

ENSURING SUPPLIES OF MEDICINES DURING PANDEMICS IN TERMS OF PUBLIC PROCUREMENT

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SUMMARY

Objectives: This article describes and comments on contemporary legal regulations concerning the supply of medicines during pandemics in terms of public procurement.

Methods: Suggestions are made for removing existing legislative shortcomings, clarifying the diction of existing laws or rendering precision to legal regulation of public procurement given purchases of medicines during periods of imminent threats of pandemics and duration of pandemics.

Results: The author reflects on improving legislation concerning the lack of clarity and the doubts concerning the contemporary legal order of the Czech Republic, with reference to speeding up and simplifying public procurement procedures for incident-free purchases of necessary medicines in time of pandemic crisis situation and then effectively supporting the struggle against any pandemic infection.

Conclusion: The issues raised should be addressed since better legislation can significantly contribute to the containment of pandemics and their consequences for individual and public health.

Key words: public procurement, medicines, legal causes of systemic shortcomings, negotiated procedure without prior publication, pandemic

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INTRODUCTION

The present text ponders over ensuring the right of health protection in pandemics or pandemic threats from the point of view of the timely procurement of medicines. In view of Article 31 of the Constitutional Charter on Fundamental Rights and Freedoms (2/1993 Coll.), which establishes the constitutional right of health protection, it should be considered whether the present wording of the Czech legal order ensures sufficient fulfilling of that constitutional right under the above mentioned health crisis situation with respect to procurement of medicines required for protection in general and those affected in particular (1, 2).

The text deals with an assumed situation caused by a vast epidemic or pandemic when in the public interest it is necessary to supply an adequate amount of medicines in bulk.

Epidemics and pandemics are transitional in nature, affecting transnational areas. In view of these epidemiological characteristics of such a disease occurrence, shortcomings in supplies of vaccines and medicines in need have been revealed in connection with the pandemic influenza of 2009, in which the mechanisms of the EU in respect of the above were guided by the existing procedures for procurement of vaccines and medicines: “Joint Procurement Agreement to Procure Medical Countermeasures”, signed in 2014, to improve their preparedness when countering border threats.

This agreement is based on the Decision of the European Parliament and of the Council Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and Decision No. 2119/98/EC.

There is evidently a public health crisis within the EU, which no single EU member state is capable to deal with itself.

Interpretative disputes cannot be ruled out where the procedure in order to protect life and health may come into conflict with the rules of fair competition. One could assume that the protection of human life and health is an absolute priority and therefore any such conflicts are out of the question. In theory, such disputes are inadmissible although in practice the situation is often different; in some cases, it is a question of whether regular procurement procedure should be applied due to the time required for realisation of normal competition. For this reason, it is necessary to mention crisis management. Crisis management in the Czech Republic is governed by the rule of the highest legal force, i.e. the Constitutional Act 110/1998 Coll. on the security of the Czech Republic (3). This Act provides for the government declaring a state of emergency in the event of natural disasters, environmental or industrial accidents, accidents or another danger that endanger lives, health or property, or internal order and security. In fact, the state of emergency has been so far declared only for floods and storms.

It can be assumed that a pandemic could be considered as another danger that, to a great extent, endangers lives and health of the population.

Emergency status is announced for a maximum of 30 days, for a longer period of time with the consent of the Government. Therefore, it can be concluded that the Constitutional Act of the Czech Republic could, by declaring a state of emergency, allow the use of Crisis Act 240/2000 Coll. This Act provides that such a procedure would only be possible for a limited time. This is covered by the Act No. 134/2016 Coll. on Public Procurement.

This provision could allow the purchase of medicines without legal restrictions. But there is no example or precedent for such

a procedure. In any case, the procedure could be applied for a very limited time.

It can be assumed that in the event of an emergency medical crisis, the Ministry of Health should be the authority responsible for the enforcement of all activities related to this legal Act.

In view of the questionability or controversy of such a procedure, its time constraints, economic risk, and no experience with such a procedure, the article does not further address this theoretical possibility of purchasing medicines. The article also deals with legal procedures.

Sometimes it is questionable whether it is appropriate or necessary to purchase the necessary medicines outside the regular legal process; such a procedure is enabled by special provision of the Act 134/2016 Coll. on Public Procurement (4). In this sense, we are dealing with the purchase of goods for which the purchase price changes throughout the financial year. If a given regular procedure is legally possible it becomes mandatory. A different procedure is then viewed in *fraudem legis* or *contra legem*.

Summary of Problems

As regards the Czech legislation, it should be noted that according to Section 49 of the Act on Protection of Public Health 258/2000 Coll., in its current wording, vaccines for special and extraordinary vaccinations are paid from the state budget (5).

The following is the summary of public purchasing problems:

- Very urgent circumstances are not defined.
- It should be defined if the circumstances are or are not a defence matter.
- Possibility of using generic drugs under the Act on Pharmaceuticals 378/2007 Coll.
- Prompt granting of a compulsory licence according to the Act 527/1990 Coll. on inventions and improvement proposals.
- Public procurement in terms of timeliness and legal options for an imminent flu pandemic.
- Procedure rules:
 - negotiation without prior publication with multiple suppliers;
 - negotiation without prior publication of a single supplier for reasons of urgency.
- Negotiated procedure with publication with multiple suppliers.
- Free competition and free movement of goods.
- Matter of patent protection.
- Political decision-making from the point of view of the prevention of epidemics or pandemics in the supply of medicines.

The definition of urgent circumstances required by the Act 134/2016 Coll., on Public Procurement is missing. To legitimize the possibility of a quick and immediate purchase of medicines, such a definition is definitely necessary. Otherwise, such a definition must be created by the procurement authority itself and may result in serious legal disputes and suspicion of infringements (8–13).

It is not determined whether the pandemic is a matter of defence. The issue should be resolved in accordance with the relevant provisions of the above Act. Therefore, the matter should not be dealt with under the provisions relating to defence and security; however, in case of an escalated military situation a pandemic could be considered a matter of defence, with respect to possible impact on the armed forces.

There is possibility of a rapid decision on the use of generics under the Act No. 378/2007 Coll. on Pharmaceuticals, in the cur-

rent version (6, 7). If the use of generics corresponds to the law, this should not present a problem.

The accelerated granting of a compulsory license is a process according to Section 20 of the Act No. 527/1990 Coll. on Inventions and Improvement Proposals in the current version. If the patentee prevents the use of a patented drug, such a situation can be successfully addressed by the above-mentioned Act.

There should be specific options for the use of open procedure for pharmaceuticals with long expiration terms and predictability related to the scope and origin of the epidemic. In the event that medicines will last then the open procedure for such medicines is optimal for their procurement. The problem may be an obstacle to patent protection by Act No. 527/1990 Coll. on Inventions and Improvement Proposals, especially for newer medicines. In case of medicines with a long history of use, the competition of generics presents a viable opportunity. In this area, we must bear in mind that on the one hand, it is necessary to proceed efficiently in terms of spending budget funds in compliance with the rules of free competition, but on the other hand to ensure timely supply of enough drugs for the protection of lives and health as an absolute priority. With regard to the expiration of medicines, this is expected only with limited stockpiling of drugs.

The likelihood of a pandemic should be taken into account when ordering medical supplies. The most likely scenario is the emergence of an influenza pandemic where the incubation period is 18–24 hours, sometimes up to 72 hours. In each case, the disease spreads very quickly (14–18). The expiration period of antivirals is 5–7 years. This means that it is necessary to supply the drug to patients quickly, but in principle, it is possible to deliver drugs from stockpiles. The size of reserves is a matter of difficult calculations. Antiviral medicines have a market value of about 600 CZK to 1,500 CZK per pack. During the outbreak of Spanish Influenza, about 500 million persons from a world population of 1.8 billion were afflicted. Presently, it is possible to expect lower morbidity rates, but even today about 30% of the population could be affected. In the event of a pandemic of severe influenza with 1 million seriously ill inhabitants, the running costs for antiviral medication can reach billions of CZK. The political implications of stockpiling medical supplies should be taken into account because we know that a pandemic will occur, but do not know when. Further, for example, the estimated amount of vaccine for 20% of the population of the Czech Republic can cost about 0.6 billion CZK. Risk groups comprise citizens aged over 65 years, and those with chronic cardiovascular, respiratory tract, kidney or liver diseases, or diabetes, as well as patients with splenectomies and hematopoietic stem cell transplantation (HSCT), persons with congenital or acquired immune system dysfunctions, cystic fibrosis or chronic anaemia. There are also other groups of people for whom vaccinations are recommended such as pregnant women, persons who frequently come into contact with risk groups, physicians or social workers in plants, relatives of seriously ill patients, and employees working in larger teams (5). Therefore, approximately 2 million persons from the above population groups in the Czech Republic are likely to be affected at a cost of around 10 billion CZK (19). Vaccines and diagnostics must be provided flexibly because they cannot be stored in advance. In this context, case law and the Court of Justice of the European Union (CJEU) interpretation practice should be considered, although only under extremely urgent conditions (not merely urgent conditions). The

difference between urgent and extremely urgent conditions is not defined. It would be better if at least this was defined in the Act, if only demonstratively. This implies the assumption that the legislature will be expected to use Negotiated Procedure without Prior Publication (NPWPP) limited to the first wave of deliveries for the first group of patients, followed by open procurement (4). In some cases, this will be possible from a medical point of view although as a consequence there may be problems of compatibility of various services such as clinical diagnostics, methodology or device settings. Certain supplies, such as antivirals, may be needed in large quantities, which are problematic due to their five-year expiry period. The unpredictable nature of pandemics makes the policy for management of these medicines markedly difficult.

The current Act No. 134/2016 Coll. in particular its provisions in accordance with relevant provisions (4), do not, in effect, deal with negotiated procedure without prior publication involving more than one supplier. Unlike the repealed Act no. 137/2006 Coll. determines that the authority of the written notice must determine: the method and principles of negotiations, if negotiations are with several interested parties, as well as in paragraph (3) which provides: in case of the negotiated procedure without prior publication with several economic operators, the contracting authority shall not disclose candidate information regarding the conditions and suggestions made without prior consent. The new legislation Act No. 134/2016 Coll. lacks any such provisions, which has all the hallmarks of a serious mistake. In the event of an imminent pandemic, a situation may arise in which negotiations with two or more suppliers is inevitable. In such a case the contracting authority comes up against *vacuum legis*: which may cause considerable and unsolvable problems.

The problem of urgency may arise, although the contracting authority should prove such urgency as a result of unpredictability. The implicit problem is, as discussed in literature, that the question is not if an influenza pandemic will occur, but when. In this the whole issue is analogous to insurance. An insurance company only insures unpredictable events, with the exception of life insurance, where death is inevitable but cannot be accurately predicted. By the same token, the predictability of pandemics should be viewed.

Theoretically, a situation may arise involving multiple vendors and there is no immediate danger of default, but the drug parameters have to be adjusted according to the client's requirements. In such a case the appropriate procedure would be in accordance with the relevant provision of the Act No. 134/2016 on public procurement in cases where the authority needs cannot be met without treatment of the provision. Here, in case of urgency, these periods can be shortened under the relevant provision of the Act 134/2016 Coll., for example, the deadline for submission of bids 10 days from receipt of a call by the contracting authority. Regarding the reduction of the period, the negotiated procedure with publication is useful, but only sometimes. Even with shorter deadlines the tender procedure may be too long for the timely delivery of medicines (4).

As mentioned above, where there is no need of supplying the medicines rapidly, and there are no legal obstacles presented by patent protection, it is necessary to select an open public procurement. In case of patent protection, NPWPP must be used according to the Act 134/2016 Coll. on Public Procurement: this is necessary for the protection of exclusive rights, including intellectual property rights. In urgent cases, the same section of

the above Act should be used: the contracting authority may also use a negotiated procedure without prior publication, if necessary, due to extremely urgent circumstances that could not be foreseen and were not caused by the authority, without adequate time for open procedures, restricted procedures and procedures negotiated with publication. Free competition can also be restricted by a ban of re-exports. After expiry of legal protection, generics are often produced and supplied in lieu of the original patented medicines. The prices of these drugs vary from state to state. There is a risk that generics purchased in one country at a lower price will be distributed to other countries where they are for sale at a higher price. Thus, in a country where generics are cheaper, their availability can be limited or even non-existent. This is now prevented by the prohibition of redistribution with relevant legal sanctions under the Act No. 378/2007 Coll. on Pharmaceuticals, as amended by 66/2017 Coll. The Ministry can forbid re-exportation by its action. Infringements can newly be penalized by a fine of up to 2 million CZK. The efficiency of this action has yet to be evaluated.

The following demands are placed on the State Institute for Drug Control (SIDC) of the Czech Republic and the professional medical community: if the original drug is irreplaceable, it is usually protected by patents; generic drugs cannot be marketed for a ten-year period from their first registration in any member state or the EU. For irreplaceable patent-protected drug purchases NPWPP is used, whereas in other cases patent protection should not be an obstacle.

In case of potential stockpiling it is necessary to take into account how much funding the government is willing to release. If the drugs are not urgently needed, it may be difficult to enforce release of additional budgetary funds in advance. In current political culture, where the norm is to spend budgetary funds for rapid electoral advantage, it is a question if appropriating funds for future medical preventive measures is at all possible.

Appropriate Legislation

The Act 134/2016 Coll., on Public Procurement, should by definition be amended in the event of extremely urgent circumstances, and ideally, in accordance with European legislation, very urgent circumstances should be defined.

This Act must necessarily be amended for situations involving essential negotiations without prior publication when dealing with more candidates, especially in terms of how the contracting authority shall deal with confidential information that it receives from the individual economic operators. Defining a pandemic or epidemic is also a matter of defence.

CONCLUSION

The proposed legislative amendments to the existing legal system are feasible. However, there is the question of policy concerning the stockpiling of the necessary drugs and preventive measures, especially vaccination, in the event of a pandemic threat. This issue is political, as stated above, and potentially sensitive. Possibly the only solution, albeit enforceable with difficulty, could be an amendment to the law on public health protection 258/2000 Coll. anchored in accordance with the Constitutional Charter 2/1993 Coll., the population and regular

purchases of drugs for the whole population as a defence against possible pandemics. Harmonization of the Act 258/2000 Coll. on the Protection of Public Health with the Public Procurement Act 134/2016 Coll. would result in the concept of unpredictable urgency in both laws. It is, therefore, desirable that the necessity of unexpected and objectively unforeseeable purchases of drugs to treat pandemic situations is secured. This article could at least modestly challenge the further development of health legislation, health policy, and hence the need for the protection and promotion of public health.

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