QUINTO EJERCICIO DE LA OPOSICIÓN AL CUERPO TÉCNICO DE AUDITORÍA Y CONTROL EXTERNO DEL TRIBUNAL DE CUENTAS (INGLÉS)

(Resolución de la Presidencia del Tribunal de Cuentas de 25 de octubre de 2021, B.O.E. Nº 265 de 5 de noviembre de 2021)

Debe traducir el siguiente texto al español:

Conclusions and recommendations

72. We examined the Commission's preparations for the procurement of COVID-19 vaccines as well as the conduct of the negotiations and the extent to which the EU's negotiators were able to secure the EU's procurement objectives in the contracts it signed with vaccine manufacturers. We also examined what remedies the EU could use when faced with supply disruptions and how the Commission helped support the production of vaccines for the EU.

73. We conclude that by signing contracts with a number of different manufacturers covering different technologies in order to spread and reduce the risk of failed vaccine development, the EU managed to procure COVID-19 vaccines it needed.

74. We found that the EU's preparations for the procurement of COVID 19 vaccines were mostly effective. The EU identified vaccines as a key element in the fight against COVID-19 early on in the pandemic and took steps to create an ad hoc and tailor-made procurement system to secure vaccines for EU citizens. However, the EU started this procurement process later than the UK and the US.

75. The EU had to act ahead of clear scientific data on vaccine candidates' safety and efficacy, and therefore chose to back a range of candidates in its initial portfolio. The initially diversified portfolio of vaccines is dominated by the Pfizer/BioNTech vaccine for 2022-2023, which the Commission states is necessary for reasons of security of supply. The Commission produced its vaccine strategy in the early stages of the pandemic, at a time when there were no COVID-19 vaccines on the market.

76. The EU's negotiators were better able to secure the EU's procurement objectives in the later contracts it signed with vaccine manufacturers. The terms of the contracts evolved over time and those signed in 2021 have stronger provisions on key issues such as delivery schedules and production location than those signed in 2020. EU negotiators took a flexible approach to negotiations with vaccine manufacturers, imposing only one negotiating red line: adherence to the Product Liability Directive[1]. The liability and indemnification clauses have remained the same: Member States have taken over some of the financial risk (i.e. compensation payments and legal costs) linked to vaccine administration from the manufacturers. This reflects the unique circumstances at the time these clauses were agreed. The Commission and ten of the 14 Member States that responded to our survey wish to see a more standard liability regime when the standard marketing authorisation has been granted.

77. We found that the Commission had limited leverage to overcome supply challenges. The Commission acted as a bridge between companies and Member States for contract implementation but it did not fully analyse the production and supply chain challenges of vaccine production until after signing most of the contracts and most contracts did not include specific provisions to address supply disruptions. The Commission could, and in one case did, take manufacturers to court. The Commission only set up a task force to support manufacturing and supply chains in February 2021 and while it did help resolve bottlenecks, its impact on the ramp-up of vaccine production was unclear.

78. A new procurement system was rapidly set up and delivered a diversified portfolio of vaccine candidates for the EU. The Commission proposed to continue the procurement approach set up for COVID-19 for future health crises, but neither the Commission's nor the Council's "lessons learned" reports on the COVID-19 pandemic examined the performance of the vaccine procurement process, beyond its overall outcome. The Commission has not studied third country procurement systems to identify good practices.

Recommendation 1 – Create pandemic procurement guidelines on the basis of lessons learnt

Once the Emergency Framework Regulation and the revised Financial Regulation have been adopted, after consulting Member State authorities and relevant stakeholders, and benchmarking with other procurement systems to identify good practices, the Commission should produce pandemic procurement guidelines and/or lessons learnt for future negotiating teams.

[1] COUNCIL DIRECTIVE of 25July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC).

79. The EU is putting in place a range of new pandemic preparedness and following the outbreak of the COVID-19 pandemic. It is as a result taking on a greater role in preparing for and responding to pandemics, notably in the field of procurement. The Commission did not evaluate and report on the procurement of medical countermeasures and the use of the Emergency Support Instrument, despite having been invited by the Council to do so.

80. The EU's new competences and activities were not determined on the basis of an ex-ante impact assessment. Issues in the EU's procurement process such as identifying which skills are needed in the EU's negotiating team or how the EU can best contribute to solving supply chain and production issues remain to be addressed.

81. Despite the WHO considering pandemic planning exercises to be an integral part of preparedness and despite the Commission supporting preparedness and response projects at EU and Member State level since 2003, the Commission is not currently planning to test its new competences for procurement of medical countermeasures through exercises and simulations to identify and address areas for improvement.

Recommendation 2 – Stress-test the EU's medical countermeasures procurement approach

The Commission should, in order to be in line with best practices and contribute to the review of the Council Regulation on an emergency framework for medical countermeasures:

(a) carry out a risk assessment of the EU's procurement approach and propose appropriate measures;

(b) run exercises to test all parts of its updated pandemic procurement framework, including information and intelligence gathering, to identify any weaknesses and areas for improvement and publish the results.