Pricing & Reimbursement

2018

First Edition

Contributing Editor:
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global legal group

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Romania

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Abstract

In a society subject to rapid technological developments and globalisation, as well as economic and social evolution, human healthcare is the central, perpetual element that has to benefit from a high level of protection at all times.

In such context, in order to observe the fundamental right of individuals to healthcare, the access to medical treatment and medicinal products should be guaranteed by both European and national laws and practices.

Market Introduction/Overview

As an EU Member State, Romania is constantly adapting the legislative enactments in the field of pricing of medicinal products so as to address the local specifics and demands of the policies and requirements existing at the European Union level.

Being generally aligned with principles set forth under the Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, the legal framework in terms of pricing and reimbursement was repeatedly amended in the last years.

In terms of pricing regulations, two enactments have been adopted in the last two years, regarding the pricing computation, while the enactment regulating the health technology assessment procedure (which is the specific procedure to be used for including, extending the indications, not including or excluding medicinal products from the list of the reimbursed medicinal products) was subject to four amendments since 2014, the last one being enacted early this year.

In an environment in which the challenges of the local pharma industry are relatively the same, most probably the continuing legislative changes are also related to the overall political context of the last years and the changes that took place at the level of the Romanian Government, which through one minister or another tried to address some of the local difficulties or gaps in terms of enactments regulating the pricing of medicinal products.

According to the "*State of Health in the EU – Country Profile 2017-Romania*",[1] "*the health status of Romanians has improved, but life expectancy at birth remains among the lowest in the EU*", while *"per capita health spending of EUR 814 in 2015 is the lowest in the EU, and under a third of the EU average*".

In line with the Press Release of the National Statistics Institute dated 29 August 2017,[2] "*the resident population in January 2017 was of 19,638 thousand decreasing with 122.0 thousand individuals as compared to January 2016*". Furthermore, the National Statistics

Institute states that the main cause of such decrease is the fact that the number of deceased individuals exceeded the number of new-borns, while the demographic ageing process gradually deepened.

Furthermore, the *State of Health in the EU – Country Profile 2017-Romania*"[3] provides that "*cardiovascular diseases and cancer account for the majority of deaths*", "*musculoskeletal conditions and mental health problems are among the leading determinants of poor health*", "*infectious diseases, particularly tuberculosis, present major public health risks […] Romania having the highest rate of tuberculosis in the EU*".

The conclusion of the *State of Health in the EU – Country Profile 2017-Romania*"[4] in terms of access to healthcare is that "*this is especially poor in rural areas and is exacerbated by gaps in population coverage*".

Romania has a deficit of medical personnel, due to the fact that numerous young physicians choose to practice outside Romania, in other EU Member States, primarily due to the low public-sector salaries. Primary care is provided by family medicine physicians and the specialised ambulatory being provided through hospital outpatient departments and polyclinics, specialised medical centres, individual medical practices.

With respect to the market access, this might prove to be challenging for reasons related to pricing computation rules for medicinal products which in certain cases, by the price to be approved in Romania, generates a new minimum at the European level (thus affecting the operations of pharma companies in other jurisdictions as well).

Another potential challenge is related to the post marketing authorisation bureaucracy, especially in terms of reimbursement. This is due to the fact that, on one hand, the Health Technology Assessment is not sufficiently developed so as to be in line with other EU Member States practices, whilst the approval of a price of the medicinal product is not correlated with the reimbursement procedure, hence significant delays in practice.

Pharmaceutical Pricing and Reimbursement

Regulatory classification

Similarly, with the EU legal provisions, the Health Law sets forth the rule pursuant to which no medicinal product may be placed on the market in Romania in lack of a marketing authorisation to be granted by the National Medicines and Medical Devices Agency (the "**NMMDA**") or in lack of an authorisation issued through centralised procedure.

The local legislation differentiates between several categories of medicinal products, *inter alia*: prescription-only medicinal products, over the counter medicinal products, proprietary medicinal products, generic medicinal products, biological medicinal products, biosimilar medicinal products.

From a pricing perspective, the local legislation provides, as a rule, that it is necessary to obtain a price approval from the Ministry of Health (the "**MoH**") in case of:

(i) Prescription-only medicinal products whose marketing authorisation was granted by the NMMDA or those authorised by the European Commission in a centralised procedure;
(ii) medicinal products authorised for special needs; as well as
(iii) over-the-counter medicinal products that are included in the list of reimbursed medicinal products, being borne from state budget sources.

As regards the eligibility of the medicinal products for reimbursement, in case of new molecules (i.e., newly authorised international non-proprietary names ("**INN**")), the criteria considered during the health technology assessment procedure are related to:

(i) a health technology assessment grounded on the therapeutically benefit;
(ii) a health technology assessment grounded on the cost-effectiveness;
(iii) the reimbursement status of the relevant INN in other EU Member States/Positive Assessment Report of NMMDA; as well as
(iv) the cost of therapy.

Who is/Who are the payer(s)?

In Romania, public health assistance is guaranteed by the State and is financed from the State budget, local budgets and National Social Health Insurance Fund; however, co-payment from patients may also be incident in some cases.

In practice, the Social Health Insurance system is administered by the National Health Insurance House (directly or through its local branches), while the Ministry of Health, as the central authority, is competent, *amongst others*, in elaborating and coordinating the national health insurance programmes in view of achieving the objectives of the public health policy.

What is the process for securing reimbursement for a new pharmaceutical product?/How is the reimbursement amount set? What methodology is used?

In order to benefit from reimbursement, the relevant medicinal products should be included in the *List comprising the international non-proprietary names corresponding to medicinal products from which the insured persons benefit with or without personal contribution, based on medical prescription in the health insurance system, as well as the international non-proprietary names corresponding to the medicinal products that are granted under the national health insurance programs, and also on the remedy at law procedure* (the "**Reimbursement List**").

The Reimbursement List is divided, depending on their reimbursement percentage, in several sub-lists, as follows:
(i) the compensation percentage of the medicinal products provided in sub-list A is 90% of the reference price;
(ii) the compensation percentage of the medicinal products provided in sub-list B is 50% of the reference price;
(iii) the compensation percentage of the medicinal products provided in sub-list C is 100% for C1 and C3 subsections; and
(iv) the compensation percentage of the medicinal products provided in sub-list D is 20% of the reference price.

As regards the C2 sub-list, this covers the INNs that are released in national health insurance programmes; in practice, the medicinal products which correspond to the INNs included in subsection C2 of Sub-list C and:
(i) are released to pharmacies and are to be borne at the level of the reimbursement price; and
(ii) are released in hospitals during the confinement period or are released through closed circuit pharmacies for ambulatory care of the patients included in the national health insurance programmes and are to be borne at a price which cannot exceed the reimbursement price.

The inclusion of a new INN in the Reimbursement List is subject to prior evaluation carried out by NMMDA during the health technology assessment procedure. Such evaluation procedure is to be done based on the criteria mentioned under "Regulatory classification","Pharmaceutical Pricing and Reimbursement", (i) to (iv) above.

From a procedural perspective, the applicant submits before NMMDA a standard form application along with relevant documentation (both hard copy and electronic format), which in case of HTA for new INNs includes without limitation:

(i) health technology assessment reports belonging to authorised agencies from France, Germany and Great Britain;
(ii) the necessary data (which is provided in a pre-requisite format) requested for the computation of the therapy costs;
(iii) the summary characteristics of products, as approved by NMMDA or, as the case may be, by the European Commission through centralised procedure;
(iv) compensation status in other EU Member States;
(v) the price approved by the Ministry of Health; and
(vi) a deed ascertaining the intention of the relevant marketing authorisation holder to be engaged in a cost-volume or cost-volume-result mechanism in case the individually computed score corresponds to conditional inclusion on the Reimbursement List.

The decision to include the medicinal product in the Reimbursement List is taken by NMMDA, which, during its assessment, may request opinions and information from the specialised committees of the Ministry of Health, National Health Insurance House and any institutions subordinated to the Ministry of Health.

The decision passed by NMMDA with respect to the inclusion or not of a new INN on the Reimbursement List (which also provides the reimbursement percentage and the inclusion of the relevant INN on one of the available sub-lists) is communicated to the applicant within seven working days as of the date the decision was adopted.

In case the applicant disagrees with the abovementioned decision, it is entitled to challenge such in a term of seven working days to be computed as of the date the decision was communicated, by lodging a preliminary complaint before NMMDA.

The complaint is assessed by a commission which includes representatives of the Ministry of Health representatives of NMMDA and of the National Health Insurance House representatives. The marketing authorisation holder or its representative are summoned to attend the meeting when the commission assesses the complaint.

Both the decision of the commission and the minutes of the meeting are to be communicated to the complainant within a seven working days term as of the date the meeting took place, being also published on the website of the NMMDA. In case the marketing authorisation holder does not agree with the final decision of the commission, it is entitled to defer such to the competent court of law.

In practice, challenging the decisions/reports of NMMDA regarding the results of the HTA assessment does not necessarily have a positive impact due to the fact that:

(i) the legal deadlines are not always observed; and
(ii) the marketing authorisation holders choose, mostly due to business grounds, to challenge only before NMMDA, without further pursuing their cause before the courts of law (as this might be time consuming and might prove to be ineffective due to the fact that, in certain cases, the legislation allows the applicant to resubmit the relevant documentation for HTA assessment).

How are drug prices set? What is the relationship between pricing and reimbursement?

Due to the fact that, in some cases, Romania applies as a benchmark, with respect to the medicinal products that are borne from budgetary sources, the reference to minimum prices of the relevant medicinal products from 12 other EU Member States (which are set forth

by the applicable legislation), in practice, a major problem over the years was the fact that such computation method determined that the approved price in Romania represented the minimum price at the EU level, thus significantly affecting the operations of pharma players in other jurisdictions as well.

As a consequence, in Romania, there are currently two price catalogues: (i) the National Catalogue of medicinal products authorised to be placed on the market in Romania, so-called "*CANAMED*" (the "**CANAMED**"); and (ii) the Public National Prices Catalogue (the "**Public Catalogue**").

CANAMED comprises the maximum prices of medicinal products of human use valid in Romania that may be used/traded by the marketing authorisation holders or their representatives, by wholesale distributors and by suppliers of medicinal products and medical services for those medicinal products that are subject to a contractual relationship with the Ministry of Health, the health insurance houses and/or the county public health departments or the Bucharest public health department.

On the other hand, the Public Catalogue comprises the maximum prices of medicinal products of human use valid in Romania that may be used/traded solely by the community pharmacies/local distribution units/closed circuit pharmacies and medicines that are not in a contractual relationship with the Ministry of Health, the health insurance houses and/or the county public health departments or the Bucharest public health department.

As regards the computation methods for determining the price of the medicinal products for human use, in principle, the following rules are incident:

(i) The manufacturer price proposed for CANAMED has to be lower or at most equal to the lowest price of the same medicinal product from the list of countries[5] that are considered for the comparison.
By way of exception to the abovementioned rule, in case of immunological medicinal products and in case of medicinal products derived from human blood or plasma, the price proposed by the marketing authorisation holder or its local representative has to be equal to the arithmetic mean of the lowest three prices of the same medicinal product from the list of countries[6] that are considered for the comparison.

(ii) The manufacturer price approved in the Public Catalogue is equal to the arithmetic mean of the lowest three prices of the same medicinal product from the list of countries[7] that are considered for the comparison; the Ministry of Health posts in a transparent way on the website of MoH only the prices which are approved in the Public Catalogue.

The secondary legislation also provides specific rules for computing: (i) the innovative/proprietary reference price; (ii) the generic reference price; and (iii) the biosimilar reference price.

However, for the prices included in the Public Catalogue, no innovative/proprietary reference prices, generic reference prices or biosimilar reference prices are approved. Also, the manufacturer's price for innovative drugs/proprietary medicinal products has to be proposed by reference to the innovative/proprietary reference prices, generic reference prices or biosimilar reference prices only after the expiry of the relevant patent.

As a rule, prices of medicinal products (both prices included in CANAMED and those included in the Public Catalogue) are subject to:

(i) an annual update (by applying the medium exchange rate RON/EUR of the Romanian National Bank corresponding to the first quarter of the year in which the update is done); and

(ii) an annual correction (*i.e.,* the annual re-computation of the maximum prices approved in

CANAMED and in the Public Catalogue by reassessing the initial approval conditions according to the applicable legislation, which might lead to maintaining, diminishing or, as the case may be, increasing the approved price); by derogation to the above, the annual correction is not applicable with respect to the medicinal products authorised for special needs.

For 2018, the applicable legislation sets forth that the documentation for the approval of the price for the annual correction has to be submitted by the marketing authorisation holder/its representative starting on 30 April 2018 until 31 May 2018.

Issues that affect pricing

- Parallel export

One of the most important issues affecting prices of medicinal products and the local pharma market in Romania is the parallel export.

In line with the abovementioned, due to the computation mechanisms provided by the applicable legislation, in many cases, Romania may have one of the lowest prices in the European Union. In practice, this allows the distributors to trade medicinal products in other Member States, thus affecting the demand/need of the local market.

However, since the jurisprudence of the European Court of Justice confirmed that medicinal products are not exempted from the rules of the common market and condemned countries that have resisted parallel exports without a just cause, in practice, there were many cases over the years when the parallel export led to the absence of medicines on the market.

In the past, in order to try to prevent the absence of medicinal products on the Romanian market, an enactment was passed with a view to prohibiting, as a temporary measure, the parallel export of several medicinal products. On grounds that the inclusion of one molecule or another in such list was done in lack of a specific transparent procedure and objective criteria, as well as for competition reasons, this enactment was abolished.

As an alternative measure aiming at preventing parallel export, as of March 2017, the secondary legislation set forth several rules regarding the "*obligation to ensure adequate and continuous stocks of medicinal products*". Based on this enactment:

(i) The marketing authorisation holders shall permanently guarantee the observance of the public service obligation by ensuring a minimum monthly level equal to the monthly average turnover[8] for every medicinal product of the Reimbursement List for which they hold a marketing authorisation.

(ii) The wholesale distributors shall permanently ensure the observance of the public service obligation by providing assuring stocks equal to the monthly average turnover, for every distributed medicinal product of the Reimbursement List.

(iii) A new concept of "*Temporary List of medicinal products under surveillance*" is included, representing a list of all commercial names related to a medicinal product referred to by INN, pharmaceutic form and concentration, which is temporarily forbidden for intracommunity delivery and export.

(iv) Wholesalers have the obligation to notify the received justified order to MAH or any other wholesalers with whom they are in contractual relationships, from whom they have traded the respective medicinal product subject to the justified order.

(v) In case wholesalers cannot deliver the received justified order, they will provide/request MAH or any other wholesalers with whom they are in contractual relationships to deliver the justified order.

In this case, MAH or, as the case might be, wholesalers with whom they are in contractual relationships with, have the obligation to deliver the received justified

order or to communicate to the relevant applicants the fact that an exceptional situation[9] notified to the NMMDA is incidental.

(vi) In case of Exceptional Situations the MAH, the wholesalers and the beneficiaries are no longer required to comply with the public service obligation.

(vii) Within a maximum of three days as of the incidence of a national alert level, the Ministry of Health will include the category of medicines having same INN, pharmaceutic form and concentration under the Temporary List.

(viii) If a medicinal product is under Exceptional Situations, the Ministry of Health will remove such from the Temporary List, respectively, and will remove the relevant category of medicines having the same INN, pharmaceutic form and concentration.

(ix) The MAH has the obligation to notify the National Health Insurance House on the exhaustion date of the stocks of a medicinal product subject to Exceptional Situations with respect to such exhaustion of the relevant stocks.

(x) If NMMDA deems that the reason of the national alert level is not subject to the Exceptional Situations, the category of medicinal products having the same INN, pharmaceutic form and concertation will continue to be provided under the Temporary List until the reinstating and maintenance of the stock on national level exceeding the monthly average turnover for 14 consecutive days as of the providing date of such category under this Temporary List.

(xi) Ten days before intracommunity delivery, including transactions between two or more representative offices of the same company, from different countries, MAH, wholesaler or pharmacies have the obligation to notify NMMDA in this respect via the template affidavit, i.e., the observance of the public service obligation.

(xii) "*The monthly average turnover*" represents the average of the monthly turnover of a particular medicinal product for the last three months, representing the necessary minimum for reaching the public healthcare needs.

- Counterfeit medicinal products

Counterfeit products come to the Romanian market either through unauthorised vendors or through illegal distributors in the regular distribution chain, thus triggering economic consequences.

In order to reduce such risks, in line with the EU principles, the local legislation provides the obligations for wholesalers as well as for brokers to comply with good distribution practice guidelines which impose the obligation to have, at the end of the distribution chain, only licensed pharmacies and approved retailers that are duly entitled to sell medicinal products.

Additionally, since the online trade of medicinal products is not highly regulated (thus being an alternative to the traditional wholesale distribution system to place counterfeit medicinal products on the market), *de lege ferenda*, amendments to the existing legislation should be adopted so as to address this matter.

Policy Issues That Affect Pricing and Reimbursement

In Romania, in 2009, the so-called "*clawback tax/contribution*" was initially implemented, which was subject to significant changes in 2011 and constantly amended thereafter. The clawback contribution is one of the most non-predicable taxes imposed in the local pharma system generating numerous case files before the competent courts of law.

Pursuant to the applicable legislation, the clawback contribution is to be paid quarterly by the Romanian marketing authorisation holders or the legal representatives of the foreign

marketing authorisation holders (not to distributors or to pharmacies) for the medicinal products included in the national health programmes, for medicinal products with or without personal contribution, used in ambulatory care based on medical prescription, through open circuit pharmacies, for the medicinal products used in hospital treatment, as well as for the medicinal products and medical services granted in the dialysis centres, borne from the National Insurance Fund and from the budget of the Ministry of Health.

In other words, the marketing authorisation holders or their legal representatives have to return to the State budget a part of the profit generated from the sales of reimbursed medicinal products borne from budgetary sources.

In case the payers do not observe the obligation to pay the clawback, the medicinal products for which the contribution is due are excluded from the Reimbursement List.

Although numerous discussions took place over the years with respect to potential changes to the clawback contribution, it appears that the amendment which is constantly promoted is the necessity to implement a differentiated clawback contribution, for generic and for out-of-patent medicinal products, as compared to new products, which are more expensive and involve a greater budgetary effort.

Emerging Trends

The challenge when doing business in Romania in the pharma industry is related to the constantly changing legal framework which, due to unpredictability and sometimes lack of transparency, impedes the pharma players to make long term business plans.

The local Competition Council proposed, over time, several legal amendments which might prove to be recommendable competition-wise, such as:

(i) in order to make the use of budget funds more efficient, the consumption of generic medicinal products is encouraged, which may imply the adoption of legislative measures to facilitate the market entry of the generic products by including them on the Reimbursement List as soon as the patent of innovative medicines has expired;

(ii) modifying the clawback tax calculation method, so that the computation method would be different for innovative drugs (the more expensive ones involving a larger budget effort), as compared to generic ones. This measure could encourage the use of cheap medicinal products and also keep them on the market; and

(iii) imposing a price reduction on innovative medicines after patent expiration in order to have the same price with the generic medicines.

Successful Market Access

Given the constantly changing legal framework, the successful entry on the market should be based on: (i) sound assessment of the legal environment in order to determine the restrictions, risks and available options; (ii) reasonable expectations related to the price approval and the inclusion of the relevant INN on the Reimbursement List tailored to the local market and doubled by identifying legal alternatives that allow the access of patients to the relevant INNs even though not included in the Reimbursement List; and (iii) relatively flexible pricing policy at the level of the pharma player and adaptability to the local specifics of the pharma market.

* * *

Endnotes

1. https://ec.europa.eu/health/state/country_profiles_en.
2. http://www.insse.ro/cms/sites/default/files/com_presa/com_pdf/poprez_ian2017r.pdf.
3. https://ec.europa.eu/health/state/country_profiles_en.
4. https://ec.europa.eu/health/state/country_profiles_en.
5. According to the applicable legal provisions the relevant countries are: Austria; Belgium; Bulgaria; Czech Republic; Germany; Greece; Hungary; Italy; Lithuania; Poland; Slovakia; and Spain. Annually, the Ministry of Health is legally entitled to modify the list of countries taken into account for comparison purposes. In practice, such amendments were not adopted by MoH so far.
6. According to the applicable legal provisions the relevant countries are: Austria; Belgium; Bulgaria; Czech Republic; Germany; Greece; Hungary; Italy; Lithuania; Poland; Slovakia; and Spain.
7. According to the applicable legal provisions the relevant countries are: Austria; Belgium; Bulgaria; Czech Republic; Germany; Greece; Hungary; Italy; Lithuania; Poland; Slovakia; and Spain.
8. Pursuant to the secondary legislation "*the monthly average turnover*" represents the average of the monthly turnover of a particular medicinal product for the last three months, representing the necessary minimum for reaching the public healthcare needs.
9. As per the incident legal provisions, "*exceptional situation*" refers to the case when MAH informs NMMDA, under the conditions set forth by the applicable legislation, with respect to quality/safety issues, the impossibility to deliver active substances, the withdrawal of conformity Certificate issued by European Pharmacopeia or of Certificate of good manufacturing practices, the temporary discontinuity of manufacturing ("**Exceptional Situations**").

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