INFORMATIVE NOTE

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HEALTH-RELATED ADVERTISING LAW

NEW GENERAL PRINCIPLES FOR ADVERTISING MEDICINES AND MEDICAL DEVICES

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In line with this, continuing the trend towards sector-specific advertising law and towards the compartmentalisation of health-related advertising law – which is increasingly subject to new regulations and public duties – the new Decree-Law no. 5/2017 of 6 January has now defined the **general principles for advertising medicines and medical devices:**

- the principle of primacy of the protection of public health and of the rational use of medicines and medical devices;
- the principle of integrity;
- the principle of respect;
- the principle of responsibility;
- the principle of moderation;
- the principle of transparency;
- the principle of cooperation.

II. Each of these *general principles* is justified because its aim is to establish stronger legal protection: transparency in the advertising, sponsorship and promotional activity carried out by the companies that manufacture, distribute or sell medicines or medical devices, and by companies in the area of healthcare technology and information, and associated areas. This legislation is based on the guidelines laid down by the European Commission in its List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector, undoubtedly in order to justify more controversial choices.

III. The legal content of these principles, which very often involves vague concepts ("respecting the integrity of its values", "promoting an atmosphere of mutual respect", "acting with moderation"), raises sensitive technical issues and numerous questions of interpretation. Importantly, there is a duty on the companies that produce, distribute or sell medicines or medical devices to identify, *at the outset*, "who may be influenced or affected by their advertising actions or campaigns and, whenever possible, to communicate their intentions in advance" (principle of responsibility). This is a rule that is uncommon in advertising law and, for example, it goes beyond the principle of objectivity in Decree-Law no. 238/2015, relating to health-related advertising practices.

IV. There is no doubt that the core of this legislation (in article 9) is the sweeping prohibition on establishments, departments and bodies of the National Health Service and the Ministry of Health from receiving, directly or indirectly, any benefit in cash or in-kind, from companies that supply goods and services. These goods and services include medicines, medical devices and other healthcare technology, IT equipment and services, and other associated equipment and services. The legislation also prohibits the National Health Service and the Ministry of Health from carrying out scientific actions in their establishments and departments that are promotional in character, sponsored by companies that manufacture, distribute or sell medicines or medical devices.

These prohibitions generate numerous difficulties in interpretation. For example, the distinction between a merely scientific action and promotional action. This raises doubts as to whether the provisions will have a disproportionate impact on mutual and incentivising cooperation between the National Health Service and the pharmaceutical companies. When it comes to the benefits that do not affect the impartiality and independence of entities, departments and bodies of the NHS, the new legislation does, in fact, allow these benefits to be offered when it can be proved that receiving them does not compromise impartiality and independence. For this, it is necessary to have the authorisation of the member of the Government responsible the area of health. There is apparently no similar exception for scientific actions, except for visits and access by medical information delegates, medical device sales representatives and representatives of medicines and medical device companies.

In the Decree-Law, we also a find a rather special rule in the medicines and medical devices sector, which appears to prohibit institutional advertising and promotion. Clearly conscious of the extensive prohibition in question, article 9(4) of the Decree-Law does, however, exempt "the visits and the system of access of medical information delegates of and medical device sales representatives, as well as other representatives of medicine and medical device companies".

V. Finally, in cases in which benefits are permitted and/or authorised, the entities that receive them must give notice, within 30 days of receipt of the benefit in question, to INFARMED (the Portuguese authority for medicines and healthcare products). The new legislation has introduced a broad concept of benefit, which now includes "any advantage, value, asset or right measurable in money, regardless of how it is given, whether it is a bonus, sponsorship, subsidy, fees, grants or other". This notion does not seem to coincide with the earlier reference to "benefit in cash or in-kind", which is enshrined in legislation for the purposes of prohibiting the receipt of benefits by companies in the industry. The relationship between these two rules will indeed need to be interpreted appropriately.

VI. With equal importance to the restrictions applied by the new Decree-Law are the amendments made to the rules set out in Decree-Law no. 145/2009, which establishes the rules applicable to research, manufacture, sale, entry into service, supervision and advertising of medical devices.

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These amendments mean that sponsorship by companies that manufacture, distribute or sell medicines or medical devices of congresses, symposiums or any scientific or promotional activities or events, must be communicated in advance to INFARMED. The amendments also eliminate the double registration of benefits, which is substituted by validation by INFARMED of the registration of the sponsorship provided by the beneficiaries. As mentioned above, the legal definition of a benefit is any advantage, value, asset or right measurable in money, regardless of how it is given.

VII. This new legislation thus continues the reorganisation of health-related advertising law, which is now broken down into a large number of different pieces of legislation that raise new and complex legal problems.