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Amendments and supplements to Law No. 95/2006 impacting marketing authorization holders and medicine distributors

Government Emergency Ordinance No. 2 of 29 January 2014 for amending and completing Law No. 95/2006 on healthcare reform as well as for amending and completing other enactments (**„GEO No. 2/2014"**) has been published in the Official Gazette, Part I, No. 104 dated 11 February 2014, and regulates several material aspects concerning healthcare institutions, medical assistance, healthcare insurance system, patients' rights, medical devices and medicines.

*Law No. 132/2014 approving Government Emergency Ordinance No. 2/2014 amending and supplementing Law No. 95/2006 on healthcare reform, and amending and supplementing certain legal enactments (**"Law No. 132/2014"**) was published in Official Journal, Part I No. 739 of 10 October 2014.* Several material provisions of Law No. 95/2006, set forth earlier this year by Government Emergency Ordinance No. 2/2014 (**"GEO No. 2/2014"**), have been amended or supplemented. The amendments and supplements refers, *inter alia*, to issues concerning the national healthcare programs, public hospitals financing, components or instruments of the health insurance system, status of physicians, medical devices and last, but not least, medicines.

First, it is worth noting the express regulation of a fair and clarifying rule on the legal status of physicians who, according to the new wording of Art. 375(2) of Law No. 95/2006, are not civil servants and cannot be classified as such, in consideration of the nature of their profession and the physician's fundamental obligations towards the patient.

As to the legal regime of medicines, the most important provisions of Law No. 95/2006, newly inserted or amended by Law No. 132/2014, impacts the marketing authorization holders (**"MAHs"**), and the wholesale medicine distributors and pharmacies, respectively, as follows:

- The definition of the "civil service obligation" and the contents of such obligation were supplemented in terms of certain determinants, in the sense that "the needs of a specific geographical area" shall be drawn up and grounded by the Ministry of Health, while the conditions whereby the MAHs and wholesale medicine distributors meet the civil service obligation shall be regulated by order of the minister of health; furthermore, failure to meet the civil service obligation shall be punished by fine ranging from RON 50,000 to RON 100,000, while the complementary punishment of temporarily suspending the authorization for a period of up to 6 months is removed;
- By order of the minister of health, exceptions from the obligation set forth under GEO No. 2/2014 may be established; according to said ordinance, the MAH/local representative thereof has to secure distribution of their own medicine, reimbursed in the health insurance system, via at least 3 wholesale medicine distributors; also, a sanction for failing to meet said obligation was regulated, consisting of a fine ranging from RON 50,000 to RON 100,000;
- For the first time, an express regulation is given to the interdiction of the persons authorized to release medicine to population (pharmacies) to carry out medicine wholesale distribution activities as well;
- In a predictable development, the legislative authority provided that the sponsorship activities and the expenses borne by the pharmaceutical companies for a number of professionals in the healthcare field shall be declared under the conditions set forth by order of the minister of health;
- The amount of the fine applied to MAH for failing to meet certain obligations related to marketing authorization, submission of certain reports and information to the National Agency for Medicines and Medical Devices, including the actual sale date or the date when the medicine ceases to be placed on the market, or supply to the National Agency for Medicines and Medical Devices or Ministry of Health of the data on the volume of sales and medicine prescriptions, was increased from RON 2,000 - RON 5,000 to RON 10,000 - RON 30,000;
- A fine ranging from RON 5,000 to RON 10,000 was set forth, and shall apply to (i) the wholesale distributor placing a medicine from another Member State on the local market without notifying its intention to MAH and the National Agency for Medicines and Medical Devices, and (ii) the manufacturer/importer/wholesale or retail distributor/MAH, as the case may be, which fails to comply with the provisions concerning the medicine advertising.

Finally, in terms of medical devices, Law No. 132/2014 provides, amongst others, that the National Agency for Medicines and Medical Devices shall be the competent and decision-making authority, while the relevant policy shall be prepared by the Ministry of Health.

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Țuca Zbârcea & Asociații offers multidisciplinary services in relation to all relevant healthcare and pharma issues. The firm's **Pharmaceutical Law Practice Group** comprises lawyers specialising in regulatory matters affecting this industry, as well as in intellectual property, competition, litigation, taxation, advertising, mergers and acquisitions, consumer protection and nowadays, areas such as insolvency, restructuring, employment, work-out.

Țuca Zbârcea & Asociații mainly advises top international players in the pharmaceutical industry on matters of compliance with Romanian/EU legal requirements, as well as in relation to various matters such as pricing policies and reimbursement issues, clawback tax, promotional campaigns and advertising, disputes with the Ministry of Health and National Health Insurance House, public acquisition procedures, reimbursement/share-risk protocols, protecting the legal rights over the innovative medicines, clinical studies, sponsorship agreements or services agreements executed with healthcare providers, etc.

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