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Material restrictions and obligations imposed to medicine marketing authorization holders as from February 2014

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.

As regards medicines regime, GEO No. 2/2014 set forth several critical restrictions and obligations primarily incumbent to marketing authorization holders (**"MAHs"**), out of which we outline the following:

- Definition of „public service obligation" has been amended in order to also include the MAH or local representative thereof; so far, the definition regarded medicine wholesale distributors only;
- Terms in which the MAHs must notify the authorities in respect of medicines' withdrawals from the market have been significantly increased, beyond the limits indicated in the European legislation; thus, if a medicine ceases to be placed on the market, either temporarily or permanently, the MAH must notify the National Agency for Medicine and Medical Devices within at least 6 months before interruption in the placing on the market (the minimum term set forth under Directive 2012/26/EU is 2 months only). Likewise, should the said interruption be grounded on "commercial reasons", the term of the notification raises to 12 months;
- Manufacturers, MAHs/local representatives thereof and wholesale/retail distributors of medicines, medical devises or sanitary materials shall have to declare to National Agency

for Medicine and Medical Devices and Ministry of Health all sponsorship activities and expenses borne in relation to doctors, medical nurses, professional organizations, patients' organizations and other healthcare related organizations; the same declarative obligations shall belong to said beneficiaries as well. The templates for declaring the above information shall be approved by an order passed by Minister of Health while the relevant information shall be posted on the websites of notified authorities, sponsors and beneficiaries.

It is noteworthy that, although GEO No. 2/2014 states that most part of its medicines related provisions transpose the Directive 2012/26/UE, there are certain provisions which significantly extend the scope of said directive or, as the case may be, do not directly related thereto (*e.g.*, the directive do not provide any obligations concerning sponsorships in the pharmaceutical market).

The said restrictions and obligations entered into force and currently apply. However, sponsorship related obligations should be further detailed and enforced through secondary legislation.

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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 offers 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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