

G-Regs™

Spain – Royal Decree 1907/1996



Full title: Royal Decree 1907/1996, of 2nd August, on advertising and commercial promotion of products, activities or services with alleged (claimed) health effects (benefits)

Real Decreto 1907/1996, de 2 de agosto, sobre publicidad y promoción comercial de productos, actividades o servicios con pretendida finalidad sanitaria

Article 3 Advertising of medicines and medical devices.

1. Advertising of medicinal products and medical devices are governed by special regulations.
2. In any event, advertising of magistral formulas¹, officinal preparations² and Investigational Medicinal products (IMPs) is prohibited.

Article 4 Prohibitions and Restrictions of advertising with alleged (claimed) health benefits (i.e. health related product advertising)

Save for those cases provided for in Art. 3.1 of this Royal Decree, any type of advertising or promotion, direct or indirect, mass or targeted, for products, materials, substances, energies, methods, with claimed health benefits, is prohibited in the following cases:

- (1) Those directed at preventing, treating or curing communicable diseases, cancer, or other tumoral diseases, insomnia, diabetes, or other metabolic diseases.
- (2) Those which claim to have (indicate) specific weight-loss/ slimming qualities or help fight obesity.
- (3) Those which claim to be of therapeutic use for one or more diseases, and do not comply with the requirements and obligations under the Medicines Act and all other applicable regulations.
- (4) Those which provide assurances of relief or particular healing.
- (5) Those which use as a basis for credibility (form of endorsement) any type of authorisations, approvals, or permits from healthcare authorities in any country.
- (6) Those which make reference to its use or distribution in health centres and pharmacies.
- (7) Those which claim to provide testimonials from healthcare professionals, famous or public figures, real or supposedly real patients, as a means for inducing consumption.
- (8) Those which claim to replace common diet or nutrition regimes, especially in the case of maternity, breastfeeding, infancy or the elderly.

¹ Magistral Formula "is a pharmaceutical compound, prepared by the pharmacist or someone under his direction, for a given patient according to a prescription and following the technical and scientific standards of the pharmaceutical art. The product is sold at the pharmacy to the patient who is given the appropriate information about the product".

² Officinal Preparation: "Is a pharmaceutical compound, developed or prepared by a pharmacist or someone under his direction, which is listed and described by the national formulary, sold at the pharmacy directly to its patients."

URL of source: <https://www.boe.es/buscar/act.php?id=BOE-A-1996-18085>

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- (9) Those which attribute specific or concrete preventative, therapeutic or healing agents to certain forms, presentations or brands of food products for daily consumption.
- (10) Those which attribute preventive or healing agents or other traits to food products intended for special or dietary regimens, which are different from those usually found in such products according to special regulation.
- (11) Those which attribute qualities/ characteristics to cosmetic products different from those accepted for such products in accordance with special regulation.
- (12) Those which suggest or indicate that its use or consumption increases physical, mental, sporting or sexual performance.
- (13) Those which use the term «natural» as a characteristic linked to claimed preventative or therapeutic effects.
- (14) Those which attribute a superfluous nature or claim to substitute the use of legally recognised medicines or healthcare products.
- (15) Those which attribute a superfluous nature or claim to substitute the need to seek advice or care from healthcare professionals.
- (16) Those which claim to have specific preventive or therapeutic effects that are not supported by sufficient technical or scientific evidence, accredited and expressly recognised by the State Healthcare Administration.
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