Romania
Health Sector Reform – Improving Health System Quality and Efficiency Project

Terms of Reference
Assistance to outline and implement a pricing and reimbursement system for all pharmaceutical products with clear governance, process and accountability rules

A. CONTEXT

Romania has received a loan from the International Bank for Reconstruction and Development (IBRD) to support the implementation of the Health Sector Reform. The Ministry of Health (MoH) through the Project Management Unit (PMU) is implementing the Health Sector Reform - Improving Health System Quality and Efficiency Project ("Project"), Project no. 8362 – RO, approved on March 28th, 2014, ratified by Law no. 179 on December 16, 2014, with subsequent amendments. The project amount is EUR 250.00 million and the closing date is December 31st, 2024. The objective of the Project is to contribute to improving access to and quality of selected public health services.

The Project supports comprehensive reforms in the Health Sector on medium and long term, focusing on four main areas/components:

- Component 1: Strengthening Health Service Delivery;
- Component 2: Public Health Sector Governance and Stewardship Improvement;
- Component 3: Project Management, Monitoring and Evaluation;
- Component 4: Strengthening of Public Health Emergency Response to COVID -19.

Component 2 of the Project aims to support the improvement of the sector governance and stewardship of the MoH and other relevant governmental institutions to bridge the gap between policy and practice and to strengthen the capacity of improving the quality of health services through the provision of goods, non-consulting services, consultants' services and training, through the following activities:

(a) adapting evidence-based standards and protocols;
(b) strengthening and supporting the implementation of health technology assessments;
(c) strengthening the capacity of the health sector to conduct surveys and studies, and providing advice in formulating evidence-based health policies;
(d) supporting selected national health programs to shift focus towards preventive care and promotion of health services among the Borrower's population;
(e) strengthening the communication strategy of the MoH to inform the general public on the reform program and expected outcomes.

B. BACKGROUND

The Romanian current pricing system for pharmaceutical products[1] was established in 2009, fully implemented in 2015, subsequently being frequently assessed for technical issues

Romania has chosen to employ the External Reference Price method, in which medicines prices are benchmarked against 12 EU member states and the lowest price is chosen.

Furthermore, prices of generic medicines and of medicines no longer subject to patent protection (originals) are capped by the Generic Reference Price which represents 65% of the price of the originator product.

[1] For the scope of ToRs, "pharmaceutical products" are equivalent to "medicines".

Selling prices calculated according to the above-mentioned methodology apply to all prescription medicines, regardless of reimbursement status. In the case of reimbursed medicines, selling prices apply to both unconditionally and conditionally reimbursed medicines. Medicines that receive an unconditional decision after the HTA process are included on one of the four reimbursement lists, depending on the percentage that the state funds. For pharmaceutical products that are not fully reimbursed by the state, the methodology implies a quartile system applied on groups of medicines at ATC3-5 level (*Please, see Annex A to the Terms of Reference).*

To mitigate the budgetary impact of medicines reimbursement against the background of increasing consumption, a clawback tax was introduced in 2011. The clawback tax applies to all medicines funded from the National Health Insurance Fund and from the budget of the Ministry of Health.

During Q4/2011 - Q4/2019 the clawback tax was calculated by applying a "p" percentage on the value of the consumption of medicines supported from the National Health Insurance Fund and from the budget of the Ministry of Health. The mechanism secured a neutral impact on the public budget and transferred the cost of incremental consumption on market authorization holders (MAHs). In 2020, the mechanism was changed, as follows:
For Q1/ 2020 the "p" percentage was capped to the value calculated for the fourth quarter of 2019, and starting with Q2/2020 the quarterly contribution was flattened and differentiated for type I, II and III medicines, as follows:
- For "type I medicines" = considered innovative medicines and for which in the last month of each quarter there isn't at least one generic medicine or biosimilar with price introduced in the Internal Reference Pricing List of the NHIH, the quarterly contribution is calculated by applying 25% on the value of reimbursed consumption,
- For "type II medicines" = medicines produced on a manufacturing line in Romania, the quarterly contribution is calculated by applying 15% on the value of reimbursed consumption,
- For "type III medicines" = medicines that do not fall within the above definitions, the quarterly contribution is calculated by applying 20% on the value of reimbursed consumption.
In addition to the regular (unconditional) reimbursement mechanism, cost-volume and cost-volume-result contracts (i.e. managed entry agreements) are implemented for medicines that receive a conditional reimbursement decision after the HTA process. They entail a quarterly payback tax that is calculated based on the intake of patients (for cost-volume contracts) or is negotiated between the National Health Insurance House (NHIH) and the MAHs.

Furthermore, a mechanism aimed at securing continuous and sufficient supply of medicines all across Romania - called "obligation of public service" for MAHs, wholesalers and pharmacies – was provided by Law no. 95/2006 on health reform. The conditions for fulfilling the obligation of public service were established in 2017 by order of the minister of health. However, the mechanism is poorly implemented and is not achieving its' purpose, namely to ensure sufficient supply of medicines for the Romanian patients. Currently, the instruments and processes are under revision as they represent a significant tool in securing the needed treatment for the Romanian patients.

Key issues with the current reimbursement mechanisms: complexity, lack of certainty and predictability of legislative provisions regarding medicines, medicines shortages, high levels of parallel export, significant and increasing budgetary pressure on the National Health Insurance Fund and the Ministry of Health.

C. SCOPE OF WORK

The purpose of the consultancy services is to support the Ministry of Health (MoH) and the National Health Insurance House (NHIH) in their institutional capacity to develop and implement health sector

governance and stewardship improvement activities within the Public Policy and Strategy Evidence-Based approach.

The technical assistance is required to:

- provide the MoH and NHIH with policy analysis and in-depth strategy advice on key decisions in pharmaceutical policies, pricing and reimbursement decisions;
- translate research into policy advice and structure new policy proposal for the Romanian context;
- facilitate policy proposal implementation in the legislative framework and at technical level;
- communicate with all stakeholders throughout the project and participate at round tables and press conference on the new policy proposal.

The Consultant will support the strengthening of institutional capabilities for the adequate stewardship, promoting the development and establishment of standards for the Public Policy and Strategy mechanism.

The task includes assisting Ministry of Health and National Health Insurance House specialists in defining suitable models' policies to employ, selecting components that are appropriate for Romanian needs, and assisting authorities during conversations with key technical stakeholders (national public health institutions, industry representatives, patient associations representatives).

The Consultant will: 1) analyse the current pricing and reimbursement structure; 2) attend working group meetings on pricing and reimbursement; 3) draft a policy proposal on pricing and reimbursement to be implemented in Romania based on lessons learned and examples of good practice from other countries; 4) assist with drafting new legislation based on the proposed policy; 5) participate in meetings with technical representatives of MoH and NHIH to ensure proper implementation of the proposed policy, and 6) support the beneficiary in communications with all concerned stakeholders throughout the entire process, including participating at round tables and press conferences.

OBJECTIVE OF THE ASSIGNMENTS

The key objectives of the project are:

- To propose a new policy for the pricing and reimbursement system for medicines, accepted by the public institutions and main stakeholders involved, including political partners, which will improve transparency, predictability, effectiveness and budget sustainability; coordination with the technical assistance on HTA will be secured throughout the process of drafting the policy proposal;
- To assess the supply of medicines and formulate proposals to improve the mechanism of "obligation of public service" for the actors involved (MAHs, wholesalers, pharmacies, etc.);
- To implement a more efficient mechanism to update prices of medicines (catalogue prices and internal reference prices);
- To ensure efficient, predictable and sustainable public spending on medicines and implement mechanisms for budget control for medicines that also reduce the pressure on out-off-pocket expenditures.

D. MAIN TASKS

Output 1/ Task 1 – *Analyse the current pricing and reimbursement structure*

In 2016, technical assistance was commissioned for the Romania Health Sector Reform Project in order to support the Ministry of Health's capacity to develop and implement health sector governance and stewardship improvement activities within the Public Policy and Strategy Evidence – Based approach. The technical assistance provided the Ministry of Health with policy analysis and in-depth strategy advice on key decisions (evidence-based policy mechanism, financing pharmaceutical policies and drug reimbursement decisions, health care financing policies), translate research into policy advice.

The specific tasks of interest for the present technical assistance are linked to pharmaceutical policies and drug reimbursement decisions and regulations, comparison of the results obtained through centralised vs decentralised pharmaceutical tendering and specific policy recommendations.

The most relevant aspects to be considered in analysing the current pricing and reimbursement system are the following:

- Romania has an **external reference price system** used to set prices for pharmaceuticals since 2009. Reviewing all approved prices has been done since 2015. The system is aiming to set the lowest prices in Romania and to use the best mix of countries as reference. However, the current system is very complex, not adequately digitalized, making yearly price revisions difficult. There are also some **ambiguous legal provisions which creates unnecessarily tensions between authorities and MAHs**. The key achievements (ex: level of prices) of the current system should be assessed and potentially preserved;
- **The prices set by MoH represent the basis for generating the internal reference prices used for reimbursement**. The reimbursement system is categorized based on a decision from the National Medicines Agency and Medical Devices (NAMMD). Reviewing the entire system and finding new mechanisms for reimbursing medicines should be done by taking into account new developments in research**,** patient needs, and available funds;
- Also, recently, a legislative provision was introduced to allow the NHIH to sign protocols with MAHs in order to co-finance patients' treatment, but few such protocols[2] have been signed to date (two protocols signed and some under discussions). Existing protocols are related to "free goods" (e.g. the initial treatment dose free of charge or a certain number of doses free of charge or diagnostic tests free of charge). There is a significant need to diversify into other mechanisms that improve public spending on medicines.

The Consultant should have a comprehensive and detailed view of how the current legislation is implemented, how the processes are interconnected and their consistency with the legislative framework. Also, it should look to what extent the current systems respond to the needs, what are the strengths weaknesses/vulnerabilities. The Consultant should perform extensive data analysis, relate pricing decisions with shortages, withdrawals, stocks, parallel trade, reimbursement decisions with drug expenditure dynamic for NHIF, the dynamic of payables and overdue payments for NHIF etc, aiming at making the system financially sustainable.

Output 2/ Task 2 – *Attend working groups meetings on pricing and reimbursement and support the discussions with key technical stakeholders*

A formal working group on price reform has been set up, including representatives of relevant authorities such as the Ministry of Health, the National Health Insurance House and the National Medicines Agency, as well as representatives of the industry (associations of innovative and generic manufacturers, association of wholesalers, associations of chain/independent pharmacies).

[2] These protocols can be considered an equivalent of MEAs such as free doses, dose/time cap

The role of this group is to identify potential new pricing models, to simulate the expected outcomes and impacts regarding the level of prices, impact on reimbursement costs, impact on co-payments etc. and finally to select the models that would be most suitable to Romania.

At an informal level, ad-hoc working groups between representatives of health authorities on reimbursement policies have been established over time on specific topics, in order to find appropriate solutions. Working groups or meetings can be arranged at any time with representatives of health authorities.

The Consultant **should participate actively in the formal or informal working groups with** representatives of health authorities and other relevant stakeholders in the system, in order to better understand the issues related to the current mechanisms in place.

The Consultant should:

- have an introductory meeting with the working group to learn the views of its' members with regard to the current system and ideas on how to move forward;
- present the analytical part of the project and discuss the findings;
- present and discuss the policy proposal once it is ready;
- present the final version of the policy proposal including inputs received.

Output 3/ Task 3 – ***Draft a policy proposal to be implemented in Romania based on lessons learned and examples of good practice from other states***

Using the content of Output 1, building on strengths and revisiting weaknesses, and considering the inputs from the interviews with the people involved in pharmaceutical processes, the Consultant should draft a policy proposal to be implemented in Romania. The policy proposal should be based on the social and economic context in the country, as well as on Romania's health profile. The Consultant should also take into consideration examples of good practice from other countries with pricing or financing systems similar with the one in Romania or with a similar social/ health/ economic profile.

An important aspect that should be in the Consultant's focus is the impact of any proposal on public expenditure with reimbursed medicines and the out-of-pocket payments. The Consultant shall seek that all proposals safeguard budget sustainability.

The detailed policy proposal will include specific guidance and mechanisms of implementation, institutions involved, processes and activities, required institutional, human, IT and budget resources, and a detailed timeline. All the components of the pricing & reimbursement system should be included in the policy proposal: price setting, public service duties (stocks, shortage and parallel trade reporting, IT system), internal reference pricing, managed entry agreements (cost-volume/ results contracts, discount agreements, free goods agreements), clawback tax, centralized procurement, revenue generation for NHIH in relation to reimbursed medicines (data sales etc.).

Output 4/ Task 4 – ***Assist with drafting of new legislation based on the draft policy proposal***

The policy proposal drafted by the Consultant will be presented to the representatives of MoH, NHIH, NAMMD and technical stakeholders (industry, patient associations and provider associations - pharmacies, family physicians, etc.) for analysis and feed-back. The final version will be submitted to the MoH and NHIH.

To ensure a correct understanding of the recommendations in the new policy, the Consultant will organize meetings with the technical representatives of the MoH, and NHIH and NAMMD directly involved in the processes. The meetings may also refer to how the policy was built and what aspects were considered in the design (including strengths and weaknesses of the current system, as well as

examples of good practice from other countries).

Once all aspects of the policy proposal are aligned with the beneficiaries, the Consultant will draft specific regulatory proposals for amending current legislation or developing new legislation to be approved by the Government or the competent health authorities. The regulatory proposals will reflect the content of the policy proposal, will be written in technical language (according to Law no 24/2000 on the standards for legislation drafting) and will be substantiated according to existing regulatory requirements (G.D. no 1361/2006 on the substantiating documents for draft regulations to be approved by the Government).

Output 5/ Task 5 – ***Assist the representatives of MoH and NHIH on technical matters during the legislative proposal circuit to ensure the approval of the policy proposal***

The objectives are to provide on-demand detailed information on the draft regulations, to offer a clear image of the principles and mechanisms implemented, to address any misunderstandings or problems that may arise, to describe the implementation processes and requirements and to present specific examples. Due to the experience with the lengthy legislative proposals circuit, the Consultant will need to be available for clarifying technical matters throughout the process that will take approx. 6 months due to the public consultation according to the national legislation.

Output 6/ Task 6 – ***Assist with communicating with all concerned stakeholders throughout the entire process***

The Consultant will offer support and assistance throughout the project in communicating with concerned stakeholders involved and addressing sensitive issues, based upon an Action Plan submitted within the inception report.

At least two round tables will be organized, at which the Consultant will play an essential role: the first-round table will focus on the draft policy proposal, discussions with the MoH and NHIH; the second one will present the draft regulations and processes required for the enactment of the policy proposal. The objectives of the round tables are to inform and receive feed-back and support from all relevant stakeholders regarding the policy proposal, the related draft regulations, the approval and implementation processes.

At least one press conference shall take place, announcing the new proposal and provisions.

A kick-off round table will be organized around the project start with the aim to properly informing all concerned stakeholders upon the scope of the project.

The first-round table shall be organized during the fifth month of the project implementation period.

The second-round table shall be organized during the eight months of the project implementation period.

The press conference shall be organized at least 14 days before the end of the project.

Milestones shall be set in the project for communicating publicly the progress, e.g. by publishing materials on the MoH and NHIH websites, social media, briefings with journalists, briefing documents for the official communication etc.

**depending on the epidemiological situation at the time of the activities, the need of physical presence will be assessed.*

E. EXPECTED REPORTING REQUIREMENTS AND DELIVERABLES

The Consultant shall submit reports to the Minister of health/ State secretary, the Head of Project Management Unit (PMU), the Head of Pharmaceutical Policy Department within the Ministry of Health, to the President of the National Health Insurance House and to the Chief Physician within the National Health Insurance House and to the President of the National Agency for Medicines and Medical Devices.

The Consultant shall deliver inception, progress and final reports to be approved by the Ministry of Health and the National Health Insurance House in order to meet objectives set forth, as follows:

- The inception report will be submitted within 2 months from the start date of services. This report will include an analysis of the recommendations from prior technical assistance reports related to the task no. 1 mentioned in the section D "Main Tasks". Also, the inception report will include a short strategy regarding the communication process with stakeholders involved with due attention to sensitive topics and will include an Action Plan;
- progress report no. 2 will be submitted at the beginning of the 5th month from the start date of services. The progress report no. 2 will include description of the current pricing system, including all instruments used for prices management for originators, off-patent originators and generics, digitalization of the processes, analysis of the vulnerabilities and impact on the availability of medicines on the market and a description of the current reimbursement mechanism, issues involved, including the calculation method, the reimbursement lists components, the cost-volume and cost-volume-result contracts and other instruments in place used in controlling the public expenditure. This analysis will include a set of conclusions of the extensive data analysis, related to pricing decisions with shortages, withdrawals, stocks, parallel trade; reimbursement decisions with drug expenditure. Also, the progress report no. 2 will include follow up outcomes of the meetings and a complete and integrated policy proposal for pricing and reimbursement, that focuses on patients' needs and finds a balance between medicines availability on the market and public expenditure on health, price setting, public service duties (stocks, shortage and parallel trade reporting, IT system), internal reference pricing, managed entry agreements, clawback tax, centralized procurement, revenue generation for NHIH in relation to reimbursed medicines (data salles, discount agreements, free goods agreements, etc.).
- progress report no. 3 will be submitted within 7 months from the start date of services. The progress report no. 3 will include a package of legislative proposals, in line with the provisions of the policy proposal, an action plan of next steps, process flow and the proposed text for legislative changes;
- progress report no. 4 will be submitted within 10 months from the start date of services. The progress report no. 4 will include a short description of the meetings organized with all concerned stakeholders, the aspects taken into consideration in designing the proposal, the new detailed proposal and will recommend specific tools to be used and address all issues raised. Also, the report will include recommendations to adequately guide proposal implementation.

Final report will be submitted within 13 months from the start date of services. The final report will include the overview of project results.

All the progress reports will include a section on implementation of task no. 6 since the Consultant will provide support and assistance throughout the project in communicating with all concerned stakeholders involved and addressing sensitive issues. Also, all the progress reports will include a section on the progress made to date, an updated working plan and the methodology for fulfilment of tasks, will identify and include any solutions to secure the success of the assignment.

The reports must be submitted in English with the exception of legislative proposals which need to be submitted in Romanian language.

All the documents must be submitted in electronic format, using the Microsoft Office products (Word, Excel, Power Point and Access). The data files and the data analysis procedures should be presented in an electronic format agreed both by the Ministry of Health and the Consultant.

All the information generated by the Consultant as a direct result of this contract shall be provided to the Client in editable electronic format. The products submitted shall be the exclusive property of the Client and may not be used by the Consultant without the Client's exclusive written consent.

The Consultant will submit for review and comments all reports and the MoH, NHIH and PMU will provide feedback and comments within five (5) working days. The Consultant must submit the final versions of the reports in maximum 3 working days.

The standard template of the final report and the chapters to be included will be jointly agreed by MoH, NHIH and PMU representatives and provided to the Consultant accordingly.

F. DURATION OF SERVICES AND ESTIMATED EFFORT LEVEL

The estimated duration of the assignment is 12 months, to start within one week from the date of contract signing. The total contract duration will be 13 months.

G. CONSULTANT'S QUALIFICATION REQUIREMENTS AND EVALUATION CRITERIA

The assignment should be carried out by a qualified Consultant with in-depth experience in the area of pharmaceutical pricing and reimbursement at European level. The Consultant will provide a Consulting Team (Consultant), formed out of at least 2 internationally recognized pharmaceutical key - experts.

The Consultant should have previous working experience in Central and Eastern Europe.
The Consultant's team members shall meet the following individual requirements:

Team leader – health economist senior expert

- Degree in Pharmacoeconomics or \another relevant field;
- PhD in Health Economics could be an advantage;
- Minimum 10 years' experience in the pharmaceutical economics and policy;
- Experience in reviewing and establishing pharmaceutical policies in European countries;
- In-depth knowledge in international pharma economics issues;
- Experience in access to medical technologies and policy effectiveness in transition countries;
- Skills in policy development;
- High facilitation and negotiation skills;
- Extensive experience in advising international and national governmental organizations;
- Experience in partnership work;
- Excellent oral and written communication skills in English;

Public health senior expert

- Post-graduate degree in public health and/or health policy and/or health economics;
- Experience in analyzing pharmaceutical regulation in Eastern European countries;
- Minimum 4 years' experience in research on availability and affordability of medicines;
- Experience in development of pharmaceutical policy proposals.;
- Excellent oral and written communication skills in English;
- Work experience in Europe is desirable.

Health policy expert with relevant experience in drafting legislation

- University degree in law, medicine or pharmacy with background in health policy and health economics;
- Deep knowledge of the regulatory framework of the Romanian health system;
- Minimum 3 years' experience in drafting health-related legislation in Romania;
- Substantial experience in health communication to professional and non-professional audiences;
- Excellent oral and written communication skills in English and Romanian;
- Work experience in Europe is desirable.

H. INSTITUTIONAL ARRANGEMENTS

The Consultant will have a participative approach, constantly working in close collaboration with the Ministry of Health, the National Health Insurance House and the decision-makers at central level.

The Consultant will ensure the communication with:

- Project Management Unit within the MoH;
- Pharmaceutical Policy Department within the MoH;
- Pharmaceutical and Clawback Department within the NHIH;
- Other representatives of the MoH, NHIH and NAMMD;
- The technical working groups;
- Other actors involved in the pharmaceutical system;
- Public institutions or committees in the health system;
- The Consultant.

For any meeting or discussions that do not directly involve the Project Management Unit (PMU) of the Ministry of Health, the Consultant shall submit the minutes of the meeting.

I. DATA, LOCAL SERVICES AND FACILITIES TO BE PROVIDED BY THE CLIENT

The Client shall provide the Consultant will all the relevant documents (laws, regulations), shall ensure access to the data required, shall contribute to the coordination of all the stakeholders involved and shall facilitate meetings with institutions, organizations and relevant stakeholders

Due to the limited capacity of PMU, the Client will not be able to secure adequate working conditions (especially as regards working premises).

The Consultant shall be responsible for arranging for translation/interpretation/transportation services and accommodation. These costs will be included in the contract. UMP shall provide, to the extent possible, suggestions for logistical assistance. The Consultant will bring own equipment for the accomplishment of the work.

Special requirement: confidentiality and absence of conflict of interests under the consultancy contract.

The maximum sale prices (manufacturer's price, wholesale price and retail price with VAT) calculated according to the above-mentioned methodology apply to all prescription-based medicines, whether or not they are included in the List of medicines that the insured benefit from in the social health insurance system (medicines with and without personal contribution and medicines that are granted within the National Health Programs). Starting with 2014, the inclusion of new medicine (INN) in the above-mentioned list, which is approved by the Government Decision, is not achieved unless by HTA mechanism. Following the evaluation of medical technologies, a medicine (INN) may receive:

- decision to be included in the List unconditioned or conditioned (the obligatory condition for inclusion in the List is related to the conclusion with the CNAS of a cost-volume/cost-volume-profit contract),
- Decision on non-inclusion

Medicines that have undergone an HTA evaluation, already included in the List, for which there have been changes in the SPC of the product (e.g. addition of population subgroup, addition or modification of treatment line), for which new concentrations or pharmaceutical forms have been approved, other than those which led to the inclusion in the List, the HTA is reassessed for the new conditions (at the request of the MAH) and may receive an inclusion decision, in which case it is not necessary to modify the List.

Medicines that have undergone an HTA evaluation, already included in the List, for which there have been changes in the SPC of the product, for the inclusion of a new indication, the HTA is reassessed and may receive a non-inclusion in the List decision, an unconditional inclusion decision or a conditional inclusion decision. The List may be modified after the issuance of a conditional inclusion decision, by including a new position for that drug, with specific annotation to the cost-volume contracts.

In the case of reimbursed medicines, the maximum retail prices and the maximum wholesale price (only for medicines used in NHP) are used to set the reimbursement prices (reference prices for medicines with and without personal contribution which are issued through community pharmacies and settlement prices of medicines used in National Health Programs) both for medicines included in the List unconditionally and conditionally. Medicines that receive an unconditional/conditional inclusion decision following the HTA process are included on one of the four reimbursement lists, depending on the compensation percentage, established by the Romanian National Agency for Medicines and Medical Devices following the HTA assessment process. For INN-related pharmaceuticals included in the List, which are not reimbursed at 100% of the reference price (respectively the INNs in sub-lists A, B and D), the methodology for calculating the reference price per therapeutic unit involves a system of quartile applied at therapeutic groups at ATC3-5 level, for pharmaceutical forms assimilated to the route of administration according to the rules of the World Health Organization, taking into account the SDD factors [calculated by reporting the amount of active substance per therapeutic unit to the standard daily dosage (SDD) according to the rules of the World Health Organization] and the maximum retail price with VAT registered in the National Catalog of Prices of Medicines Authorized for Marketing in Romania, approved by order of the Minister of Health (CANAMED), with reference to the first interval (first quartile). For medicines with 100% compensation of the reference price/settlement price, these prices are calculated per therapeutic unit according to the ATC classification system, at level 5 on each International Nonproprietary Names (INN), assimilable pharmaceutical form/route of administration and concentration. For medicines subject to cost-volume

and cost-volume-profit contracts, the reference price/settlement price is identical to the maximum retail price with VAT/maximum wholesale price, calculated per therapeutic unit, provided in Canamed.