

Medical Device & AI Regulations

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Effective Management in Times of Health Crisis

The COVID-19 pandemic and the rapid evolution of events on a national and international scale required the adoption of immediate and effective measures to deal with these events.

In this article we would like to share our experience as a public procurement department that faced the pandemic by taking innovative actions to respond to this world-wide health crisis.

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key points

- The rapid responsiveness of Public Procurement Units to the pandemic.
- The need for public-private partnerships is illustrated.
- The importance of collaboration between different public administrations is key.

Introduction

The COVID-19 pandemic has illustrated the need to change the ways in which health care tasks have been carried out, generating expectations and opportunities, which must be reflected in the day-to-day work of the Public Procurement Units, with an eye towards consequences for the organisation as a whole.

The immediacy of the pandemic and its high incidence has forced us to undertake a transformation in the public procurement model, including tasking professionals to perform actions without previous experience, and establishing new systems with clearly differentiated actions and responsibilities. This was done in order to optimise the response to the increased demand for contracts in order to cover the increasing procurement needs to which the healthcare centres were subjected.

As soon as the declaration of the state of emergency in Spain, all activities of a contractual nature ceased in accordance with the provisions of the Fourth Additional Provision of the Suspension of the Limitation and Expiry Periods of Royal Decree 463/2020 of 14 March.

Exceptions were those activities derived from the monitoring and payment of agreements, concerts, contracts and other agreements with external funds, including hospitals under concession, given the serious

damage that the cessation of these activities would have entailed.

It should also be remembered that the legislation in force in Spain is Law 9/2017 of 8 November on Public Sector Contracts, which absorbs into Spanish law the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (Hereinafter PSCL).

Our Experience

One of the first responses to the pandemic was the reorganisation of the staff of the Subdirectorate General of Public Procurement (hereinafter SGPP), creating two working teams to draw up the different types of contracts.

The first team was dedicated to the formalisation of those procurement files for services and/or equipment, in which it had more experience and prior knowledge.

The second team was dedicated to the procurement of medical supplies and personal protective equipment (PPE) in response to an unprecedented demand for products, which also involved the management of suppliers and the development adjustments of the logistics of these supplies and medical devices, tasks that had not been carried out before the pandemic by the SGPP.



The second initiative was to develop a network of suppliers in order to guarantee the supply of medical equipment and PPE.

As we were asked to collaborate in the provision of the IFEMA COVID-19 Field Hospital, which had to be able to treat patients within 48 hours, we decided to contact the Spanish Federation of Healthcare Technology Companies (FENIN), in order to facilitate contact with associated suppliers. The response was immediate, and that weekend in March we were able to start contracting the much-needed supplies.

Emergency Service.

Aware that we could only respond to PPE acquired from the SGPP and not to other PPE received in the warehouse from different sources, we formalised a procedure called: “Management of enquiries regarding personal protective equipment”.

The aim of this procedure was to standardise the methodology to be followed for the management of enquiries made by healthcare centres of the Madrid Health Service (hereinafter SERMAS) (hospitals, primary care centers and Summa 112) regarding

The high responsiveness of Public Procurement Units to the pandemic

This relationship, still active, has enabled us to provide the healthcare centres such as the IFEMA COVID-19 Field Hospital and later the Enfermera Isabel Zandal Emergency Hospital, with appropriate supplies, medical devices and PPE within the regulatory framework.

With centralised public procurement in place as well as the start-up of the IFEMA COVID-19 Field Hospital, the next step was a central warehouse.

The already smooth communication with the personnel stationed there led to the creation of a single e-mail address for the management of any incidents that might arise in the warehouse with any of the deliveries of goods to ensure a prompt solution, as well as the monitoring of stocks to help us identify the specific needs for material, especially PPE.

The next initiative involved guaranteeing the traceability of the material. The formalising of the public procurement process necessitates tracing the process of ordering, billing and payment of the corresponding invoice. To safeguard that entire chain of events we decided to implement the SAP “NEXUS LOGISTICO” environment application for PPE material contracts.

We were aware that this system involves a large number of administrative transactions, but it allows us to have total control of the entire purchasing, logistics and payment process, from the formalisation of the contract, request to the supplier, receipt of the product, and finally billing and payment.

In time, and with the increasing number of patients affected by the COVID-19 disease, we began to receive requests for information regarding the suitability of the PPE distributed from the central warehouse to the hospitals, Primary Care centres, and the “SUMMA 112”

compliance with the regulations required of the PPE supplied to them during the pandemic.

In order to respond to queries on PPE not acquired by us, we contacted the National Centre for Means of Protection (hereafter CNMP), through the National Institute for Safety and Health at Work of the Ministry of Labour and Social Economy, in its capacity as the authorised centre for carrying out the tests considered critical to verify whether the self-filtering masks type FFP2 and FFP3 submitted offer protection against the penetration of particles, with a view to allowing their use during the COVID-19 pandemic.

Along the same lines, we got requests for gloves not acquired by us. It was agreed to validate those gloves through tests considered critical to verify whether the gloves submitted offer some protection against contact with micro-organisms, with a view to their use during the COVID-19 pandemic.

All the information resulting from these validations was sent to the health centres and is also available in the common electronic folder created for this purpose.

This procedure received special recognition by the International Hospital Federation (hereinafter IHF) under the “Beyond the call of duty for COVID-19” programme.

We presented the above described under the title “Beyond Health Public Procurement: How We Manage To Improve The Protection Of Health Professionals Against COVID-19” and were recognised among the 15 best projects for “having shown initiative, agility and an incredible ability to innovate under extraordinary circumstances”.

A PPE advisory group was also formed with technical staff and doctors from SERMAS who voluntarily



accepted to form part of the project, and who have contributed to the drafting of the technical prescriptions that will be used for the centralised acquisition of PPE.

We also had an important collaboration with the General Directorate of Industry, Energy and Mines of

actions can respond to the needs that may arise from a resurgence of the pandemic caused by COVID-19, or any other similar situation. All of them remain active.

None of us expected the events that took place, neither the 14 weeks of state of alarm that we experienced nor

The need for public-private partnerships is illustrated

the Regional Ministry of Economy, Employment and Competitiveness on the technical requirements of PPE.

Finally, we are aware that the implementation of a single catalogue of health products for all SERMAS health centres means facilitating centralised purchasing and its subsequent distribution to health centres. In this sense, work has expanded on the implementation of the single catalogue, and since the beginning of the pandemic, 9 health centres have been included in this single catalogue. We believe that this is the only way to have a centralised logistics platform.

Finally, it is worth noting that from the very first moment the pandemic was declared by the World Health Organisation, an information system was set up at the SGPP to monitor the pandemic, using various Spanish and international data sources. These sources reported on the pandemic situation in real time.

This exhaustive monitoring gave rise to our own information system, which allowed us to acquire what we needed before the appearance of the second pandemic wave, and this dynamic was maintained in successive waves. This working dynamic allowed us to guarantee material to the health centres by acquiring it before other public procurement departments, without any stock-outs. It also allowed us to introduce diagnostic tests for COVID-19 ahead of the decisions of other public procurement departments.

At least in Spain, we were the first to go to the market for these tests.

Conclusion

In a very short time we have taken practical and immediate measures to meet the strong demand for care caused by the pandemic, trying to guarantee the health care demanded by citizens and to guarantee the protection of healthcare professionals. As a result, these

the weeks that followed. But it is not all behind us, we are still in a state of health crisis and we are aware that new pandemics may occur. This makes us vigilant and alert, but we are convinced that in future situations we will be able to cope with what we have learned so far.

Our experience shows us the importance of maintaining and intensifying coordinated and collaborative work between different areas (procurement, logistics-warehouse, hospitals, SUMMA 112, Primary Healthcare, suppliers...), both in our own organisation and in other organisations, whether public or private. Multidisciplinary work, such as that formed with prevention technicians, also guarantees new synergies. For this reason, we are working on forming groups of experts even for the technical design of new public contracts.

Telemedicine has proven to be useful especially in risk situations for health care workers.

But it has also proved useful in streamlining processes, and it is a tool that has been a boost to the motivation and dedication of public procurement professionals. We must not forget that people are the real driving force of any organisation. That is why their motivation is so important, and this requires training and professionalisation, which is why we provide training tools and work towards staff recognition.

I am sure that all these activities will continue to grow, as they are lines of action that have a positive impact on improving the public procurement of goods and services that are so important and have such an impact on the entire organisation. We dedicate every day to this objective.

Conflict of Interest

None. ■

references

For full references, please email edito@healthmanagement.org or visit <https://iii.hm/1jxw>



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