**Information request** on rules on advertising for medicinal products

**Requested by:** RAC, RO

**June 2015**

**Background**

In Romania, there is a proposal for a law introducing ban on advertising for over-the-counter medicines. Therefore, the Romanian SRO, RAC, would like to learn more about relevant legislation and SR rules applicable in other European countries.

**Questions**

- Please provide us with any relevant legislative and self-regulatory rules regarding advertising for medicinal products in your country.

**Answers**

| 1. AUSTRIA | 9. HUNGARY | 17. ROMANIA |
| 2. BULGARIA | 10. IRELAND | 18. SLOVAKIA |
| 3. CYPRUS | 11. ITALY | 19. SPAIN |
| 4. CZECH REPUBLIC | 12. LITHUANIA | 20. SWEDEN |
| 5. FINLAND | 13. LUXEMBOURG | 21. SWITZERLAND |
| 6. FRANCE | 14. NETHERLANDS | 22. TURKEY |
| 7. GERMANY | 15. POLAND | 23. UK |
| 8. GREECE | 16. PORTUGAL |  |
Legislation regarding medicinal products

- Pharmaceuticals Act (Arzneimittelgesetz); 1983

The law regulates the advertising of pharmaceuticals: only non-preservation (OTC) products may be advertised to the general public. Also restricts content (e.g. no images of medical professionals, not addressed to children). Fewer restrictions apply to advertisements in professional publications.

Legislation regarding medicinal products

- Pharmaceuticals Act (Закон за лекарствените продукти в хуманната медицина - Zakon za lekarstvenite produkti v humannata medicina); 2007

The law contains provisions about the advertising of medicines, including a ban on prescription-only medicines.

Legislation regarding medicinal products

- Act 70(I)/2001 on Medication for use by humans (Control of quality, supply and prices); 2011

The law stipulates provisions on advertising for medicinal products. The provisions are included in Chapter VI on Advertising.

Legislation regarding medicinal products

- Law Regulating Advertising (Zákon o regulaci reklamy); 1995

The law contains general provisions (e.g. definition of advertising) and specific regulations concerning the advertising of tobacco, alcohol, medicines and firearms. Important updates: 2002 (general amendment), 2003 (tobacco products). Pharmaceutical advertising must not be aimed at and addressed to youth under the age of 15 years of age.

Other SR bodies

The International Association of Pharmaceutical Companies (Mezinárodní asociace farmaceutických společností) supervises the advertising of medicines.
Statutory authorities

Ministry of Health (Ministerstvo zdravotnictví ČR). Responsible for medical and pharmaceutical advertising.

FINLAND

Other SR bodies

Supervisory Commission for the Marketing of Medicinal Products (Lääkemarkkinoinnin valvontakunta)

Pharmaceutical marketing is controlled by the Supervisory Commission for the Marketing of Medicinal Products. Inspection Board I of the Supervisory Commission for the Marketing of Medicinal Products does preclearance.

More information: Supervisory Commission for the Marketing of Medicinal Products – Clear Ground Rules for Pharmaceutical Marketing

Marketing is also covered by the industry’s Code of Ethics of Pharma Industry Finland (2014) which complements the legislative regulation.

Statutory authorities

Finnish Medicines Agency (Lääkealan turvallisuus- ja kehittämiskeskus, Fimea)

The authority is responsible for regulating pharmaceutical advertising.

FRANCE

Legislation regarding medicinal products

- Pharmaceutical Products Advertising Law no. 94-43 of 18 January 1994, codified as Art. L 551 of the Public Health Regulations (Code de la Santé Publique)

The law controls the advertising of pharmaceuticals.

Other SR bodies

French Agency for the Safety of Health Products (Agence Française de Sécurité Sanitaire des Produits Santé, AFSSPS).

The body is responsible for the advertising of non-prescription (and non-refundable) medicines and medical products to the general public.
Legislation regarding medicinal products

- **Medical Treatments Advertising Law** (Heilmittelwerbegesetz, HWG); 1994, 2013

The law regulates advertising for medicines, methods, treatments, etc.

- **Medicines Law** (Arzneimittelgesetz, AMG), 2005, 2014

The law regulates the advertising and retailing of medicines.

**Complaint handling**

The German SRO, Wettbewerbszentrale, amongst others, deals with such areas as health matters and medicines.

In addition to the Wettbewerbszentrale, the Association for Fair Advertising of Medical Products (Integritas) also handles complaints concerning the advertising of medicines.

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**GREECE**

**Pre-clearance**

Pre-clearance is Greek is only carried out in regard to OTC medicines. The pre-clearance is mandatory and is handled by the National Organisation for Medicines (EOF).

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**HUNGARY**

Legislation regarding medicinal products


The statute specifies rules for medicine advertisements, and provides for the words of the compulsory disclaimer to be used in ads as well as the reminders for medicines and homeopathic products.
Legislation regarding medicinal products

- Medicinal Products (Control of Advertising) Regulations of 2007 (S.I. No. 541 of 2007)
- Medical Preparations (Licensing, Advertisement and Sale) Regulations; 1996
- Medicinal Products (Prescription and Control of Supply) Regulations; 2003

Other SR bodies

With the exception of specialised advertisements addressed to the medical and allied professions, the advertising to which the various sectoral codes of practice relate is also subject to the ASAI Code, which is regarded as the primary self-regulatory Code. The sectoral codes often specifically require compliance with the ASAI Code or repeat its provisions verbatim. ASAI does not have formal relationships with the other organisations but does have informal ones in some cases, e.g. Copy Clearance.

Irish Pharmaceutical Healthcare Association (pharmaceutical products): code of standards of advertising practice for consumer healthcare industry; (member of ASAI)

The Dental Council (dentists): guidelines on public relations and communications;

The Medical Council (doctors): guide to ethical conduct (advertising and the media);

The Opticians’ Board (opticians): rules of the opticians’ board relating to advertising.

Statutory authorities

The Minister for Health has certain regulatory functions under the Medical Preparations (Control of Advertising) Regulations, 2007 and the Tobacco Products (Control of Advertising, Sponsorship and Sales Promotion) Regulations, 1991 and Tobacco Products (Control of Advertising, Sponsorship and Sales Promotion Amendment) Regulations, 1994 and 1996.

ITALY

Legislation regarding medicinal products

- Legislative Decree no. 219/2006 on Medicines (Decreto Legislativo 219/2006 attuazione della direttiva 2001/83/CE (e successiva direttive di modifica) relativa ad un codice comunitario concernente i medicinali per uso umano, nonché della direttiva 2003/94/CE); 2003, 2006

The law regulates the advertising of non-prescription medicines and authorises pre-clearance by the IAP (except for television). Advertising is allowed only for non-prescription (OTC)
medicines and is subject to prior approval by the Ministry. For press and radio advertising the IAP can provide advice prior to formal approval by the Ministry.

**Pre-clearance**

In Italy, the self-regulatory system is officially recognised by the law. The Law on Medicines, that requires advertisements for over-the-counter medicines to be pre-cleared by the Ministry of Health, also contains a legislative decree that allows advertisers intending to create an advertisement for radio and press to request copy advice from the Italian SRO, IAP, before formal approval from the Ministry.

Advertisements for non-prescription medicines for human beings and animals require authorisation from the Ministry of Health. Legislative Decrees allow advertisers to ask the IAP Review Board for advice before pre-clea"rce of such advertisements in radio and press. A fee is charged for this service. Please note that formal approval by the Ministry still needs to be sought after the advertisement has been cleared by IAP.

**SR rules**

The SR Code of the Italian SRO includes special provisions regarding advertising for medicines products.

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*Title II - Special rules*

*Art. 25 – Medicinal Products and Curative Treatments*

*Marketing communication relating to medicinal products and curative treatments should consider the sensitivity of the matter and display the utmost sense of responsibility; it must also accurately reflect the details contained in the fact sheet summarising the product specifications.*

*Such marketing communication should draw the consumer’s attention to the need for caution in using the product, explicitly and clearly encouraging consumers to read the package warnings and advising against the improper use of the product.*

*In particular, marketing communication relating to over-the-counter products should include the name of the medicinal product as well as the common name of the active ingredient; this latter information is not compulsory if the medicinal product contains more than one active ingredient or the communication is intended solely as a generic reminder of the product’s name.*

*Moreover, marketing communication relating to over-the-counter medicinal products and curative treatments should not:*

*Rules on advertising for medicinal products*
suggest that the efficacy of the medicine is devoid of side effects or that its safety or efficacy profiles are due to the fact that it is a natural substance;

claim that the efficacy of the medicine or treatment is equal to or better than others;

suggest that a medical consultation or surgical procedure is unnecessary or lead consumers to make an incorrect self-diagnosis;

exclusively or principally address children or lead minors to use the product without appropriate adult supervision;

make use of recommendations by scientists, health professionals or persons well-known to the public, or refer to the fact that the medicinal product has been approved for sale, or improperly or misleadingly report certificates of recovery;

compare the medicinal product with a foodstuff, cosmetic or other consumer product;

suggest that the medicinal or the curative treatment can improve normal good health, or that avoiding a certain product or treatment can be harmful, unless the message refers to vaccination campaigns;

use improper, misleading or frightening depictions of changes in the human body caused by disease or injury, or due to the effects of the medicinal product.

As regards marketing communication relating, in particular, to veterinary medicines, the rules contained in the relevant Regulations shall apply, and form an integral part of this Code.

LITHUANIA

Legislation regarding medicinal products

- Law for medicinal products available on prescription (Lietuvos respublikos farmacijos istatymas); 2006

The law regulates advertising for medicinal products. It also bans the advertising of prescription-only medicinal products to the general public.

LUXEMBOURG

SR rules

The SR Code of the Luxembourgish SRO includes special provisions regarding advertising for pharmaceutical products and other products related to health.

Il – Règles déontologiques spécifiques

Rules on advertising for medicinal products
3.  De la publicité relative aux produits de santé

La publicité relative à des produits pharmaceutiques ou de santé en général doit s’abstenir d’encourager à leur consommation abusive. Elle précisera, en outre, qu’il est recommandé au consommateur de demander conseil auprès d’un médecin, pharmacien ou autre spécialiste de la santé.

**NETHERLANDS**

**Legislation regarding medicinal products**

-  **Law on medicines** (Geneesmiddelenwet); 2007

The law prohibits the advertising of medicines that have not been registered and/or licensed with a trade permit (Art. 84), as well as the advertising of prescription-only medicines to the general public (Art. 85).

**Complaint handling and pre-clearance**

SRC collaborates with several organisations to handle complaints which concern them.

**Council for the Public Evaluation of Registered Medicines and Council for the Evaluation of Health Products** (Keuringsraad Openlijke Aanprijzing Geneesmiddelen - KOAG en Keuringsraad Aanprijzing Gezondheidsproducten - KAG). This is a dual self-regulatory body with its own guidelines for the advertising to the general public of medicinal products (KOAG) and natural remedies and other health products (KAG). KOAG/KAG pre-vets all public advertising for non-prescription and homeopathic medicines and for health products. Costs for pre-clearance vary for different types of advertisement and also depend on whether the applicant is a member. It takes five working days for the KOAG/KAG to respond to a pre-clearance request.

**SR rules**

**Code for Public Advertisements of Medicines (CPG) 2015**

**Code for Advertising of Medical Self-Help Products (CMH)**

**POLAND**

**Legislation regarding medicinal products**

-  **Act of August 30, 1991, on Health Care Institutions** (official journal „Dz.U.”, No. 91, item 408, as further amended), (Ustawa z dnia 30 sierpnia 1991 r. o zakładach opieki zdrowotnej (Dz. U. Nr 91, poz. 408, z późn. zm.); 1991

The law is related to prescription-only medical services.

**Rules on advertising for medicinal products**
The law is related to prescription-only medicinal products.

**PORTUGAL**

**Legislation regarding medicinal products**

- **Decree-Law 100/94 of April 19 relating to advertising of medicines for human use** (Decreto-Lei n.º 100/94, de 19 de Abril – Publicidade dos medicamentos de uso humano); 1994

The law regulates advertising of medicinal products for human use.

- **Decree-Law 176/2006 of August 30th** (Decreto-Lei n.º 176/2006, de 30 de Agosto – Estatuto do Medicamento); 2006

The law stipulates provisions regarding marketing, manufacture, labelling and advertising of medicines.

- Decree-Law 25/2001; 2011

The law establishes the obligation to indicate the selling price on the labelling/packaging of medicines products.

- Decree-Law 128/2013; 2013

The law establishes and defines parameters for the advertising of medicinal products and for labelling, leaflet information and advertising.

**Statutory authorities**

The National Authority of Medicines and Health Products (Infarmed) is responsible for monitoring the advertising of medicinal products for human use.

**ROMANIA**

**Legislation regarding medicinal products**

- Urgent Governmental Ordinance no. 152 concerning medicines for human use as approved by Law 336 (as further modified and completed); 1999, 2002

The law restricts consumer advertising for medicines to over-the-counter (OTC) products available without prescription.
SR rules

The SR Code of the Slovak SRO includes special provisions regarding advertising for medicines, medical aids and/or medical services in Chapter V (Articles 40-43).

CHAPTER FIVE ADVERTISING OF MEDICINES, MEDICAL AIDS AND/OR MEDICAL SERVICES

Article 40

General Provisions on Advertising of Medicines, Medical Aids or Medical Services

(1) The provisions of this Chapter do not relate to providing information to the professional public, including e-letters, advertisements in professional journals and other forms of communication targeted exclusively for professional public.

(2) In medication advertisement may appear only medicaments and medical aids which are registered in the Slovak Republic or approved by a legal procedure.

(3) Narcotic or psychotropic substances advertisement is not permitted.

(4) Inadmissible advertising is also advertising of

a) medicines to be obtained on a prescription or a veterinary prescription,

b) medicines that are reimbursed by public health insurance, unless otherwise stipulated by the Code, and

c) containing a reference to the effects of medicines intended to treat tuberculosis, sexually transmitted diseases, serious infectious diseases, cancer diseases, chronic insomnia, metabolic disorders diseases or mental illnesses.

Article 41

Broadcasting of Advertising of Medicines and Medical Services

(1) An advertisement of medicines, which are reimbursed by public health insurance but not prescribable can be promoted in radio or television broadcasting.

(2) An advertisement of medical services covered by public health insurance in radio or television broadcasting is inadmissible.

Article 42

Protection of Consumers in the Advertising of Medicines, Medical Aids or Medical Services

Rules on advertising for medicinal products
(1) Advertisements of medicines, medical aids or medical services shall not contain data leading to misjudgement of medical condition.

(2) Advertisements shall not include data describing harmless effects of medicaments if the only reason for such harmless effect is its natural origin.

(3) An advertisement of medicine or medical aid shall include name of the medicine or medical aid. Where possible, the advertisement shall include a call for a more thorough consultation on the effects of the medicine with a doctor or pharmacist.

Article 43

Conflict of Interest

No specific natural person or a representative of a legal person shall act in the advertisement of medicines or medical aids, who may due to their function or business interests influence the consumption of medicines or medical aids.

Legislation regarding medicinal products

- Royal Decree on Advertising of Medicines for Human Use (Real Decreto 1416/1994, por el que se regula la publicidad de los medicamentos de uso humano); 1994

The law regulates the advertising of medicines for human use, addressed to the general public or to medical practitioners.

- Royal Decree on the Regulation of Health Products (Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios); 2009

The law requires this category of advertising to be pre-cleared by health authorities.

- Royal Decree on the Advertising and Promotion of Products, Activities or Services making purported Health Claims (Real Decreto 1907/1996, sobre publicidad y promoción de productos, actividades o servicios con pretendida finalidad sanitaria); 1996

The law stipulates provisions on advertising for “miracle products”. It restricts the claims that can be made for a product or service, material or method, that appears to the consumer to have an effect on health but that is not a medicine.

SR rules

Spanish Code of Best Practice of the pharmaceutical industry (FARMAINDUSTRIA) (2014).
**Self-Regulatory Advertising Code for the promotion and advertising of OTC pharmaceutical products not financed by the National Health Care System and other health care products, adopted by the National Association for Home Health Care** (Asociación Nacional de Especialidades Farmacéuticas Publicitarias – ANEFP); 2007.

Code agreed between the Spanish Federation of Health Care Technology Industries (FENIN) and Autocontrol; [2006, updated 2011](#).

**Pre-clearance**

In Spain, advertising for non-prescription (OTC) medicines had to be pre-cleared by the Directorate General of Pharmacy, Ministry of Health and Consumer Protection till 2014.

**Statutory authorities**

Directorate General of Pharmacy, Ministry of Health, Social Services and Equality (Dirección General de Farmacia).

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**SWEDEN**

**Legislation regarding medicinal products**

- [Pharmaceuticals Act](#) (Läkemedelslag); 1992

**Other SR bodies**

Information Practices Committee of the Association of the Swedish Pharmaceutical Industry (Nämnden för bedömning av läkemedelsinformation – NBL) was set up by the Association of the Swedish Pharmaceutical Industry (LIF). The body applies the “Rules Governing Medicine Information in Sweden”. These rules control the advertising of medicinal products to health professionals and to the public. Decisions on breaches of the Rules are published in the Swedish Medical Journal. Repeated breaches may lead to expulsion from trade associations. The pharmaceutical industry’s Information Examiner monitors the marketing activities of pharmaceutical companies. Administrative fees are imposed on parties losing a case.

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**SWITZERLAND**

**Legislation regarding medicinal products**

- [Federal Law on Medicines, 2000](#) (Heilmittelgesetz/Substances thérapeutiques); 2000

The law restricts advertising for pharmaceutical products.


*Rules on advertising for medicinal products*
The law restricts radio and television advertising in terms of amount and content. Prohibits advertising for tobacco products, alcoholic beverages above 15% ABV and medicines on television and radio.

**SR rules**

The SR Code of the Swiss SRO includes special provisions regarding advertising for quasi-cosmetic and paramedical products and methods (*French/German*).

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*Règle n° 5.7 Publicité pour des produits cosmétiques ou paramédicaux*

Toute publicité en faveur de produits ou méthodes destinés aux soins corporels et hygiéniques ou prétendant améliorer le bien-être est réputée déloyale si elle ne tient pas compte des directives suivantes:

1. La publicité doit définir clairement le produit ou la méthode qu’elle prône et s’abstenir d’affirmations prétendant à des vertus curatives ou préventives contre la maladie, analgésiques ou somnifères.

2. La publicité ne doit pas donner le sentiment que le recours à ces produits, substances ou méthodes soit à même d’éliminer de façon durable les rides, la calvitie, les défauts de pigmentation de la peau, des anomalies anatomiques ou d’autres affections irréversibles ou encore de raffermer la poitrine ou d’augmenter le volume des seins.

3. Toute prétention à une diminution de poids durable sans un contrôle simultané de l’alimentation, soit un régime et des exercices physiques appropriés, est proscrite. Il en va de même de la publicité pour des produits ou méthodes prétendant favoriser le développement ou l’entretien des muscles sans entraînement physique durable.

4. Les personnes ou situations représentées avant et après le traitement ne peuvent être reproduites en image que si les conditions de prise de vue sont identiques en ce qui concerne la position, l’échelle de reproduction, la présentation et la mise en scène des sujets ainsi que du décor, l’angle de vue, l’éclairage et les autres éléments de comparaison. Il est, dès lors, interdit de recourir à des moyens phototechniques ou autres manipulations destinés à noircir la situation avant et à l’embellir après le traitement.

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*Grundsatz Nr. 5.7 Werbung für quasikosmetische/-medizinische Erzeugnisse und Methoden*

Jede werbliche Anpreisung von Erzeugnissen und Methoden, die der Körperpflege und -hygiene sowie dem Wohlbefinden dienen, ist unlauter, sofern sie nicht den nachstehenden Richtlinien nachkommt:

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*Rules on advertising for medicinal products*
1. Die Werbung hat das Erzeugnis oder die Methode klar zu umschreiben und darf keine Angaben enthalten, die den Anschein krankheitsheilender oder -verhütender, schmerzstillender oder schlaffördernder Wirkung erweckt.


3. Jede Anpreisung ist zu unterlassen, die eine dauernde Gewichtsabnahme ohne gleichzeitige Nahrungskontrolle, d.h. Diät und körperliche Bewegung glaubhaft machen will. Das gleiche gilt für die Anpreisung von Erzeugnissen und Methoden für die Entwicklung und Erhaltung von Muskeln ohne dauerndes körperliches Training.

4. Personen oder Situationen vor und nach der Behandlung dürfen nur wiedergegeben werden, wenn sie unter gleichen Bedingungen hinsichtlich Position, Massstab und Aufmachung sowie Dekor, Aufnahmewinkel, Beleuchtung und dergleichen aufgenommen worden sind oder dargestellt werden, sowie wenn sie sich weder phototechnischer noch anderer Vorkehren bedienen mit dem Zweck, die Abbildung vor der Behandlung nachteilig zu verändern oder die Wiedergabe nach der Behandlung zu verschönern.

Statutory authorities

Swissmedic, Swiss Agency for therapeutic products (Schweizerisches Heilmittel Institut / Institut suisse des produits thérapeutiques) is responsible for advertising of medicines.

Legislation regarding medicinal products

- **Law on Medicinal and Pharmaceutical Products** (Işpençiyari ve Tibbi Müstahzarları Kanunu); 2003

The law prohibits advertising of prescription-only medicines in all media, including medical journals. Due to a technicality, the law also effectively prohibits the advertising of over-the-counter medicines.
Legislation regarding medicinal products

- Human Medicines Regulations; 2012

The law establishes a comprehensive regime for the authorisation of medicinal products for human use, for the manufacture, import, distribution, sale and supply of those products, for their labelling and advertising, and for pharmacovigilance.

Other SR bodies

The Proprietary Association of Great Britain (PAGB) administers the Code of Standards of Advertising Practice on the Public Advertising of Non-Prescription Medicines.

SR rules

UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code) includes special provisions regarding advertising for medicines, medical devices, health-related products and beauty products – overview of the SR under the CAP Code and related legislative rules

UK Code of Broadcast Advertising (BCAP Code) includes special provisions regarding advertising for medicines, medical devices, treatments and health – overview of the SR rules under the BCAP Code and related legislative rules

Statutory authorities

The Medicines and Healthcare Products Regulatory Agency regulates medicines and medical devices in the UK.