

Tax & Legal Alert

ROMANIA 7 July 2008

Emergency Government Ordinance no. 93/2008 amending and supplementing Law no. 95/2006 on healthcare reform

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Emergency Government Ordinance no. 93/2008 amending and supplementing Law no. 95/2006 on healthcare reform ("Ordinance") has been adopted. The Ordinance introduced a series of amendments, the most important being:

- Significant amendments under the Title related to the distribution of medicinal products;
- Monitoring duties for distribution activities were transferred from the Public Health Ministry ("PHM") to the National Medicinal Agency ("NMA");
- The NMA will also implement the good pharmaceutical practice rules provided under the law;
- A new definition of "medicinal products for advanced therapy";
- Following the entry into force of the Ordinance, National Health Programmes ("NHP") are defined as a package of multiannual actions;
- Medicinal products, sanitary materials, medical devices and the like, released through open access pharmacies to patients covered by NHP, designated by Governmental Decision, are refunded at the level of the reimbursement price;
- Medicinal products, sanitary materials, medical devices and the like used in bedded healthcare units, throughout the hospitalisation period, for specific treatment as well as for patients covered by the NHP, designated by Governmental Decision, are acquired by such units against a price not exceeding the reimbursement price approved by order of the health minister under the law;
- The Ordinance provides a new definition of "reimbursement price";
- Pursuant to the Ordinance, pharmacists in hospital pharmacies are authorised to release medicinal products, sanitary materials, medical devices and the like both to hospital departments and to out-patients covered by NHP;
- PHM sets, authorises and approves, by order of the health minister, the maximum prices of medicinal products for human use covered by marketing authorisations in Romania, with the exception of OTC medicinal products;
- The Ordinance introduces the concept of "specialised units", including public and private healthcare units, public institutions, authorised and evaluated suppliers of medical services, medicinal products and medical devices, under contract with the national health insurance houses and other government and non-government institutions and organisations;
- The term "state sanitary inspection" is replaced by "public health control";
- The Ordinance carries new regulations on setting up and operating family medicine practices;
- Under the new regulations, local public authorities may grant incentives for family physicians to settle, set up and run medical practices for family medicine, in accordance with the legal provisions in force;
- A new physician category covered by the regulations on incompatibility and conflict of interests, namely anyone holding positions on steering committees;
- The ordinance regulates the situation of people deriving non-taxable income. The contribution to the social health insurance fund is calculated with reference to the income derived;
- Not submitting the statement on time regarding the liability to pay social health insurance contributions and proof of their payment by people engaged in liberal professions or duly authorised to carry out independent activities qualifies as misdemeanour;
- Failure to abide by good pharmaceutical practice rules qualifies as misdemeanour and is punishable by fines;
- The following qualify as misdemeanours: not observing the marketing authorisation terms and restrictions related to the release and use of medicinal products, as well as those relating to the safe and efficacious use of medicinal products; not reporting adverse reactions and not

submitting periodic safety update reports to the NMA; changes (variations) to the marketing authorisation terms and not notifying the NMA of the effective marketing date or the date when the medicinal products are withdrawn from the market; not submitting data on sales and prescription volumes for medicinal products to PHM or, as appropriate, the NMA, ;

- Failure to comply with the terms under which independent laboratories or laboratories recognised by the NMA were issued authorisations constitutes a misdemeanour and punishable by a fine;
- Failure by importers to comply with their commitment to report to the NMA the precise status of each import pursuant to the legislation in force constitutes a misdemeanour and is punishable by fines;

- The Ordinance prescribes the start of the reorganisation process for privatising the Transports, Construction and Tourism Ministry Health Insurance House within a period of 12 months.

[Source: Official Gazette part I no. 484/30.VI.2008]

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