INOVATIVNA FARMACEUTSKA INICIJATIVA
Inovativna farmaceutska inicijativa
info@ifi.hr | www.ifi.hr

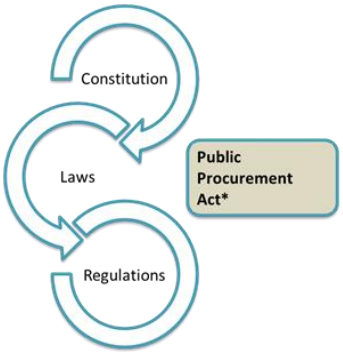
POSITION OF THE INNOVATIVE PHARMACEUTICAL INITIATIVE

WHY MEDICINES ARE NOT SUBJECT TO THE PUBLIC PROCUREMENT ACT

IF IN THE CHOICE OF TENDERER, THE PRICE WOULD CONTINUE TO AMOUNT TO 90 % OF THE CRITERIA, THE WORST SCENARIO OPENS THE POSSIBILITY OF MARKET DISCRIMINATION THAT CAN RESULT WITH THE SHORTAGE OF MEDICINES SUPPLY AND VIOLATION OF THE CONSTITUTIONAL RIGHTS OF PATIENTS REGARDING THE SELECTION OF THE BEST THERAPY AND MEDICINE

In accordance with the EU acts, the Croatian Public Procurement Act is in force since 1 January 2017, and will be fully operational from 1 July of the same year for all goods or services whose price is not already defined by a specific law or regulation. The criterion of the most economically advantageous tender becomes the exclusive criterion for the selection of tenderers for all goods or services whose price is not already defined by a particular law or regulation, with the price indication still having a crucial influence on the selection (up to 90 % of the tender offer), while other criteria defined by the contracting authority amount to a minimum of 10 % of the tender offer. Although, in principle, this is a very good solution for the state bodies' procurement of goods and services, when it comes to the health sector, a number of problems emerge.

LEGISLATIVE FRAMEWORK CIRCLE



* Application of EU Public Procurement Directive 2014/24/EU

The Public Procurement Act is included in the legal framework governing rights and obligations within the health system involving patients, health and hospital administration, physicians, pharmacists and the pharmaceutical industry, and ultimately the fiscal impact on the state budget. When we talk about public procurement in healthcare, the law will have a positive impact on certain segments.

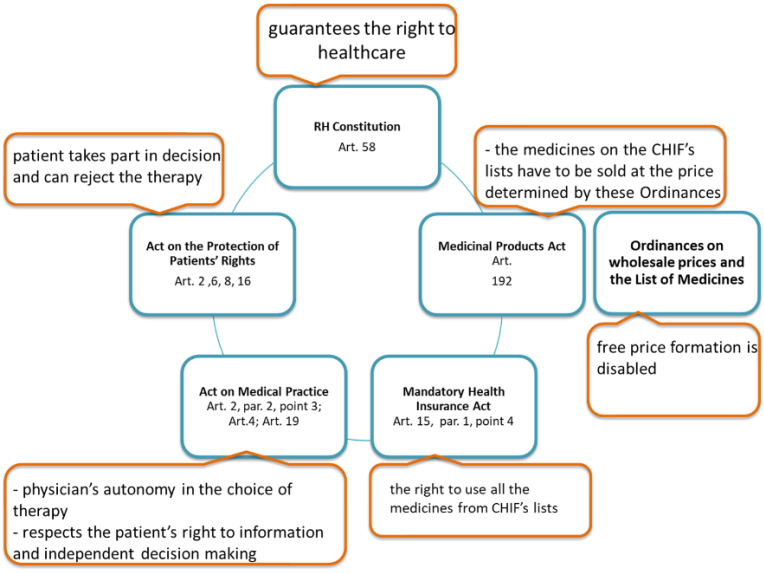
However when it comes to medicines, there is already a set of rules and regulations that regulate procurement, which represents a highly regulated process that includes all elements of technology assessment. A positive aspect of this Act is manifested in the fact that the

evaluation of qualitative parameters is an exclusive element of the best tenderer selection in the process of medicines procurement, thus ensuring the continuity of providing therapy options for patients.

THE LAW LIMITS THE RIGHTS OF PATIENTS

As a fundamental legal act, the Croatian Constitution guarantees equality, but also the right to healthcare. Our attitude is based also in the Act on the Protection of Patients' Rights (which guarantees the right to information and decision making) and the Medicinal Products Act which regulates pricing rules as well as the List of Medicines. The aforementioned legislative framework also includes the Act on Medical Practice and the Mandatory Health Insurance Act, according to which the patient is entitled to all medicines from the Croatian Health Insurance Fund's (CHIF) list. Marketing authorization holders are obliged to have medicines available to patients and to sell them at the prices set out in the regulations. This has prevented the free formation of medicines' prices, and the previously mentioned laws and regulations allow physicians the autonomy in the choice of therapy. If medicines would become subject to the Public Procurement Act and if the price would amount to 90 % of the criteria in the selection of the tenderer, we would find ourselves in the situation in which the constitutional right of the patient to choose the best therapy and medication would be violated.

LEGAL OPPORTUNITIES AND LIMITATIONS



IN CROATIA, THERE IS A DECREASED AVAILABILITY OF INNOVATIVE MEDICINES, WHICH, COMPARED TO EUROPEAN COUNTRIES, RESULTS IN PATIENTS' DELAYED ACCESS TO INNOVATIVE MEDICINES

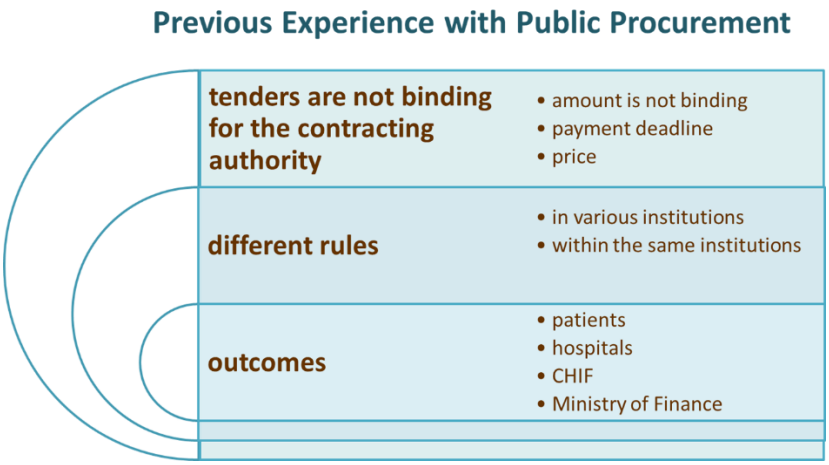
Selecting one of the tenderers demotivates others to be present on the market and maintain the registration of medicines, and then, when there is no alternative for a certain medicine, we could end up in the situation that the price of the chosen medicine remains the same or even increases. This completely destroys market competition and increases the risk of medicine shortages, while the constitutional right of patients to choose the best therapy and medication is violated. Therefore, our recommendation is to create such a procedure that will respect the

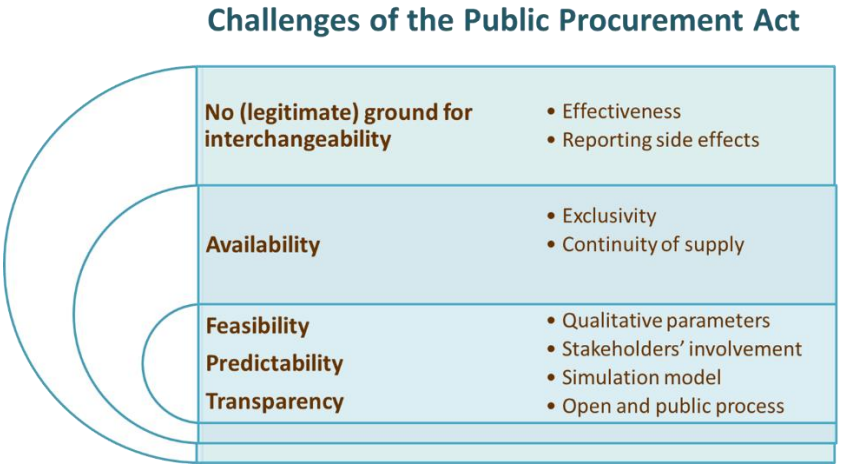
multi-winning selection of tenderers and ensure the availability of all medicines from the CHIF List of Medicines at a hospital institution, since it represents a list of patients' rights. There is no (legal) answer to the question of what will happen with patients who have to use new therapies due to questionable efficacy or side effects - there is no list of interchangeable medicines. From the so far gained experience in public procurement, it is easy to conclude that the implementation of the public procurement procedure for the contracting authority (health institution) is obligatory in accordance with the adopted annual procurement plan, but the amounts defined in the public procurement processes are only the reflection of the estimated quantities and are not binding. It should also be noted that the contractual deadlines of 60 days payment, set according to the Financial Business Act and the pre-bankruptcy settlement, are in most cases not respected, while the tenderer is obliged to ensure the continued availability of medicines at defined prices. Finally, public procurement does not take into account outcomes for patients, hospitals, CHIF and the Ministry of Health. The additional challenge of the Public Procurement Act is the availability of medicines, in which we must bear in mind the protection from exclusivity, as well as the continuity of supply. Recently, the term "tax scissors" is often mentioned, which can also be applied on the pharmaceutical industry to point out that the medicines are subject to multiple pricing cuts, even before they reach the patient and before they are paid. The first step is to determine the price in the procedure of listing medicines on the CHIF lists. For a large number of hospital medicines, as well as for all medicines listed on the List of Particularly Expensive Medicines, it is necessary to sign a financing agreement according to which drug manufacturers bear all the risk of exceeding the agreed amount. The next step involves international referencing, then therapeutic price referencing where original medicines are compared to generics, leading to a reduction in the price of innovative medicines which certainly does not encourage innovation. All of the above are the reasons why the availability of innovative medicines in Croatia is decreased and why these medicines enter the Croatian market later than other European countries, as well as why the pricing and reimbursement process when entering the CHIF List of Medicines is long and results in reduced and limited indications covered by CHIF. This is also the case with the use of the Supplementary List of Medicines in hospitals where, due to public procurement procedures, very often the patient cannot receive the same medicine which the patient is already using, and we are faced with the lack of system to compensate for differences. The Innovative Pharmaceutical Initiative welcomes the Act that is a step towards the exclusion of medicines from the public procurement process. We remind you that medicines should not be the subject of public procurement, since referencing at ATC level 5 ensures the lowest price and the availability of other medications at an extra charge. We must not forget that the CHIF List itself is a sort of public procurement process since it takes price and qualitative factors into account. A unified public procurement, in which price continues to play a decisive role, ignores the value of innovative products and solutions, and does not take into account their impact on clinical outcomes and the efficient use of limited resources in healthcare, nor the fact that they provide

greater benefit to the contracting authority, such as shortened hospital stay or minor side effects.

NEW MODELS CONTRIBUTE TO BETTER PATIENT TREATMENT

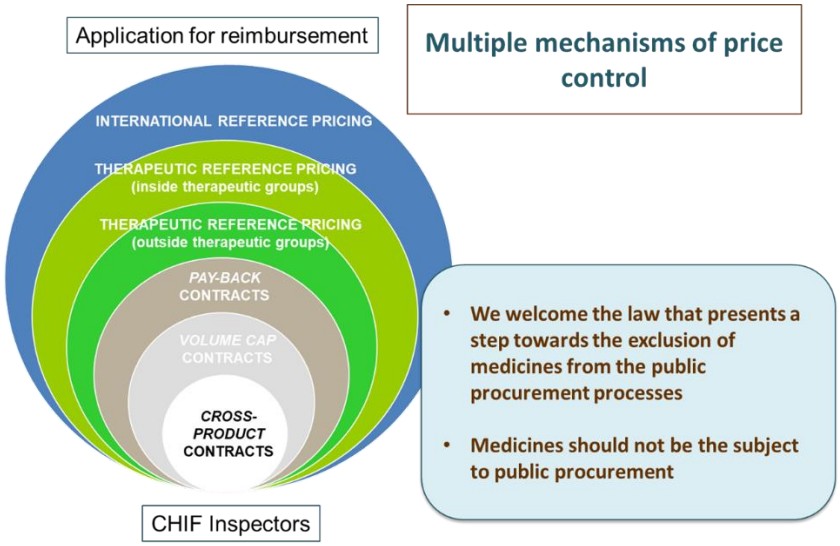
Both in terms of value and the number of packaging, Croatia per capita consumption is lower compared to other countries, and the cost of medicines themselves is significantly lower compared to other countries. Adding to the fact that in Croatia the prices of medicines are extremely low, we come to the conclusion that medicines are not the generator of rising healthcare costs. Costs are conditioned by aging population, increased chronic disease share, new technologies and population expectations, leading to limited therapeutic opportunities for doctors and their patients. All European administrations will have to find a solution that will allow physicians not to reduce therapeutic opportunities to their patients due to insufficient funding for healthcare and to ensure that the money they have available is spent in the best way possible.





EUROPEAN HEALTH ADMINISTRATIONS WILL HAVE TO FIND THE SOLUTION AND ENABLE PHYSICIANS NOT TO DECREASE PATIENTS' THERAPY OPTIONS BECAUSE OF FINANCIAL LIMITATIONS

In order to provide the most effective treatment for patients, it is necessary to provide treatment guidelines, to provide a multidisciplinary approach (especially for oncological diseases), to establish diseases registries, to systematically measure clinical outcomes of treatments and to collect and analyse all available data for the purpose of monitoring and improving treatment outcomes. The cost of a medicine can no longer be the criterion of choosing a type of therapy that will be used in the treatment; the criterion must be well-defined parameters such as the duration of medicine presence on the market, clinical experience, form of packaging, treatment outcomes, cost and time of medicine administration.



The Public Procurement Act, as well as any other legal framework, must be enforceable, predictable and transparent. It should contain qualitative parameters, enable stakeholder involvement and model simulation, being an open and public process. Recognizing the qualitative parameters as the sole choice criterion in public procurement of medicines, stimulates the valorisation of proven efficacy, safety and experience, which will surely create additional benefits for patients. Finally, the key argument is contained in the Public Procurement Act itself (Article 284, paragraph 6), which states: "If the price of certain goods or remuneration for certain services is prescribed by law or other regulation, the public contracting authority shall not through public procurement procedures use the price as a criterion for selection of tenderers." The Medicinal Products Act (legally speaking - Lex Specialis) together with the pricing and reimbursement ordinances overrides the Public Procurement Act (legally speaking - Lex Generali), which means that the price of medicines should be formed in the aforementioned ordinance and not in public procurement procedure! We welcome the Act that is a step towards the separation of medicines from the public procurement process, given that the issue is completely and effectively resolved by the Medicinal Products Act and the related regulations. Medicines should not be the subject of public procurement.

INOVATIVNA FARMACEUTSKA INICIJATIVA

Croatian association of innovative medicines manufacturers iF! (Innovative Pharmaceutical Initiative) has been gathering and representing 23 innovative pharmaceutical companies employing 812 employees and providing nearly 60% of medicines in Croatia for 23 years. The association is a member of EFPIA - the European Association of Innovative Pharmaceutical Companies and Associations based in Brussels. More detailed information can be found at www.ifi.hr.

iF! members:

AbbVie d.o.o., Amgen, Astellas d.o.o., AstraZeneca d.o.o., Bayer d.o.o., Berlin-Chemie Menarini Hrvatska d.o.o., Boerhringer Ingelheim Zagreb d.o.o., Eli Lilly and Company, GE Healthcare, Glaxosmithkline d.o.o., Johnson&Johnson S.E.d.o.o., Lundbeck Croatia d.o.o., Medis Adria d.o.o., Merck d.o.o., Merck Sharp & Dohme d.o.o., Novartis Hrvatska d.o.o., Novo Nordisk Hrvatska d.o.o., Pfizer Croatia d.o.o., Roche d.o.o., Sanofi-Aventis Croatia d.o.o., Servier Pharma d.o.o., Shire d.o.o. and Takeda Pharmaceuticals d.o.o.

LITERATURE

1. Constitution of the Republic of Croatia (OG 85/2010)

2. Public Procurement Act (OG 120/2016)

3. EU Public Procurement Directive (2014/24/EU)

4. Act on the Protection of Patients' Rights (OG 169/2004, 37/2008)

5. Medicinal Products Act (OG 76/2013, 90/2014)

6. Act on Medical Practice (OG 121/2003, 117/2008)

7. Mandatory Health Insurance Act (OG 80/2013, 137/2013)

8. Ordinance on standards and the method for determining wholesale prices and the manner of reporting wholesale prices (OG - 83/2013, 12/2014, 69/2014, 22/2015, 84/2015)

9. Ordinance on establishing the criteria for inclusion of medicines in the basic and the supplementary reimbursement list of the Croatian Health Insurance Fund (OG 83/2013, 12/2014, 69/2014, 22/2015 i 84/2015)