American Chamber of Commerce in North Macedonia
Healthcare Committee

The need for immediate introduction of Managed Entry Agreements in the Rules on reimbursement

Skopje, November 2022

Key points on why it is necessary to immediately introduce the special agreements (Managed Entry Agreements/Risk Sharing Agreements) in the Rulebook which regulates the placing of medicines on the reimbursement list, and not to link their introduction into the legal framework with the rules on public procurement.

Introduction

The special agreements in the countries throughout the region are regulated in the by-laws that determine the conditions and criteria for placing medicines on the reimbursement list.

These agreements are not public procurement agreements. They are one of the conditions for placing a new innovative medicine on the list of medicines funded by the state budget, usually through the Health Insurance Fund. It is obvious from the nature, the subject, the elements of these agreements that they are different from a public procurement agreement.

They are a mechanism of the state that provides better control over the budget funds, more favorable conditions and sharing of risk with the medicine manufacturer, in order to enable access to the most state-of-the-art therapies through the reimbursement list for all patients in need.

The American Chamber of Commerce in North Macedonia (AmCham) is of the opinion that it is necessary to introduce this mechanism in our legal framework and in practice without delay, to enable more effective and faster placement of new modern therapies on the reimbursement list of medicines after years of standstill. AmCham is available for support in organizing events to share best practices and expertise from other countries, especially from the countries of the region, in order to clarify all questions and dilemmas around these agreements and to find the most appropriate solution that will suit our system.

As an initial step towards clarifying this mechanism, this document explains the basic characteristics and nature of these agreements, how they work in the countries of the region, and how they fit into the public procurement system.

1. Definition of the concept of special agreements

Special agreements (managed entry agreements/risk sharing agreements) have been used for a while in the countries of the European Union and in the region. Various terms are used in the legal framework and in practice to define them, among which are "special commercial agreements", "financing agreements", "risk-sharing agreements", or "managed entry agreements" for the entry of new health technologies on the reimbursement list in a country. For consistency, the term "special agreements" is used in this document, considering that this term is formally used in the draft - Rulebook on reimbursement of medicines, which is currently in the process of preparation.

There are several definitions of this type of agreement. One of them, used in publications of the OECD, is as follows:

"Arrangement[s] between a manufacturer and payer/provider that enable access to (coverage/reimbursement of) a health technology subject to specified conditions.

These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use, or limit their budget impact."

They are usually divided into two types - financial and agreements based on performance or outcomes (performance based). In practice, in most countries, especially in countries where the health system is not based on measuring outcomes, that is, on value - based healthcare, the first type of financial agreements is used. This is because the subject of these agreements is easier to define and measure - for example confidential price discounts, placing maximum cap on costs which the state can allocate for a given medicine, placing the cap on the number of patients who can be treated with a given medicine at the expense of the budget in a given period, and so on.

From the definition quoted above, from the nature and subject of these agreements, from their practical application in a number of countries, the following characteristics of special agreements can be drawn:

- Legal mechanism of the state, with which the state ensures control of the budget and conditions under which a new health technology (new medicine) will be put on the reimbursement list or otherwise be covered by the state budget

- Usually governed by the by-law that governs the conditions for placing medicines on the reimbursement list or otherwise under the state budget coverage

- Step in the process for placing new medicines on the reimbursement list. In some countries (Croatia) the conclusion of such agreements for expensive medicines is a mandatory condition for the medicine to be placed on the reimbursement list.

- Bilateral agreements concluded between manufacturers of new health technologies and the healthcare payer

- Of a confidential nature, however usually in situations where there is a legitimate interest third parties can gain access to the confidential elements of the agreement

- They enable putting new, innovative, expensive medicines on the reimbursement list in order for all patients to have access

- Allow part of the risk to be shared with the manufacturer of the medicine, if the agreed state budget or other agreed capping parameters are exceeded (e.g. number of patients, number of doses/cycles of treatment annually covered by the state, etc.)

- They are usually concluded for a period of 2-3 years, whereby for each year there can be modalities of the obligations that are the subject of the agreement. After that period, new agreements with new or revised conditions can be concluded.

It should be emphasized that these agreements are not agreements for the public procurement of medicines, in the sense of public procurement regulations. The subject of these agreements is not the procurement of medicines, rather, it is setting conditions under which a new, innovative medicine will be placed on the reimbursement list of medicines or will become otherwise available at the expense of the state budget. The draft – Rulebook in Article 24 (version of July 2022) defines that these agreements "govern financing relations" and the types of relations which are the subject of such agreements are listed further in the same Article. The procedures and agreements for public procurement for the same medicines are a completely different and separate issue from a legal and practical point of view, and they should not be confused with the special agreements that are part of the reimbursement process.

The benefits of using these agreements are manifold. Putting innovative medicines on the reimbursement list using special agreements will allow health authorities control, long-term planning and limitation of the budget burden. At the same time, according to the rules that apply to medicines that are on the reimbursement list, continuous and guaranteed access to medicines for all patients is enabled. Doctors are given more choice to prescribe the most appropriate medicine for each individual patient, and a clear and transparent process is established for pharmaceutical companies.

Considering that this legal instrument is a novelty for our system, AmCham is ready to help in organizing workshops and discussions with experts from the region and more broadly, who can share experiences from countries where such agreements already work, to open a technical discussion and collect good practices and solutions which can help in the legal definition and implementation of this mechanism in our system.

2. How the special agreements work in the countries of the region

Special agreements have been introduced and applied to in the countries of the region as part of the reimbursement system. Croatia, Slovenia, Bulgaria, Serbia, Montenegro have adopted modern by-laws on the criteria and procedure for placing medicines on the reimbursement list, in which special agreements are also regulated. Reimbursement lists in these countries are regularly updated to include new medicines, usually at least once a year. With that, their citizens have continuous access to the latest and the most effective medicines under the conditions specified in the special agreements that in these countries are already regular practice.

- ***Slovenia***

In Slovenia, risk sharing agreements are concluded between manufacturers and the payer - Health Insurance Institute, usually for every new medicine that enters the market. The process of negotiation and conclusion of the agreement is part of the procedure for placing the medicine on the reimbursement list.

Most often, the subject of these agreements are price discounts. It can also be patient coverage or other limitation. Agreements are confidential, but those parties who have a legitimate interest (such as certain state institutions) may get access to all elements of the agreement.

Once a risk-sharing agreement has been concluded, and the medicine is placed on the reimbursement list following fulfillment of all the criteria provided by the regulations, regular public procurement process is carried out. In Slovenia, the hospital issues a tender with the price of the medicine that is officially listed on the reimbursement list. Considering that the real price is lower and confidential, there is a system of pay-back between the hospital and the Institute, to cover the difference between the published price paid by the hospital and the agreed price with the Institute which is invoiced to the manufacturer. The audit to perform calculations and paybacks is done once a year.

- ***Croatia***

In Croatia, agreements are mandatory for medicines that are put on the reimbursement list through the special List of expensive medicines, for which there is a specially allocated budget. Those agreements govern financial aspects such as price and other restrictions. They are of a strictly confidential nature. Public procurement for expensive medicines is usually conducted through a central tender at the national level, by the Ministry of Health for the needs of all hospitals.

- ***Bulgaria***

In Bulgaria, special agreements are a prerequisite for medicines to be placed on the reimbursement list. The agreements are of a financial nature and refer mainly to pricing discounts, however other mechanisms can be specified with these agreements. They are confidential, that is, they are not publicly available. Price discounts are given to the payer - the Fund.

After the medicine is placed on the list, hospitals carry out public procurement procedures for these medicines, according to the regulations on public procurement. Most often they carry out an open procedure. The hospitals that implement the tenders, and that have an obligation for monthly reports with invoices to the Fund, receive from the Fund a refund of the difference between the price which the hospital paid according to the tender and which is equal to the official price of the medicine on the list, and the price agreed between the manufacturer and the Fund.

- ***Serbia***

These agreements are concluded for each innovative medicine that is placed on the reimbursement list.

Negotiations and the conclusion of agreements are carried out with the Fund, according to model - agreements which simplify the conclusion procedure. There are several defined model - agreements, each with a certain limitation to enable the planning of state funds. The rulebook on reimbursement and the model - agreements have been prepared jointly with the pharmaceutical companies, with the Public Prosecutor's Office, the Ministry of Finance and the Fund, in order to ensure that the content of the agreements will be in accordance with other regulations and the legal system as a whole.

When concluding an agreement, the model agreements are filled in and specific elements and conditions are defined. The most commonly used are agreements for discounts/rebates and for taking over the cost of treatment by the company in case if the budget for the given medicine assessed by the expert Commission is exceeded. These agreements are confidential, but anyone who has a legitimate interest can gain access to the price that is not published on a tender.

The fund implements a centralized tender later on behalf and at the expense of the hospitals, which only withdraw the quantities according to the needs. The price in the tender is the same as the price listed on the reimbursement list.

3. Possible solutions for implementation of public procurement after the medicines for which special agreements have been concluded are placed on the reimbursement list

It is clear that special agreements are a legal mechanism used as a condition for putting innovative medicines on the reimbursement list. Public procurement procedures and public procurement contracts follow later, after the medicine is already on the list and the special agreement is concluded.

In terms of public procurement rules, our Law on Public Procurement is harmonized with the EU rules in this area. Several types of procedures are provided for in Article 47 of the Law, however in practice there is no case - by - case assessment of which procedure would be most appropriate each time hospital medicines are procured, and instead by default the open procedure is used most frequently. Of course, according to the practice in other countries, there is no obstacle to using the open procedure, however other procedures can also be used when a special agreement has previously been concluded.

Apart from the open procedure, when it comes to new innovative medicines that are under patent protection and in most cases are produced only by one economic operator on a global level, the negotiated procedure without publication of an announcement can be used (Article 55 of the Law on Public Procurement). Its advantage is that it is simpler and more efficient as it can allow faster availability of medicines to patients once the medicine has been placed on the reimbursement list. This procedure can be applied under certain conditions. Among others, it can be used when the medicines can only be provided by a certain economic operator due to protection of exclusive rights, including the rights of intellectual property (paragraph 1 point v) line 3). This basis covers the legal protection with a patent as an intellectual property right, provided there is no alternative or substitute and provided the absence of competition is not a consequence of unjustified limitation of the specifications of the subject of procurement (paragraph 2). The contracting authority must seek a prior opinion from the Public procurement office before using this procedure (paragraph 5), and explain why it uses this procedure (paragraph 9). If these conditions are met for an innovative medicine that is already on the reimbursement list, it would be appropriate to use this procedure.

Also, this procedure can be used on the basis of urgency that the public healthcare institution could not foresee (paragraph 1 point g) of Article 55). We have examples of using this basis for procurement of reagents, diagnostic materials and medicines for patients with COVID-19, or due to shortages of medications that are not the fault of the hospital (for example, due to cancellations

of previous tenders by state authorities). Given that innovative medicines are mostly used for severe, life-threatening conditions and diagnoses, situations may arise in which the need to purchase a given medicine is urgent. In practice across Europe, urgency as a condition for using a negotiation procedure without announcement is also sometimes used within the framework of "the doctor's freedom to prescribe therapy", in a situation where a doctor in a hospital prescribes a therapy that is not available at the moment.

Another possibility is the conclusion of a framework agreement (Article 57 of the Law on Public Procurement). According to paragraph 1 of Article 57, a framework agreement is concluded using any procedure established in Article 47, which means that a negotiated procedure can also be used. The term of validity is a maximum of 3 years (paragraph 2). Individual contracts must be in accordance with the conditions established in the agreement (paragraph 6). When using a framework agreement, the contracting authority takes into account the maximum estimated value without VAT of all agreements planned for the entire duration of the agreement (Article 39 paragraph 5). Framework agreements for the procurement of medicines are often used in the UK and Spain.

Regardless of which procedure is used under the Law on Public Procurement, according to practices presented above in the countries across the region, and given the confidential nature of the special agreements, there is no obstacle for the procurement to be carried out according to the price determined on the list, and then the contracting authority, by means of a credit note or another appropriate way, to claim from the Fund, as a player with which an agreement for a discount or lower price was previously concluded, a payback of the difference between the tender price and the agreed reduced price.