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The Hungarian national medicine factory will produce Russian Sputnik V and Chinese Sinopharm

On Monday, September 6, 2021, the groundbreaking ceremony for the national drug factory (nemzeti oltóanyaggyár) in Debrecen took place. The factory is to be launched next year and is also to produce vaccines against COVID-19, including the Russian Sputnik V and Chinese Sinopharm vaccines. The investment is expected to increase Hungary's security in the face of the current SARS-CoV-2 pandemic, but also to serve future medical challenges.

Pandemic as a catalyst for change. Hungary has been talking about a national vaccine factory for a long time. Debrecen is the second largest city in Hungary, located in the north-eastern part of the country in the county of Hajdú-Bihar. Plans to build a factory in Debrecen were drafted in 2017, but were sped up by the coronavirus pandemic. A year ago, when the Hungarian government declared its interest in acquiring the Russian Sputnik V vaccine, there was talk of the possibility of producing this drug in Hungary. The factory is to be a significant contribution of Hungary to technology and innovation related to the vaccination market. It is worth recalling in this context that during a meeting between Viktor Orbán and Benjamin Netanyahu, which took place in March 2021, the Hungarian Prime Minister expressed his willingness to involve Budapest in the Israeli initiative related to the construction of a consortium in which vaccines for further diseases will be developed and produced in Israel. Perhaps the vaccines will also be produced in Debrecen. Orbán said then that "experience teaches that it is better to be a producer than a customer who wants to buy this type of product".

The investment is to guarantee the production of not only SARS-CoV-2 vaccines, but also—and in fact, mostly – other domestic vaccines. Minister Palkovics said that the factory would also provide effective protection against other potential pandemics, as well as jobs (the number was not specified). Palkovics stressed that vaccines were produced in Hungary until the 1990s; however, after that period, with the economic transformation, the industry collapsed.

During the pandemic, the Hungarian government proposed a formula of cooperation with four medical universities in Hungary and with research institutes, which were to propose new initiatives related to the production of medical equipment and the development of new treatment procedures. There were 120 such projects. Palkovics pointed out that the situation Hungary faced at the beginning of the pandemic in March and April 2020, i.e., the lack of protective equipment, but also other medical equipment, proved that "in such a situation, we can only count on ourselves". On the other hand, it is worth pointing out here that throughout the entire pandemic period, Hungarian politicians even prided themselves on the fact that they were "not alone" thanks to the help mainly from China.

Among other opinions that appeared in the context of the investment in Debrecen, two statements can be cited. The first is that the vaccine is related to freedom of movement, so an initiative will be taken in Debrecen to put the city on the global health map. In turn, the rector of the University of Debrecen described the investment as "one that will affect the fate of the country".

Sinopharm and Sputnik V made in EU? The Chinese and Russian vaccines are the first known to be (or at least, planned to be) produced in Debrecen. This fact may have some influence on obtaining approval for Sinopharm and Sputnik V from the European Medicines Agency (EMA) for use in the European Union, as they will receive a label that they were produced in the European Union. However, it should be borne in mind that the current prohibition of the above-mentioned "eastern" vaccines is not only due to the place of their production, but above all the results of clinical trials.

The Sinopharm and Sputnik V vaccines have been approved in Hungary directly by OGYÉI (Országos Gyógyszerészeti és Élelmezés-Egészségügyi Intézet), an equivalent of the Polish Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products, and the minister, Péter Szijjártó, could also take this decision on

the basis of extraordinary powers and foreign trade. The issue of admitting eastern vaccines is extremely important for Hungary, because the EU COVID certificate is not issued to persons who have been vaccinated with products not approved by the EMA.

From the beginning of the vaccination program, the Hungarian authorities issued a national “certificate” confirming vaccination. Such a document could be obtained 8 days after receiving the first dose of the vaccine. The regulation on introducing a national certificate was quickly amended by removing the name of the product that someone was vaccinated with. This was intentional, as patients vaccinated with products not approved by the EMA may not be considered vaccinated under the laws of other countries. At the time, Hungarian authorities spoke of a policy discriminating against types of vaccines that save lives.

In total, 7,000,000 doses of Sputnik V and Sinopharm were delivered to Hungary, which means that up to 3,500,000 people could have been vaccinated with these products. According to data from September 8, 2021, the total number of vaccinated persons in Hungary was 5,826,000. After deducting from this number those who could have been vaccinated with Sputnik V or Sinopharm, the number vaccinated with EMA-approved products would be approximately 2,326,000, i.e., a definite minority of patients. This has significant consequences, as 3,500,000 people cannot move freely within the territory of the European Union. Another possible consequence is that Hungarians have an insufficient level of herd immunity, which will meet the accepted criteria in terms of numbers (i.e., the number of vaccinated people), but not in terms of actual medical immunity.

As an aside, it is worth adding that on March 22, 2021, OGYÉI allowed the use of two more vaccines – from China, CanSino, and from India, Covishield – but the government did not order these products.

Conclusions. Hungary’s policy is to prove that the country can become self-sufficient in the event of successive waves of the COVID-19 pandemic as well as possible new pandemics. Self-sufficiency is to be achieved in two ways. On the one hand, by producing products that counteract the pandemic, and on the other hand, by ensuring the continuity of supplies not only from the European Union, but also from outside it.

The question remains whether Hungary’s vaccine policy will in any way affect the EMA’s decisions regarding the potential approval of Sinopharm and Sputnik V, which will be an extremely important issue. It cannot be ruled out that [a lack of] freedom of movement will become one of the topics determining next year’s election campaign in Hungary. The Hungarian state is seeking further agreements under which Hungarians vaccinated with products not approved by the EMA will be able to travel freely to other countries – but there have been no announcements recently on this matter.