(https://marketing4health.net/links-to-global-healthcare-advertising-guidelines/)

Links to global healthcare advertising guidelines

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by Nat Bourre

A global healthcare advertising guidelines and guidances resource for medical writers and healthcare advertising agencies around the world

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This global healthcare advertising guidelines resource will continue to be updated over the coming months to include links to guidelines from other countries.

Click on the country that you are looking for to jump directly to that section:

Australia:

The Australian Regulatory Guidelines for Advertising Therapeutic Goods (https://www.tga.gov.au/advertising-advertising-code-and-guidance)(ARGATG) contains links to the Therapeutics Goods Advertising Code (https://www.tga.gov.au/publication/australian-regulatory-guidelines-advertising-therapeutic-goods-argatg) and multiple guidance for various advertising situations.

The Australia Government Advertising Hub (https://www.tga.gov.au/advertising-hub) “brings together news and information about the regulation of therapeutic goods advertising. It contains tools for both consumers and advertisers, including fact sheets, e-learning modules and forms for reporting unlawful advertising and for submitting enquiries.”

A detailed Advertising Compliance Checklist (https://www.tga.gov.au/sites/default/files/advertising-compliance-checklist-consumer-advertising.pdf) can be used to ensure that you have not left any stone unturned when it comes to following the regulations in your consumer advertising.

Canada:

In Canada, pharmaceutical advertising targeted to healthcare professionals is allowed, but there are guidelines to follow. Promotional direct-to-consumer advertising of prescription products is not allowed in Canada. Only the prescription product name, price and quantity are acceptable information that can be promoted to patients.

There are two 3rd party pre-clearance reviewer agencies that are recognized by Health Canada for vetting Canadian healthcare and pharmaceutical advertisements. Both have a specific

mandate. They are the Pharmaceutical Advertising Advisory Board (PAAB) and Advertising Standards Canada. Both reviewers ensure that content is in sync with the Health Canada food and drugs advertising regulations (https://www.canada.ca/en/health-canada/services/drugs-health-products/marketing-drugs-devices/advertising-requirements-drugs-medical-devices.html).

The PAAB reviews advertising for prescription products, non-prescription pharmaceutical products, biologicals, natural health products and homeopathy products.

PAAB reviewers give guidance to help Canadian medical marketers revise the copy and design until the entire promotional piece is deemed to be in accordance with local regulatory requirements. Once the advertisement is completely within the requirements, PAAB provides the pharma company with an approval number and the right to affix the PAAB logo onto the advertising piece (a symbol meant to reassure HCPs and patients that the content that they are reading has been vetted by a 3rd party for credibility, accuracy and completeness). The PAAB code can be found at https://code.paab.ca/ (https://l.facebook.com/l.php?u=https%3A%2F%2Fcode.paab.ca%2F%3Ffbclid%3DIwAR09ec-GFQt3lGriz6lQVtg9SuXqlWWkCumYaOrc2ZWPMJFGf_OoxAfLF8A&h=AT29EILAWEjEpK1yovJ9_nk0fMvW9lHgi7b37n3NKq7J7d7Mlc1l2uQlUOTS40aKMDD_0RP7Z_ALmofJg7qziGj25bad1pej8yUErFDDnN5gjel9qL8DBD3zuD5_SJ3QIw&__tn__=-UK-R&c[0]=AT2Jc6vi3OmaihWOPZEWdn4TjRh2ZwxIw6Q1QIUtWfc1jETr1-vBakFm9tSrY7vQIn0hh2Cfv7_zBBF7OswQRkt-AnLH1aaW4Kd_gO8nC-4LTi0-XJi2vZDG6WWzeG2n_mKZj9vnW5IulJuR1ZhNxfRguvwn-A5ZhnHCQHyrBfiaqXBY7WwEzSGaYAHpfTgkFPb79hJEM0leCw). An official forum with questions and answers managed by PAAB can be found at https://forum.paab.ca/ (https://l.facebook.com/l.php?u=https%3A%2F%2Fforum.paab.ca%2F%3Ffbclid%3DIwAR0iXjE3ZvTVX7H--UGkb4acYD84aftI8xolVMvGtHIk0g_VayDQhco2HLE&h=AT34NCql2wQ0yXSZbG9M79ABFlOwTb_9DEqtEPEE3JFn4dFJ0OYIADc0dNGcBeS_es3OdTBnMm2lq8YZxkj6Oi3ElyMkPo4UWV3TF_TqHlbaHxgtTE6PYecUFOwXbmEZXg&__tn__=-UK-R&c[0]=AT2Jc6vi3OmaihWOPZEWdn4TjRh2ZwxIw6Q1QIUtWfc1jETr1-vBakFm9tSrY7vQIn0hh2Cfv7_zBBF7OswQRkt-AnLH1aaW4Kd_gO8nC-4LTi0-XJi2vZDG6WWzeG2n_mKZj9vnW5IulJuR1ZhNxfRguvwn-A5ZhnHCQHyrBfiaqXBY7WwEzSGaYAHpfTgkFPb79hJEM0leCw).

On the other hand, Ads Standards (https://adstandards.ca/preclearance/advertising-preclearance/consumer-drugs/) reviews consumer-directed nonprescription drug advertising, natural health product advertising, vaccine advertising, medical device advertising, and prescription drug direct-to-consumer-advertising and direct-to-consumer-information. Similarly to the PAAB logo which symbolizes that the materials have been reviewed and approved by a neutral third party, Ad Standards also provides a logo that can be affixed to advertising materials that have been reviewed by and received approval from Ad Standards Clearance Services.

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China

In China, the State Administration for Market Regulation (SAMR) is responsible for overseeing the vetting of advertisements for drugs, medical devices, health food and food for special medical purposes. Provincial-level SAMR bureaus vet these advertisements within their respective administrative areas.

Recently, the Interim Measures for the Examination and Administration of Advertisements for Drugs, Medical Devices, Health Food and Food for Special Medical Purposes (http://gkml.samr.gov.cn/nsjg/fgs/201912/t20191227_309564.html) (link in Chinese) were issued and have taken effect since 1 March 2020. The Interim Measures have detailed rules on advertising these products.

An advertisement for drugs, medical devices, health food and food for special medical purposes shall display its approval number on a prominent place. No advertisement on any drug, medical device, health food or food for special medical purposes shall be released without being vetted.

The validity period of an advertisement is the same as the shortest validity period of a product registration certificate, notification certificate or production permit. If the certificate or permit does not specify a validity period, it will be two years for an approved advertisement.

When only a product name (including a drug's generic name and trading name) is advertised for drugs, medical devices, health food and food for special medical purposes, the content is exempt from being vetted.

Drugs

The content of a drug advertisement shall comply with the product package insert approved by the drug administration agency of the State Council. When a drug advertisement involves a drug name, indication, function or pharmacology, it shall fall within the scope of the product label.

A drug advertisement shall clearly indicate contraindications and adverse reactions. Besides, advertisements for prescription drugs shall clearly state that "This advertisement is for medical and pharmaceutical professionals only". Advertisements for Over-The-Counter drugs shall clearly display the OTC mark, and state "Please purchase and use the drug according to the package insert or under the guidance of a pharmacist".

Medical Devices

The content of a medical device advertisement shall comply with the registration certificate, notification certificate or package insert approved via registration or notification from the drug administration agency.

Where an advertisement involves a name, scope of application, mechanism of action, structure or composition of a medical device, it shall fall within the scope of the registration certificate, notification certificate or package insert approved via registration or notification.

Advertisements for medical devices recommended for personal use shall clearly state that “Please read the product instruction carefully. Purchase and use under the guidance of a medical professional”. When a registration certificate contains contraindications and precautions, the advertisement shall clearly state “See the instruction for contraindications and precautions”.

Health Food

The content of an advertisement for health food shall comply with the registration certificate, notification certificate, or package insert approved via registration or notification from the market administration agency. The advertisement shall not suggest disease prevention or treatment. When an advertisement involves health care functions, functional ingredients, characteristic ingredients and content, suitable population and dosage, it shall fall within the scope of the registration certificate, notification certificate or package insert approved via registration or notification.

A health food advertisement shall clearly state that “Health food is not a drug and cannot replace drugs to treat diseases”. It shall also clearly display the health food mark, and suitable and unsuitable population.

Food for Special Medical Purposes

The content of an advertisement for food for special medical purposes shall comply with the registration certificate, product label or package insert approved by the SAMR. When an advertisement involves product name, formula, nutrition characteristics, or suitable population, it shall fall within the scope of the registration certificate, product label and package insert.

An advertisement for food for special medical purposes shall clearly indicate a suitable population. It shall also clearly state “Not suitable for non-target population”, and “Use under the guidance of a physician or clinical nutritionist”.

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Indian

India:

International Comparative Legal Guides has compiled a comprehensive document in July 2020 covering the advertising landscape in India. Link to the article (https://iclg.com/practice-areas/pharmaceutical-advertising-laws-and-regulations/india) Full credit to Mr. Krishna Venkat (https://www.linkedin.com/in/krishna-venkat-5276ab28/) for this document.

Primarily, there are no sign-offs in India for the advertisement of pharmaceutical copy. There is no legally prescribed standard operating protocol governing advertising activities.

On December 12, 2014, the Department of Pharmaceuticals (DoP) prepared a voluntary code of marketing practices called the Uniform Code for Pharmaceuticals Marketing Practices (UCPMP). (https://pharmaceuticals.gov.in/sites/default/files/UCPMP.pdf) Sections 2 and 3 covered the “Claims and comparisons” and “Textual and Audio-visual promotional material”, respectively. Owing to the voluntary nature of the code, the DoP sought to make the code mandatory so that compliance to the code by pharma companies would be legally obligated.

In July 2017, the DoP sent the draft Essential Commodities (Control of Unethical Practices in Marketing of Drugs) Order, 2017 (“*Order*“) to the Law Ministry for final clearance. There are differences between the code and the proposed Order and are captured in Annexure C of a whitepaper here (http://nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Uniform-Code-for-Pharmaceutical-Marketing-Practices_Decoded.pdf). The draft is not available on the public domain (https://web.archive.org/web/20200810120051/https:/www.dnaindia.com/business/report-loopholes-emerge-in-pharma-ban-code-2516329). The Law Ministry has rejected the idea of the draft’s placement under Essential Commodities Act.

In August 2019, a report (http://sathicehat.org/wp-content/uploads/2019/12/Pharma-study-report_by-SATHI.pdf) by a non-governmental organization alleged that medical representatives bribed health care professionals with foreign trips, expensive smartphones, e-vouchers, credit cards and even sexual favors. Four months later, in December 2019, the secretary of the DoP, P.D. Vaghela, conducted a review meeting (https://theprint.in/india/govt-warns-pharma-firms-after-report-says-doctors-bribed-with-women-foreign-trips-gadgets/340737/) with the Indian Drug Manufacturers’ Association, the Indian Pharmaceutical Alliance and the Organization of Pharmaceutical Producers of India. The issue of non-compliance with **the UCPMP guidelines** was brought up.

In 2020, the UCPMP still remains a voluntary code- toothless and unenforceable (https://www.thehindu.com/sci-tech/health/centre-persists-with-toothless-pharma-codes/article30755290.ece)– and rampant violations occur but cannot result in prosecution of wrong-doers.

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(Follow his #TheKeyTakeaway (https://marketing4health.net/wp-admin/post.php?post=12677&action=edit#TheKeyTakeaway) tips on LinkedIn)

New Zealand:

In New Zealand, pharmaceutical companies can promote to both HCPs and patients.

The industry association for prescription medicines, Medicines New Zealand, publishes the Medicines New Zealand Code of Practice (https://www.medicinesnz.co.nz/fileadmin/user_upload/Code_of_Practice_Edition_17_published_April_2019_effective_September_2019.pdf), applicable to both member and non-member companies. The 'code' covers advertising to both HCPs and consumers.

All material intended for use by consumers or patients must be reviewed and approved by TAPS (Therapeutic Advertising Pre-vetting Service) for compliance with the Advertising Standards Association Therapeutic and Health Advertising Code (https://www.asa.co.nz/codes/codes/therapeutic-and-health-advertising-code/) and legislation. TAPS also provide advice to advertisers and guidance (https://www.anza.co.nz/taps) on specific topics. HCP content can be reviewed and approved by an internal company employee, acting as a delegated authority of TAPS (known as TAPS DA).

Medsafe, the New Zealand health regulatory agency, publishes a Guideline on the Advertising of therapeutic products (https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part7_Advertising_of_therapeutic_products.pdf), summarising the requirements of the New Zealand Medicines Act, Medicines Regulations and Misuse of Drugs Act which all contain information relevant to the advertising of medicines.

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Serbia:

In Serbia, pharmaceutical advertising is targeted to both healthcare professionals and patients. Prescription drugs can only be promoted to healthcare professionals, whereas over-the-counter drugs can be promoted to both healthcare professionals and patients.

Regulation of pharmaceutical advertising is the responsibility of the National Centre for Information on Medicines and Medical Devices within the Medicines and Medical Devices Agency. The Agency reviews applications from the pharmaceutical industry, i.e. marketing authorization holders, and requires a pre-approval of all advertisements. Also, the Agency and the Ministry of Health publish guidelines (https://www.alims.gov.rs/latin/regulativa/humani-

lekovi/pravilnici/) and instructions (https://www.alims.gov.rs/latin/regulativa/humani-lekovi/uputstva/) (links are only available in Serbian) to be used by applicants in preparation and submission of promotional materials. According to the guidelines, mentioning only the name of a drug and/ or generic name is not considered to be marketing and pre-approval is not required in this situation. It is forbidden to advertise an unregistered drug or a drug whose license has expired.

Direct-to-consumer advertisements must contain the name of a drug, method of administration and warning to a patient or a consumer to carefully read the instructions and to consult a doctor or a pharmacist about the possible risk and adverse reactions. Direct-to-consumer advertising is not allowed for prescription drugs, including drugs intended for the treatment of tuberculosis, sexually transmitted diseases, infectious diseases, chronic insomnia, diabetes and other metabolic diseases and drugs containing narcotics or psychotropic substances. Also, it is not allowed to promote drugs for paediatric use by directly addressing children.

Advertisements for healthcare professionals must comply with the approved Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL). In addition to information about the drug and information taken from SmPC and PIL, these advertisements can include claims from medical journals or other scientific papers that are relevant and recent. These sources must be assessed by the Agency and they must be referenced in the material itself.

The Agency can have several requests to revise the promotional material until it is in accordance with local regulatory requirements. Once the advertisement is satisfactory, the Agency issues an approval number that is to be affixed onto the advertisement in printed or digital form. This indicates that the material has been reviewed and officially approved. The approval is valid for a limited time, usually until the validity period of the marketing authorisation.

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Singapore:

Advertisements of therapeutic products to the general public and healthcare professionals do not require prior approval from the Health Sciences Authority (HSA), the governing body for regulations that apply to medical products in Singapore.

The rules and requirements for advertising of therapeutic products prohibit advertising of unregistered product, unregistered indication for a specific product, material aimed at children below 14 years of age, promotions suggesting monetary reimbursements for use of product, false claims of endorsement by public authorities. The rules prohibit advertisements by healthcare professions or celebrities. Use of logos of HSA or affiliated groups is also not allowed.

Advertisements of prescription medicines to the general public is prohibited, which means advertisements in waiting areas of clinics and hospitals are not allowed. Advertising copy making claims of better efficacy in comparison to other products is also not allowed. The regulations specify that no claims of cures or preventions of a list of about 20 diseases and conditions is allowed. This list diseases and conditions like cancer, diabetes, blindness, deafness, sexual function and hypertension. Samples of therapeutic product alone or other health products along with therapeutic product are not to be provided to the general public. Any direct-to-consumer advertisements of pharmacy-only medications should include advisories to patients to read information leaflets and to consult their doctor if symptoms persist.

Advertising to Health Care Professionals are allowed as long as the information is not open to the general public. Any advertisements of products relating to the above mentioned list of conditions must be non-promotional. Comparative claims are allowed in advertisements that are limited to HCPs.

Advertisements of any unregistered product or unapproved use can only be made in the form of a scientific publication, conference presentation, or pharmaceutical trade exhibition which is not open to the general public. Any such advertisement of unregistered product can indicate the purpose and efficacy of the product. Unregistered products must contain a statement that is not registered in Singapore and must be registered in at least one other country.

Health supplements:

Advertisements of Homeopathic, Traditional Indian, Malay, or Chinese proprietary medicines require a valid permit. These rules also apply to personal care products such as medicated soaps and toothpastes. Vitamin and mineral supplements, medicated oils and balms also require a permit.

Such advertisements have to include the permit number in the promotion materials and cannot be amended without prior approval by HSA.

Permits are not required for advertising that is directed to traders (who can lawfully sell these products) and HCPs.

No promotional sample distributions are allowed as part of advertising strategy.

Reference:

https://www.hsa.gov.sg/therapeutic-products/advertisements (https://www.hsa.gov.sg/therapeutic-products/advertisements)

https://www.hsa.gov.sg/health-supplements/advertisements-and-promotions-of-medicinal-products (https://www.hsa.gov.sg/health-supplements/advertisements-and-promotions-of-medicinal-products)

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United States:

The US Food and Drug Administration (FDA) provides guidance regarding advertising healthcare products in the United States. The Federal Food, Drug and Cosmetics Act, several guidances as well as enforcement actions can be found here (https://www.fda.gov/drugs/drug-information-consumers/drug-marketing-advertising-and-communications).

I would like to thank the contributors who are helping me make this resource possible. This could not be done without their expertise and initiative.

Help make this resource more helpful to others. If you are an expert in your country's healthcare marketing guidelines and that particular country is not listed below, or information is lacking, then please send me a direct message on LinkedIn (https://www.linkedin.com/in/natbourre/) informing me that you would like to be a contributor to this resource.

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