Pharmaceutical Manufacturers and Associations

MA: Marketing Authorisation

MAH: Marketing Authorisation Holder

MHRA: Medicines & Healthcare products Regulatory Agency

MoH: Ministry of Health

MS: Member States

OPPROS: Outsourcing Platform on Promotional Material Services

OTC: Over The Counter

PAGB: Proprietary Association of Great Britain

PhR: *Pharmacien Responsable* – French Responsible Pharmacist

PMCPA: Prescription Medicines Code of Practice Authority

QP: Qualified Person

RSS: *Responsabile del Servizio Scientifico* – Italian Scientific Responsible Person

UK: United Kingdom

UWG: *Gesetz gegen den unlauteren Wettbewerb* – German Act against Unfair Competition

WHO: World Health Organization

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France

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Germany

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