

26 November 2014

# Legal Bulletin



## Pharmaceutical Law

In this issue:

1. Significant amendments and supplementations to the framework applicable to the clawback tax

### Significant amendments and supplementations to the framework applicable to the clawback tax

---

Government Emergency Ordinance No. 69/2014 on certain financial measures in the health field and for amending certain enactments (“GEO No. 69/2014”) was published in the Official Journal, Part I, No. 807 of 5 November 2014.

The ordinance contains several amendments and, in particular, supplementations to the legal regime of the quarterly contribution (clawback tax) regulated by Government Emergency Ordinance No. 77/2011 on establishing a contribution for funding certain expenses in the health field, as further amended (“GEO No. 77/2011”). More specifically, GEO No. 69/2014 provides for other financial measures applicable in the regional development or research-development fields.

Essentially, the new enactment sets forth two different regimes for levying and determining the clawback tax, one applicable to medicines currently reimbursed by the national social health insurance system, and the other to the new medicines conditionally included in the List of international non-proprietary names corresponding to the medicines out of which the insured persons benefit within the social health insurance system or within national health programs (the “INN List”).

We stress the following amendments concerning the clawback tax applicable to medicines already reimbursed in the public system:

- The value of the quarterly aggregate consumption of medicines (CTt), used in order to determine the “p” percentage, shall be reported to CNAS by the health insurance houses based on the data recorded in the health insurance IT platform; in its turn, the value of the centralized consumption of medicines notified to each taxpayer (taxable base) will be based on the same data recorded in the said platform;

- Taxpayers, i.e. marketing authorization holders (“MAH”), that are Romanian legal entities, as well as the legal representatives of foreign MAHs, shall submit to CNAS, on a quarterly basis, the updated list of medicines for which the clawback tax is due in accordance with a methodology and a template approved by an order of the CNAS President;
- Taxpayers shall determine and calculate the due tax with the exclusion of VAT from the value of the quarterly consumption notified by CNAS (in fact, this is the regulation of the current practice);
- The objections to the consumption values notified by CNAS should only concern the data related to the quarter for which they were communicated.

GEO No. 69/2014 supplements GEO No. 77/2011, by setting forth a separate taxation regime for those medicines which, further to the procedures for assessment of medical technologies, are the subject of a decision for conditional inclusion in the INN List. Briefly, the new rules provide as follows:

- Cost-volume / cost-volume-outcome agreements (“CV Agreements”) may be concluded for the medicines aforementioned, within the limits of the funds obtained by excluding and/or amending the reimbursement percentage of the medicines included in the INN List, as well as by applying certain pharmaceutical policies (elements apparently unknown to potential interested MAHs); failure to execute such agreements shall result in the impossibility to include the relevant medicines in the INN List;
- CV Agreements are qualified as mechanisms for ensuring the financial sustainability and the predictability of costs in the public health system, whereby local MAHs or the local representatives of foreign MAHs undertake to supply the medicines conditionally included on the INN List according to the rules set forth by GEO No. 69/2014, for a certain category of patients and for a certain period;
- The negotiation of CV Agreements may be initiated according to prioritization criteria expressly provided, while the template agreement and the methodology used for negotiating, executing and monitoring the implementation of said agreements shall be determined by means of a joint order passed by the Minister of Health and CNAS President;
- The clawback tax due by taxpayers shall be determined based on the CV Agreements by applying the percentage set forth in the agreement to the value of the quarterly individual consumption communicated by CNAS;
  - The value of the quarterly consumption shall be calculated by multiplying the VAT-free retail sale price/the wholesale price by the volume of medicines quarterly consumed, within the limits of the volumes established by the CV Agreements; and
  - The clawback tax percentage is made up of the value of the «p» percentage related to the quarter preceding the execution of the CV Agreement, calculated

in accordance with the formula set forth by Article 3(2) of GEO No. 77/2011 (the common percentage applicable to the clawback tax due for unconditionally reimbursed medicines), plus 5 to 30 percent, depending on the percentage of patients contractible for each therapy as compared to the number of eligible patients (the percentage being referred to in the relevant CV Agreement);

- If the aggregate medicine volumes consumed exceed the volumes set in the CV Agreements, the taxpayers shall bear the entire value of the medicines consumption related to the excess, exclusive of VAT; the value of such excess shall not be taken into account upon the calculation of the quarterly aggregate consumption of medicines (CTt);
- Within 15 days from the issuance of the decision for conditional inclusion in the INN List, the foreign MAHs should appoint a Romanian legal entity as their legal representative to negotiate and conclude CV Agreements, and to declare and pay the clawback tax, respectively; likewise, within 30 days from the execution of the CV Agreements, local MAHs or the legal representatives of foreign MAHs must fiscally register with the National Agency for Fiscal Administration as taxpayers of the clawback tax.

It is noteworthy that the rules concerning the communication by CNAS of the quarterly data, challenging thereof and the payment terms applicable to the medicines conditionally included on the INN List, although distinctly regulated, are identical/similar to those applicable to the medicines reimbursed without specific restrictions in the social health insurance system, for which the clawback tax determined as per Article 3 of GEO No. 77/2011 is due.

The new enactment also sets forth the obligation of all foreign MAHs that hold medicines within INN List (including the new products) and that have not yet appointed a legal representative, to communicate to CNAS, within 30 days from the date of Government ordinance's entry into force, the identification data of such representative which, within the same deadline, shall have to be also registered for tax purposes.

*[ciprian.dragomir@tuca.ro](mailto:ciprian.dragomir@tuca.ro)*

*[dominic.morega@tuca.ro](mailto:dominic.morega@tuca.ro)*

## Editors

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.



Ciprian Dragomir  
Partner  
+4 021 204 88 98  
ciprian.dragomir@tuca.ro



Dominic Morega  
Managing Associate  
+4 021 204 88 90  
dominic.morega@tuca.ro

### TUCA ZBARCEA ASOCIATII

Șos. Nicolae Titulescu nr. 4-8  
America House, Aripa de Vest, et. 8  
Sector 1, 011141, București, România  
T + 4 021 204 88 90  
F + 4 021 204 88 99  
E office@tuca.ro  
www.tuca.ro

This material is for reference only. It does not seek to provide legal advice, which may be requested according to each specific legal issue and may not be relied upon for any purposes whatsoever. For details and clarifications on any of the topics dealt in this Legal Bulletin, please do not hesitate to contact the attorneys indicated hereinabove.