Conseil de
l'Union européenne

Bruxelles, le 8 juin 2022
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NOTE

Origine:	Secrétariat général du Conseil
Destinataire:	Conseil
Objet:	Lettre conjointe à la CE concernant la révision des dispositions relatives aux contrats d'achat de vaccins, en ce qui concerne les surplus de vaccins *- Informations communiquées par la délégation polonaise, au nom des délégations bulgare, croate, estonienne, hongroise, lettone, lituanienne, polonaise, roumaine, slovaque et slovène*

Les délégations trouveront en annexe une note ainsi qu'une lettre conjointe de la part des délégations bulgare, croate, estonienne, hongroise, lettone, lithuanienne, polonaise, roumaine, slovaque et slovène à la Commission européenne concernant la révision des dispositions relatives aux contrats d'achat de vaccins, en ce qui concerne les surplus de vaccins, qui sera traitée sous point « Divers » lors de la session du Conseil EPSCO (santé) du 14 juin 2022.

Rada EPSCO (Zdrowie), 14 czerwca 2022 r.

Punkt AOB: Wspólny list do KE w sprawie zmiany postanowień umów zakupu szczepionek w kontekście nadwyżek szczepionek

Polska, we współpracy z Bułgarią, Chorwacją, Estonią, Węgrami, Łotwą, Litwą, Rumunią, Słowacją i Słowenią, informuje o przesłaniu wspólnego listu skierowanego do Komisji Europejskiej w sprawie zmiany przepisów umów na zakup szczepionek w kontekście nadwyżek szczepionek.

Mając na uwadze obecną sytuację, chcielibyśmy ponownie wyrazić nasze zaniepokojenie znaczną nadwyżką szczepionek COVID-19. Pomimo oznak, że pandemia ustępuje i że osiągnięto zadowalające poziomy szczepień w UE, umowy z producentami szczepionek przewidują dostawy szczepionek, których wielkości znacznie przekraczają potrzeby państw członkowskich i ich zdolność do absorpcji i wykorzystania tych preparatów.

Ponadto, ze względu na niski popyt ze strony państw trzecich istnieje bardzo duże prawdopodobieństwo, że dawki dostarczane do Unii Europejskiej mogą zostać zutylizowane.

Mamy świadomość, że Komisja Europejska prowadzi już negocjacje z producentami szczepionek, ale dotychczas zaproponowane przez nich zmiany nie rozwiązują problemów w dłuższym okresie, w sposób zrównoważony pod względem prawnym, finansowym i etycznym. Zaproponowane już modyfikacje są niewystarczające i jedynie przesuwają w czasie problem przechowywania szczepionek co nie likwiduje jednak zagadnienia produkowania dawek, które będą przeznaczone do utylizacji.

Niezbędna jest rewizja postanowień umownych na zakup szczepionek – brak działań w tym zakresie będzie równoznaczny ze złym zarządzaniem środkami publicznymi i wzrostem nieufności obywateli UE do działań podejmowanych w interesie ogółu społeczeństwa. Nie możemy wydawać środków publicznych na działania, które nie przynoszą korzyści dla zdrowia publicznego. Działania państw i instytucji unijnych muszą być racjonalne, gospodarne i dostosowane do faktycznych potrzeb Europejczyków.

W załączonym liście przedstawiamy propozycje rozwiązań, które powinny zostać uwzględnione w ramach uelastyczniania kontraktów.

Apelujemy do Komisji Europejskiej o zajęcie oficjalnego stanowiska w sprawie tych propozycji na posiedzeniu Rady EPSCO 14 czerwca 2022 r.

Zachęcamy również inne państwa członkowskie do poparcia podejścia zaproponowanego we wspólnym liście.

EPSCO Council (Health), 14 June 2022

AOB point:

Joint letter to EC concerning revision of the provisions of the purchase agreements for vaccines, with regard to the surplus of vaccines

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Poland, in cooperation with Bulgaria, Croatia, Estonia, Hungary, Latvia, Lithuania, Romania, Slovakia and Slovenia would like to inform about sending a joint letter addressed to the European Commission concerning revision of the provisions of the purchase agreements for vaccines, with regard to the surplus of vaccines.

Bearing in mind the current situation we would like to reiterate our concern with regard to the significant surplus of COVID-19 vaccines. Despite signs that the pandemic is subsiding and that satisfactory vaccination levels across the EU have been achieved, the contracts with vaccines' manufacturers provide for supply of quantities of vaccines that significantly exceed the Member States' needs and capacity to absorb them.

In view of the low global demand from third countries, there is a very high probability that doses supplied to the European Union might end up being disposed of.

We are aware that the European Commission is already negotiating with the vaccine manufacturers, but the solutions proposed by the contractors so far do not solve our problems in a long term, in a sustainable, and legally, financially and ethically sound manner. The proposed amendments to the purchase agreement are insufficient and only delay the problem of vaccines storage, which does not eliminate the issue of producing doses that will be intended for utilisation.

Revision of the provisions of the contracts for the purchase of vaccines is essential - the absence of action will result in Europe's financial mismanagement and mistrust of the EU citizens' of actions taken in the interest of the general public.

We cannot spend public funds on activities that do not bring benefits to public health. The actions of the Members States and the EU institutions must be rational, economical and adapted to the real needs of Europeans.

In the attached letter we put forward suggestions for specific provisions to be included in the amended contracts. We urge the European Commission to take official position with regard to the solutions proposed during the EPSCO Council meeting on 14 June.

We also encourage other Member States to support the approach suggested in the joint letter.

Joint letter

of Bulgaria, Croatia, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia concerning revision of the provisions of the purchase agreements for vaccines, with regard to the surplus of vaccines

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TO
MS STELLA KYRIAKIDES
MEMBER OF THE EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY

Dear Commissioner,

Let us first express our gratitude for all the efforts to support Member States that the European Commission showed during the COVID-19 pandemic, especially in the area of the agreement to conclude, on behalf of the Participating Member States, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID-19 pandemic at Union level. This mechanism was a response to the difficult situation in which the whole Europe found itself, we believe that the experiences and lessons learned can contribute to building a stronger, solidary Europe.

We all truly appreciate your help and willingness to cooperate. However, bearing in mind the current situation we would like to reiterate our concern with regard to the significant surplus of COVID-19 vaccines. Despite signs that the pandemic is subsiding and that satisfactory vaccination levels across the EU have been achieved, the contracts with vaccines manufacturers provide for supply of quantities of vaccines that significantly exceed the Member States'needs and capacity to absorb them. We must remember that the conditions in the agreements negotiated by the Commission were based on the impossibility of predicting how the pandemic would develop at that point of time. Currently we witness excessive burden on state budgets, combined with delivery of unnecessary amounts of vaccines and short remaining shelf life of the vaccines.

In view of the low global demand from third countries, there is a high probability that doses supplied to the European Union might end up being disposed of: again, a waste of public resources that cannot be reasonably explained to the public.

We are aware that the European Commission is already negotiating with the vaccine manufacturers, but the solutions proposed by the Contractors so far do not solve our problems in a long term, in a sustainable, and legally and financially sound manner. The proposed amendments to the Purchase Agreement with Pfizer are an insufficient solution and only delay the problem of vaccine utilisation in time. Member States still have not clear guarantees concerning the development of an adapted vaccine, there is no requirement for minimum remaining shelf life at the time of delivery.

This situation requires action to minimise losses and in particular urgent amendments of the agreements concluded by the European Commission on behalf of the Member States in order to safeguard public interest by providing flexibility to Member states. In our opinion, we need to make the concluded contracts more flexible. Revision of the provisions of the contracts for the purchase of vaccines is essential - the absence of action will result in Europe's financial mismanagement and EU citizens' mistrust. We cannot spend public funds on activities that do not bring benefits to public health. The current inflexibility of contracts leads to a situation where public funds are allocated to large quantity of vaccines which are already destined for destruction. Additionally, we need to keep in mind the big environmental impact of large quantity of unused vaccines.

We propose to consider the following provisions to be included in the amended contracts and the following actions to be taken on the EU level:

1. reduction of the amounts of quantities and adaptation to the real needs of Member States and their national demand; possibility to spread the vaccine supply over a longer period conditional on the development of adapted vaccines, based on national demand and depending on the epidemiological situation. It is necessary to allow termination of agreements, including to ensure that the APA cease to be effective if they are no longer needed from health and epidemiological perspective;
2. to renegotiate the contracts not only in commercial terms, as outline above, but also in biomedical terms, since the virus is constantly mutating and vaccines must be adapted to new virus strains; it is necessary to emphasize the safety, adequacy and quality of products and their adaptation to the current epidemic situation. In view of citizens' trust, liability is an aspect, which also merits reflection;
3. to introduce requirements for minimum shelf life taken from the time of delivery;
4. to introduce mechanism where HERA Authority ("the buyer") repurchases Member States' vaccines to cover unmet global needs in a more coordinated manner and to create a joint stockpile that Europe might need for the emergency crisis.

Dear Commissioner,

We do hope that the European Commission will analyse proposed solutions related to the surplus of vaccines resulting from the current terms of vaccines agreements and will take action aimed at renegotiating these contracts in the way that will be beneficial for national healthcare systems of all Member States. We truly believe that the discussion among the EU Member States and the European Commission will make vaccine agreements more flexible in a way that achieves in the same time public health objectives in the EU and the sustainability of public finances.

We expect that the European Commission will present a formal position on this matter during the EPSCO Council in June.

Sincerely,

Asena Serbezova
Minister of Health
Republic of Bulgaria

МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО

Vili Beroš
Minister of Health
Republic of Croatia

REPUBLIC OF CROATIA
MINISTRY OF HEALTH

Tanel Kiik
Minister of Health and Labour
Republic of Estonia

REPUBLIC OF ESTONIA
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Sándor Pintér
Minister of Interior
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Daniels Pavļuts
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