Pharmaceuticals

LEGISLATION AND AGENCIES

1. What are the main regulations on medicinal products?

In line with European regulations and practice, the regime of medicinal products in Romania is highly regulated.

Law No. 95/2006 on the healthcare system reform - Title XVIII (Health Law) is the main regulation in this field while detailed substantive provisions are included in secondary legislation issued by the Government or competent public authorities. The main secondary enactments on medicinal products include Minister of Health Order No. 368/2017 on pricing, Government Decision No. 140/2018 approving the services packages and Framework contract regulating the conditions for granting medical assistance within the social health insurance system for 2018-2019 (extended for 2020 – March 2021), and Government Decision No. 720/2008 on the list of INNs corresponding to reimbursed medicinal products.

Essentially, the Romanian legislation in the pharmaceutical area observes the European one, with which it has been properly harmonised during the past 14 years. There are, however, specific requirements set forth by the Romanian regulatory authorities in certain domains, such as reimbursement and pricing of prescription-based medicinal products, clawback tax applied to the marketing authorisation holders or the health technology assessment (HTA). Notably, these special regulations may be subject to unpredictable changes, depending on variations in economic policies and budgetary constraints.

2. Which are the primary government agencies responsible for the enforcement of regulations related to medicinal products?

The Ministry of Health is the public authority that establishes and monitors the implementation of general policies, strategies and regulations in the healthcare system, including the pharmaceutical area. Among other important attributions, the Ministry

of Health approves the prices of prescription-based medicinal products, coordinates the national health programs concerning the treatment of major diseases with specific products and approves the relevant HTA criteria and methodology.

The National Health Insurance House (CNAS) is the public institution that issues secondary legislation within the social health insurance system, monitors allocations made from the National Fund for Social Health Insurance and oversees the release and payment of the reimbursed medicinal products. CNAS also has attributions in establishing the consumption data on reimbursed medicinal products, which are quarterly notified to the marketing authorisation holders in view of determining the amount of clawback tax they owe.

The National Agency for Medicines and Medical Devices of Romania (Agency), subordinated to the Ministry of Health, is the specialised public institution empowered to issue certain regulations concerning authorisation, marketing, manufacturing, import and distribution of medicinal products, to oversee the activities of wholesale distributors, manufacturers or brokers, and to monitor compliance with pharmacovigilance-related requirements. The Agency also authorises and regulates the performance of the clinical trials and endorses the advertising materials used for the promotion of medicinal products.

In 2014, the Agency was empowered to implement the HTA mechanism used for having the medicinal products included in or excluded from the list of medicines reimbursed in the social health insurance system (DCI List), as well as a means of proposing to the Ministry of Health the draft of such list (to be further approved by Government decision).

AUTHORISATION

1. How can a medicinal product be placed on the local market?

According to the Health Law, medicinal products may only be marketed in Romania based on a valid marketing authorisation issued by the Agency or an authorisation issued under the EU centralised procedure. Applicants not headquartered in Romania or in another EU member state may not receive marketing authorisations for the Romanian market.

The Agency issues authorisations for medicines to be marketed in Romania only (the national procedure) or in several EU Member States, including Romania,

simultaneously (the decentralised procedure). Likewise, a valid authorisation for marketing medicines in one or more EU Member States may be recognised for Romania by the Agency (the mutual recognition procedure). Finally, the marketing authorisation may be issued directly by the European Medicines Agency in accordance with Regulation (EC) No. 726/2004 (the centralised procedure).

The marketing authorisation procedure in Romania is generally in line with the one set forth under the European regulations. The marketing authorisation application form to be filed with the Agency is similar to the application form required by the European Medicines Agency in the centralised procedure, while the procedures carried out before the Agency entirely transpose the requirements laid down under Directive 2001/83/EC.

The initial validity period of the marketing authorisation issued by the Agency is of five years. The authorisation may not be denied, suspended or withdrawn for reasons other than the ones set forth in the Health Law. As regards the exclusivity data period set forth under Directive 2001/83/EC, Romania decided to grant a 10-year period of protection.

PRICING

1. Are there any price restrictions to be observed?

The Ministry of Health establishes and approves, by order of the Minister, the maximum prices for prescription-based medicines and reimbursed non-prescription medicines (OTCs) to be marketed in Romania. The pricing of all other OTCs is not subject to specific approval and needs only to be notified to the Ministry of Health.

The legal regime of prescription medicines pricing is set forth in Minister of Health Order No. 368/2017, as further amended and supplemented (Pricing Order). According to it, the order for approval of the manufacturer price proposed by the marketing authorisation holder or its local representative is to be issued by the Ministry of Health within 90 days after the complete application is lodged.

In order to obtain approval, the proposed manufacturer price must be lower or equal at most to the lowest price of the same product available in twelve reference countries provided in the Pricing Order. As an exception, the maximum price of immunological and blood/plasma-based products must be lower or equal at most to the average of the lowest three prices of the same product in the said reference countries). Another special rule, aimed at reducing the allowed manufacturer price threshold for

reimbursed medicines, states that the maximum manufacturer reference price for generic medicines or biosimilar ones cannot exceed 65% (80% in case of biosimilars) of the manufacturer price of the correspondent innovative product.

The prices of the innovative medicines which lose their patent protection after the entry into force of Pricing Order (29 March 2017) must be proposed by their marketing authorisation holders at a level that may not exceed the generic/biosimilar reference price established at the time of the first generic/biosimilar market entry. As for the innovative medicines that have lost their patent before said date and for which generic/biosimilar medicinal products are available at that date, the manufacturer price proposed may not exceed 65%/80% of the approved price of relevant medicine valid at the moment of approval of the first/biosimilar generic medicine price, updated with the official inflation rate until 31 December 2016.

The maximum wholesale and retail (pharmacy) distribution prices of medicines are computed in accordance with a specific formula that takes into account the approved manufacturer price and the maximum wholesale and pharmacy margins, which are also regulated by the Pricing Order.

Once determined, the manufacturer prices as well as the wholesale and pharmacy prices for medicines subject to reimbursement are included in the National Catalogue of Medicine Prices (CANAMED), which is periodically approved by order of the Minister of Health, and may not be exceeded.

The prices thus approved are valid for a maximum one-year period and are subject to an annual correction procedure undertaken by the Ministry of Health.

There is also a National Public Catalogue of Prices, which provides the maximal prices of all medicines authorised in Romania and is approved annually by the Ministry of Health. The level of the prices within said catalogue is set by a more relaxed method (i.e. the maximum price is lower or equal at most to the average of the lowest three prices of the same product available in the said 12 reference countries), however there are no detailed rules on the actual applicability of such prices (they may not be used for medicinal products sold to be reimbursed from public funds).

REIMBURSEMENT

1. How can a medicinal product be reimbursed?

Medicinal products may be reimbursed only if included in the reimbursed DCI

(INN) List, which is approved by Government decision (amending and completing Government Decision No. 720/2008). The DCI List provides for the international non-proprietary name (DCI) of the medicines which are subject to reimbursement by the State in the social health insurance system or within national health programs.

In order to be included in the DCI List, new medicinal products must first be evaluated and endorsed by the Agency in accordance with the HTA criteria and methodology set forth under the Minister of Health Order No. 861/2014, as further amended and supplemented. The HTA rules also apply to the INNs already included in the DCI List, for which an extension of the therapeutic indications is sought.

Depending on the score obtained following the HTA process, the INNs may be unconditionally included on the DCI List, or included based upon a conditional decision, or denied inclusion. A decision for conditional inclusion may be taken should the marketing authorisation holders and the health authorities (i.e. Ministry of Health and CNAS) conclude cost-volume or cost-volume-outcome agreements concerning the medicines in question. The medicines conditionally included on the DCI List and thus reimbursed are subject to a special tax burden (i.e., percentage of the aggregate costs of the consumed medicines, contractually undertaken by marketing authorization holder), higher than the customary clawback tax applied to medicines already on the list.

2. Are there any special coverage and pricing rules applicable to reimbursed products?

The products included on the DCI List are reimbursed by the State in accordance with specific rules highly regulated by secondary legislation. Essentially, medicinal products are reimbursed according to a specific reference price, which is lower or, as an exception, equal to the approved price set out in CANAMED.

The DCI List includes three main sub-lists (A, B and C), with sub-list C including three sections (C1, C2 and C3). The percentage of reimbursement is of 90% for medicines on Sub-list A, 50% for medicines on Sub-list B and 100% for medicines on Sub-list C (sections C1 and C3), and applies to the reference price. Medicines within Section C2 of Sub-list C are covered at the value of the reimbursement price. CNAS and its county branches reimburse the value of the medicines on the DCI List (save for medicines within Sub-list C, section C2) in accordance with the rules set forth in the bi-annual framework contract regarding the conditions for granting medical assistance in the social health insurance system (approved by Government decision) and in the secondary legislation issued by CNAS and/or the Ministry of Health.

With regard to determining the reference price used in the social health insurance system for medicines included on Sub-lists A and B, the secondary legislation issued by CNAS provides for a formula based on a breakdown of the DCIs into therapeutic clusters as per the relevant ATC codes and the defined daily dosage. The reimbursement reference price will be determined at the value of the medicinal product with the lowest price in the relevant cluster. Determining the reference price of medicines included on Sub-list C, sections C1 and C3 takes into account the ATC classification per each DCI, assimilated pharmaceutical form, and strength. The reference price will be computed as per said elements, by applying a specific percentage to the lowest price per therapeutic unit.

For the medicines within section C2 of Sub-list C, which are used in the national health programs, the secondary legislation issued by the Ministry of Health provides that the reimbursement price is determined by a applying a specific percentage (120%) to the lowest retail price per therapeutic unit, per each DCI, assimilated pharmaceutical form and strength.

DISTRIBUTION

1. Is any special authorisation required for medicine wholesalers?

According to the Health Law and secondary legislation issued by the Ministry of Health, a wholesale distributor involved in any activities of sale, purchase, warehousing, handling, transportation, delivery or export of medicinal products must hold a wholesale distribution authorisation. Authorised manufacturers of medicines are deemed authorised as wholesale distributors of the manufactured products.

The wholesale distribution authorisation is issued by the Agency within maximum 90 days as of the date when the applicant files complete and valid documentation, subject to a favourable result of the inspection carried out by the Agency's representatives to the warehouses and headquarters of the applicant. The authorisation is valid for an indefinite period of time and may be revoked by the Agency should the holder fail to comply with the conditions for authorisation or operation requirements. The wholesale distributors must also obtain from the Agency and maintain a good distribution practice certificate.

The applicant should not necessarily be the owner of the warehouse but may not use such an authorised warehouse other than based on a contract concluded with the authorised owner of the warehouse. The secondary legislation permits certain

activities such as handling, transportation or delivery to be contracted from third party wholesalers.

In line with European regulations and practice, Romanian legislation imposes on wholesale distributors a public service obligation to properly and continuously supply the Romanian market with adequate quantities of medicines in order to cover the needs of patients to be covered.

ADVERTISING

1. Which are the forms of advertising and promotion set forth under the local regulations?

Advertising of medicinal products must be performed with strict observance of the rules laid down in the Health Law and the Minister of Health Order No. 194/2015 on the Rules for assessment and approval of advertising of medicinal products (Rules). Under the law, advertising includes any form of information disseminated through direct contact (door-to-door system) and any form of promotion aimed at stimulating prescription, distribution, sale or consumption of medicines.

The Health Law expressly identifies the following forms of advertisement:

- Advertisement of medicines addressed to the wide public;
- Advertisement of medicines addressed to persons qualified to prescribe or distribute them;
- Visits of medical sales representatives to persons qualified to prescribe medicines;
- Supply of medicine samples;
- Stimulation of prescription or distribution of medicines, by offering, promising or granting pecuniary advantages, unless such have a symbolic value;
- Sponsorship of promotional meetings attended by persons qualified to prescribe or distribute medicines;
- Sponsorship of scientific congresses attended by persons qualified to prescribe or distribute medicines, especially by way of paying for travelling and accommodation expenses.

2. Are there any restrictions and prohibitions imposed on advertising activities?

Advertisement addressed to the wide public is allowed only for medicines that may

be used without a prescription from the physician and is forbidden for prescription-only medicines, medicines reimbursed in the health insurance system, and medicines containing psychotropic or narcotic substances.

Advertisements addressed to persons qualified to prescribe or distribute medicines must provide at least the essential information compatible with the summary of product characteristics and its classification for release. The law expressly forbids the advertiser from offering or promising any gifts or any other advantages, pecuniary or in kind, while carrying out advertising activities to persons qualified to prescribe or release medicines, except where such advantages are inexpensive and relevant for medical or pharmaceutical practice.

Hospitality within promotion events is allowed should it be strictly limited to its main scope and be not extended to persons other than healthcare professionals.

The competent authority to oversee the advertising of medicines is the Agency, which endorses the advertising materials and applies sanctions for failure to observe the relevant legal requirements. The Rules apply not only to pharmaceutical companies, their subsidiaries and representation offices, but also to any other partners (agents, agencies, representatives of marketing authorisation holders) contracted in connection with the performance of any form of advertisement for medicines. Pharmaceutical companies are held liable to observe the obligations set forth in the Guide even if they assigned the promotion or advertising activities to specialised third parties.

3. Is there any special disclosure requirement in respect of the interactions with healthcare providers?

On February 2014, the Health Law has been supplemented to regulate special disclosure obligations related to certain interactions between pharmaceutical companies and healthcare providers.

Thus, medicine manufacturers, marketing authorisations holders or local representatives thereof as well as wholesale or retail distributors have to annually declare to the Agency all sponsorship activities and any other expenses borne for physicians, nurses, professional organisations, patient organisations or other organisations within the healthcare field; the same obligation is also incumbent upon the beneficiaries of said sponsorships and expenses.

Once disclosed, the information is posted on the websites of the Agency, sponsors and beneficiaries.

TAXATION

1. Is there any special tax burden related to medicinal products?

In order to control medicine consumption and to ensure financing for increased consumption, the Romanian Government imposed a special tax on marketing authorisation holders, or their local representatives, in connection with medicines subject to reimbursement from public funds. The so-called "clawback tax" was introduced in October 2009 and was subject to several legislative changes due to enforceability and transparency flaws. The clawback tax is still being challenged by the entire pharmaceutical industry demanding a more transparent taxation mechanism.

The current tax, which applies with certain variations starting October 2011, is computed by applying a specific percentage to the value of the quarterly consumption of reimbursed medicines that belong to each marketing authorisation holder. Starting with 2020, said percentage, which was previously variable and determined by CNAS, became fix and differentiated per type of the relevant medicinal products (innovative, generic/biosimilar or locally manufactured ones); medicinal products are classified by a quarterly order issued by the Ministry of Health.

A higher level of tax burden, whose computation formula uses certain elements set forth in the price-volume or price-volume-outcome agreements, applies in respect of the medicines conditionally included in the DCI List.

Based upon the consumption data unilaterally issued and notified by CNAS, the taxpayers must determine the amount of tax owed, declare it to the competent fiscal bodies and pay it by the 25th of the second month following the end of the relevant quarter. The tax is collected by the fiscal bodies under the rules set forth in the Fiscal Procedure Code.

COVID-19

1. What were the major changes brought by the COVID-19 crisis in the field? Will these changes stick?

The state of emergency and subsequent state of alert instituted against the background of the Covid-19 crisis entailed certain exceptional and derogatory measures in the health field, which were regulated through normative acts of an exceptional

nature (decree-laws or military ordinances) as well as through or usual enactments (Government ordinances and decisions or Minister of Health orders).

Among others, the duration of the normative acts on the provision of medical services and medical products within the social insurance system (especially the Framework Contract and the legislation of national health programs) was successively extended; the prescription of "off-label" treatments for patients infected with SARS-CoV-2 virus was allowed (based on the endorsement given by the medicine policy committee within the healthcare unit); the export/distribution abroad of medicinal products and medical devices used to treat COVID-19-associated diseases was suspended for a determined period (6/12 months).

The above measures have an exceptional and temporary nature and derogate from the common legal regime, hence they should cease at the stipulated deadline or at the end of the state of alert, respectively.