



OVER-TAXATION OF PHARMACEUTICAL MARKET: LEGAL CHALLENGES IN ROMANIA

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“The art of taxation consists in so plucking the goose as to obtain the largest amount of feathers with the least amount of hissing”

Jean-Baptiste Colbert



INTRODUCTION

Features of medicines' regime in Romania

- // Large formal and informal powers of health authorities
- // Price of Rx-medicines approved by Ministry of Health (“MOH”)
 - // Maximum manufacturer price = minimum price approved in one of 12 comparison countries (Greece, Hungary, etc.);
 - // Maximum margins (wholesale/retail) set forth by law;
 - // Long payment deadlines (more than 210 days until 2014)
 - // Generic reference price - maximum 65% of innovative product's price whilst innovative product price may not exceed the generic reference price with 35%
 - // Reimbursement (reference) price and various other restrictions trigger significant decrease of medicines' acquisition costs paid by public sector
- // Poor access of new and innovative products in public health insurance system
 - // Reimbursed INN List not updated in the last 6 years

Clawback tax history

// Two main periods

- // October 2009 - September 2011: Government Emergency Ordinance No. 104/2009 (“**GEO 104/2009**”) and secondary legislation
- // October 2011 - present: Government Emergency Ordinance No. 77/2011, as further amended (“**GEO 77/2011**”)



GEO 104/2009 AND SECONDARY LEGISLATION - “DARK AGES” OF CLAWBACK TAX REGIME

GEO 104/2009 - Overview

- // Published on 7 October 2009 following no preliminary public consultation / study of impact
- // Introduced a new and special quarterly tax
 - // Aimed at financing “*certain health related expenses*”
 - // Due for medicines (i) included in national health programs; (ii) granted to insured persons in ambulatory care and reimbursed by social health insurance system; and (iii) used in hospital care
- // Specialized category of taxpayers:
 - // Local marketing authorization holders (“MAHs”), which obtain encashments from trade in Romania of relevant medicines
 - // Entities which obtain encashments from trade in Romania of relevant medicines, as a result of trade right directly or indirectly granted by foreign MAHs

GEO 104/2009 - Overview (2)

- // Due tax: progressive percent of 5-11% (as per quarterly sales) x receipts(minus VAT)
- // Payment deadline: 25th day of the month subsequent to the end of relevant quarter
- // Sanctions: lose of reimbursement right/ delay penalties
- // No involvement of tax authorities in tax collection/administration
- // Other details to be regulated in the Application Norms issued by MOH and National Insurance House (“NHIH”) within 15 days as of ordinance’s entering into force

Applications Norms

- ✓ Approved by MOH/NHIH Order No. 928/591/2010 - 25.06.2010 (8 months delay)
- ✓ Definitions:
 - ✓ Volume of sales: quantity of relevant medicines quarterly sold in the public health system towards suppliers of medicines in the ambulatory care (*i.e.*, pharmacies) and the sanitary units with beds (*i.e.*, hospitals)
 - ✓ Aggregate quarter incomes: amount resulted from sale of the entire quantity of relevant medicines, encashed by the taxpayer in a quarter (minus VAT) - taxation basis
- ✓ Taxpayers file with NHIH statements concerning medicines quarterly sold to said suppliers of medicines: 5 days as of the end of a quarter (imposed starting with Q1 2010 onwards)
- ✓ Hospitals file with NHIH statements concerning medicines acquired in the relevant quarter
- ✓ Due tax notified by the NHIH within 15 days as of the date of submitting sales statements
- ✓ Objection to payment notifications filed with same NHIH (3 day-deadline)

Clarifications to Applications Norms

- // Issued by MOH and NHIH on 7 July 2010
- // Not an enactment (debatable legal force)
- // Important provisions which significantly add to the binding legislation
 - // All entities within medicines distribution chain (MAHs, wholesale distributors and pharmacies) to submit quarterly statements on sold medicines and related incomes - all of them seen as taxpayers (Hungarian model)
 - // Quarterly statements to separately provide medicines sold to hospitals, pharmacies and third party distributors
 - // Actual calculation and payment of due tax regard exclusively medicines sold to final users (*i.e.*, pharmacies and hospitals); medicines sold to third distributors not taken into account
- // Ignored by wholesale distributors and pharmacies; finally, by the issuing authorities as well

Amendment to Applications Norms

- // MOH/NHIH Order No. 351/464/2011 - 28 April 2011
- // Taxpayers have to submit to NHIH statements concerning quantity/value of medicines quarterly sold to the ambulatory care and sanitary units with beds, which have been encashed
- // Said statements submitted until the 5th day of the month subsequent to the one when the incomes related to a specific quarter have been entirely encashed (!?)

GEO 104/2009 - Legal issues

- // Major dilemma: **taxpayers for foreign medicines** - MAHs or local wholesalers/others?
 - // Foreign MAHs usually do not sell their medicines on local market
 - // MAH's foreign affiliates which hold the "right to trade" medicines may not actually sell medicines to final users in Romania / register receipts from public funds (Directive 2001/83 - Article 81, Article 77.1 not properly applied)
 - // Foreign MAHs/wholesalers
 - // Not fiscally registered in Romania
 - // Do not hold information on the actual quantities/value of medicines sold to final users/reimbursed by Romanian State from public funds
 - // Local wholesale distributors
 - // Actual entities which sell reimbursable medicines to pharmacies and hospitals / register receipts from such entities (not expressly indicated as taxpayers in law)
 - // Ignored the clawback tax legislation and requirements set forth thereunder

GEO 104/2009 - Legal issues (2)

- // No enactment properly clarified taxpayers' issue
 - // Inconclusive exception: GO No. 17/2012 (Article 6) and GEO No. 53/2012 (Preamble) - MAHs “may” also pay the due clawback tax for Q4 2009 - Q3 2011 period vs. local wholesalers have to pay the tax
- // Taxation basis - quarter receipts from public funds/integrally registered: must be declared by taxpayers/ not known
- // Unpredictable practice of NHIH
 - // Various scenarios embraced by NHIH: taxation of declared quarterly sales, taxation of declared receipts(the only part known by sellers), lack of sanctions, issuance of payment notifications with “estimated” value of due tax
 - // Many litigations lost by NHIH - suspension / cancellation of payment notifications
 - // Clawback tax principles not settled so far by MHIH or tax authorities (which issued various and contradictory opinions
 - // Low collection of clawback tax due for Q4 2009 - Q3 2011 ⇒ unpredictable tax audits / disputes & litigations / insolvency risks - *dormant volcano in the statute of limitation period*

GEO 104/2009 - Legal issues (3)

Legal and constitutional principles adversely impacted

- ✓ **Legality** - all taxes must be regulated by law (Romanian Constitution, Article 139)
- ✓ **Equity / Fair establishment of fiscal burden** (Romanian Constitution, Article 53) - fairness, proportionality, clarity, reasonability
 - ✓ Tax applied to MAHs/wholesale distributors for reimbursed medicines vs collected tax used for various healthcare related expenses (not only medicines) - discrimination / uncompetitive support for other undertakings / “Robin Hood” tax?
 - ✓ Ambiguity of legal provisions: not correctly understood/enforced even by authorities
- ✓ **Security of tax burden** (Tax Code, Article 3 b)) - clear legal provisions, no arbitrary enforcement, taxpayer’s possibility to understand and keep track of tax burden / determine influence of financial management decision over its tax duties
- ✓ Combined with other restrictions applied to reimbursed medicines - potential breach of Article 1 (Protection of property) to First Protocol to European Convention on Human Rights, Article 14 ECHR (Prohibition of discrimination)



GEO 77/2011 - “MIDDLE AGES”

GEO 77/2011 - Overview

- // Published on 26 September 2011
- // More “fiscal” enactment
 - // Tax bodies take over administration and collection of clawback tax
 - // Subrogation in health authorities’ rights set forth in previous legislation
 - // Clawback tax expressly assimilated to a tax duty
- // Applies for same categories of medicines sold after 1 October 2011
- // Repeals former legislation / ultra-activation of former legislation for medicines sold until 1.10.2011 - raised various issues
- // Main elements of the new tax system:
 - // Taxpayers - local MAHs / “legal” representatives of foreign MAHs
 - // New formula - “p” percent x reimbursed consumption of MAH’s medicines quarterly notified by NHIH to each MAH/legal representative thereof
 - // “p” = $(CTt - BA_t) / CTt \times 100$ - same for all MAHs
 - // CTt - aggregate quarterly consumption of medicines reimbursed from public funds; BA_t - budget of reimbursed medicines quarterly approved (fixed amount set forth by law)

GEO 77/2011 - Overview (2)

- // Consumption notified by NHIH and CTt - determined by NHIH as per centralized data and information conveyed by local health insurance houses - based upon the data submitted by final users (pharmacies, hospitals & dialysis centers)
- // Consumption data contain VAT and distributors' margins (VAT removed from Q1 2012 based upon Romania's Constitutional Court's Decision No. 39/5.02.2013)
- // No audit system available / all errors within information circuit projected on taxpayers
- // Taxpayers must automatically take the information notified by NHIH, compute the due tax and declare/pay it to tax bodies
- // Potential objections to NHIH data - 10 days as of the communication date

GEO 77/2011 - Legal and practical issues

- // Scope of the clawback tax: control and limitation of medicines expenditures' growth - not achieved due to the same "p" generally applied to all taxpayers
- // Taxpayers may not verify any centralized information received from NHIH as regards "p" and quarter consumption of reimbursed medicines but must declare and pay the due tax based upon such information
- // **Legal and constitutional principles adversely impacted**
 - // Equity / Fair establishment of fiscal burden (Constitution of Romania, Article 53)
 - // Fairness, proportionality, clarity, reasonability of tax burdens
 - // "p" varied between 16 and 33%, no instruments to verify the tax burden, thirds' incomes included in taxation basis
 - // Security of tax burden (Tax Code, Article 3b))
 - // No connection between taxpayer's incomes (sales) and notified tax burden (determined by NHIH as per its internal criteria)
 - // No possibility of taxpayer to understand and keep track of tax burden / determine influence of financial management decision over its tax duties

GEO 77/2011 - Legal and practical issues (2)

- ✓ Right to effective remedy before court, right to defense
(Romanian Constitution, Articles 24 and 52; EU Charter of Fundamental Rights, Article 47)
 - ✓ NHH practice to refuse providing in/to court relevant data
 - ✓ Taxpayers may not enforce their right to verify accuracy/thoroughness of tax burden's elements → right to redress adversely impacted
- ✓ Legal actions: national courts of law, Constitutional Court; EU Courts?

Conclusions / Q&A

Thank you!

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