



## SPECIAL ARTICLE

Bilingual edition English/Spanish

**Hospital Pharmacy: Comprehensive management of medical devices during SARS-CoV-2****El servicio de farmacia: Gestión integral de productos sanitarios en SARS-CoV-2**

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DOI: 10.7399/fh.11486

**How to cite this paper**

Climent-Ballester S, Selva-Otaola J. Hospital Pharmacy: Comprehensive management of medical devices during SARS-CoV-2.  
Farm Hosp. 2020;44(Supl 1):S21-3.

**Abstract**

Medical devices have become essential to the prevention and control of the COVID-19 pandemic, being crucial for health professionals and patients in particular, and the population in general.

It is important to be aware of the laws that regulate the management, distribution, and control of medical devices. Article 82 of the Spanish Law 29/2006 on Guarantees and Rational Use of Medicines and Medical Devices establishes that it is the responsibility of Hospital Pharmacy Services "to participate and coordinate management of purchase of medicines and medical devices in the hospital to ensure an efficient acquisition and rational use of medical devices". For this reason, working groups of the Spanish Society of Hospital Pharmacy and other scientific societies have issued technical guidelines and consensus statements to provide technical support and updated information on the use of masks, individual protection equipments and other medical devices.

In addition, the shortage of medical devices caused by the high demand has resulted in the uncontrolled production and distribution of medical devices. This phenomenon, added to the fraudulent selling of medical devices, highlights the need for a closer surveillance of the market to guarantee the efficacy and safety of available medical devices.

A rational use of medical devices is necessary to ensure the availability and safety of these products, which requires the involvement of different stakeholders, including hospital pharmacists. Thus, it is essential that hospital pharmacists receive specific training in technical aspects concerning the possession and use of medical devices. This will help guarantee an effective and safe use of medical products.

**Resumen**

Los productos sanitarios se han convertido en imprescindibles en la prevención y control de la pandemia actual generada por COVID-19, tanto para el personal sanitario y pacientes, como para la ciudadanía en su totalidad.

Los productos sanitarios cuentan con una legislación propia que es preciso conocer para su correcta gestión, distribución y control. El artículo 82 de la Ley 29/2006 de garantías y uso racional de los medicamentos y productos sanitarios establece que es responsabilidad de los servicios de farmacia hospitalaria "participar y coordinar la gestión de las compras de los productos sanitarios del hospital a efectos de asegurar la eficiencia de la misma y así contribuir al uso racional de los mismos". Por este motivo, grupos de trabajo de expertos de la Sociedad Española de Farmacia Hospitalaria, junto a otras sociedades científicas, han desarrollado durante esta pandemia documentos técnicos y consensos para dar soporte técnico e informativo de forma actualizada en relación con las mascarillas, los equipos de protección individual y otros productos sanitarios.

Por otro lado, los problemas de desabastecimiento secundarios a la elevada demanda han llevado a una producción y comercialización descontrolada de productos sanitarios. Este hecho, asociado a la comercialización fraudulenta de productos sanitarios en el mercado, ha generado la necesidad de una vigilancia exhaustiva, capaz de garantizar la eficacia y seguridad de los productos sanitarios en circulación.

El uso racional, para asegurar la disponibilidad y seguridad de los productos sanitarios, es una responsabilidad multidisciplinar compleja. Para

**KEYWORDS**

Pharmaceutical care; Hospital pharmacy service; Coronavirus; SARS-CoV-2; Pandemic; Management; Medical devices.

**PALABRAS CLAVE**

Atención farmacéutica; Servicio de Farmacia Hospitalaria; Coronavirus; SARS-CoV-2; Pandemia; Gestión; Productos sanitarios.



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The acquisition and use of medical devices requires a keen understanding of the technical and legal aspects concerning these products, which makes hospital pharmacists essential for the integral management of medical devices.

## Introduction: challenges and objective

In the current public health crisis, medical devices (MD) have been at the epicenter of the pandemic both for health professionals, patients and the general population. Although there are regulations in Spain governing the use and distribution of MD, these may be inadequate due to the lack of training and knowledge of professionals, added to leadership conflicts in critical situations may favour the inadequate management and use of these products.

Royal Decree 1591/2009 defines medical devices as any instrument, device, equipment, software, implant, reagent, material or other article intended by the manufacturer to be used on humans for the diagnosis, prevention and/or treatment of diseases which principal intended action in the human body is not achieved by immunological, pharmacological or metabolic means. MD include devices for the washing, disinfection or sterilization of other MD, and instruments intended to regulate or support conception. This definition illustrates the relevance of MD in the prevention and control of the pandemic. In accordance with this definition, masks, gloves, gowns, and other individual protection equipment (IPE) are medical devices for hygiene and protection<sup>1</sup>.

European Union regulations allow the free movement of MD within the European market and guarantee health protection and product safety. In Spain, the use and distribution of MD is regulated by Royal Decree 1591/2009, which transposes the European Directive 93/42/CEE<sup>2</sup> and classifies them as I, IIA, IIB and III according to the risk they pose to the human body. In accordance with this classification, Class I products are low-risk; class IIA are medium-risk; IIB are medium/high-risk; and class III are high-risk. Classification rules are based on considerations related to the duration of contact with the patient, the invasive character or modification of the anatomy affected by the use of the MD, and categorization as an active or non-active device.

Additionally, article 82 of Law 29/2006 on guarantees and rational use of medicines and medical devices obliges hospital pharmacies to take part in and coordinate the procurement of medicines and MD in the hospital to ensure an efficient and rational use<sup>3</sup>. The duties and tasks of hospital pharmacies are described in Chapter 3, article 84.2 of the Royal Legislative Decree 01/2015, which approves the Reformed Text of the Law on Guarantees and Rational Use of Medicines and medical devices. "Participate in and coordinate the procurement of medicines and medical devices in hospitals to guarantee efficiency. These functions are exclusive of this unit and are not shared with other units such as that of clinical pharmacology"<sup>4</sup>.

In a situation of risk where the safety of patients, health professionals and the general population is compromised, active surveillance of MD is crucial and the ultimate responsibility of the hospital. The person in charge of MD surveillance is the Head of the Service/Section of Pharmacy or other professionals including the medical director, the head of the service/section of preventive medicine or the charge nurse, among others. Surveillance tasks include the supervision, coordination, channeling, and promotion of adverse-event reports. The person responsible for MD surveillance also acts as a representative before health authorities and is accountable for the recording of adverse events reported to the center and communicating alerts to users.

Considering their duties and responsibilities, hospital pharmacists are included in clinical teams in critical situations such as a pandemic or a disaster. In the COVID-19 pandemic, hospital pharmacists apply their technical skills and understanding of the potential risks associated with the use of MD to guarantee a rational use.

The Workgroup on Medical Devices (GPS) of the Spanish Society of Hospital Pharmacy (SEFH), in collaboration with other SEFH workgroups such as GEDEFO and the Workgroup on Pharmacological Technology, is

actively engaged in training and information activities related to MD. During the pandemic, this Workgroup has generated resources of interest and solved the most frequent doubts about the COVID-19 pandemic<sup>5</sup>. Their effort is illustrated by the large amount of technical and information documents, reviews, recommendations and information leaflets published. Information on the use of masks, IPE, and MD is constantly updated.

El conocimiento técnico y legal que requieren los productos sanitarios hace imprescindible la implicación del farmacéutico de hospital como uno de los profesionales sanitarios capacitado para la gestión integral de estos productos.

ello, es fundamental una formación específica como la del farmacéutico de hospital en aspectos técnicos de tenencia y uso que permite salvaguardar las garantías de eficacia, seguridad y calidad de los productos sanitarios.

Masks have been the most relevant MD during the COVID-19 pandemic due to their crucial role in preventing disease transmission. Below you can find a list of documents published to facilitate MD quality control and provide guidance on what to do in situations of MD shortage. This list was prepared by the GPS of the SEFH.

- 1) A review of the standards established in China (GB/T 32610-2016) for protective masks, as compared to ongoing trials in the European Union (UNE-EN 149:2001). This Review provides the degree of equivalence between filter masks certified under different standards as a result of the importation of masks from China, which certifications are not standardized<sup>6</sup>.
- 2) Basic information about filter and surgical masks. This document compares the filtration efficiency of the different types of masks and their standards, namely, UNE 149:2001 (Europe), NIOS 42 CFR 84 (USA) and GB2626 (China). This document also establishes the equivalence between different types of surgical masks based on their filtration efficiency and the technical standard EN 14683 (Europe), ASTM F2100 (USA) and YY 0469 (China)<sup>7</sup>.
- 3) Information on hygienic masks: definition and specifications of hygienic masks to help users identify and differentiate them from other types of masks and understand the level of protection offered by each one (hygienic, surgical, and filter masks)<sup>8</sup>.
- 4) A review of the information and evidence published in relation to the disinfection and re-sterilization of masks to face MD shortage during epidemics<sup>9</sup>.
- 5) A summary of guidelines issued by the European Centre for Disease Prevention and Control (ECDC), the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC)<sup>10</sup>.
- 6) Information on the different types of filter masks: identification and optimization of their use in pharmacy services<sup>11</sup>.
- 7) Basic information on the use and testing of surgical masks, classification, and equivalences between the different types of surgical masks<sup>12</sup>.

SEFH has designed a website that offers resources of interest on COVID-19 for pharmacists and other health professionals<sup>13</sup>, including information on MD.

For a marketing approval to be granted to a MD, it is required to meet a set of safety, efficacy and quality standards. Documents that demonstrate that the MD complies with all laws and regulations are also required. The CE marking is of special relevance, as it indicates compliance with European regulations, whereas the CE declaration of conformity guarantees that the product passed the conformity assessment procedure and has the certificate of conformity of the Notified Body. In Spain, the Spanish Agency for Medicines and Medical Devices (AEMPS) is the only Notified Body designated by the Ministry of Health (number 0318) and is also a health authority.

As a result of the unprecedented demand for MD and the resulting shortage caused by the COVID-19, a myriad of companies have emerged to offer protection equipment against coronavirus (gloves, masks, gowns etc.) of poor quality and suspicious origin marketed at exorbitant prices and suspected to come from the black market. If these products are not granted by the relevant Notified Body the certification required for that type of MD, as in the case of filter masks, it cannot be guaranteed that they meet European safety and efficacy standards. These products are not subject to postmar-

kerting surveillance and may compromise users' health. Fraudulent products have also appeared in the market with a false identity, origin, CE marking and/or falsified documents related to CE marking.

### Lessons learned. Future applicability in pharmacy services

The procurement and rational use of medical devices during this crisis is a multidisciplinary responsibility. The technical and legal knowledge required for these tasks render the role of hospital pharmacists (HP) essential, as they are qualified for the integrated management of medical products (MP). HP have extensive experience in the management of medicines, understand the technical criteria governing it, and are integrated in clinical teams<sup>14</sup>. Moreover, they are helping perform

a correct cost-benefit assessment during this public health crisis, and contribute to the evidence-based selection, surveillance and traceability of MP. Hospital pharmacists participate in central MP selection and evaluation boards, and are integrated in hospital boards for the selection and design of MP-use policies in their hospitals. Other tasks include the procurement, distribution, and integrated management of MP (similar to that of medicines). In sum, HP are responsible for the selection, procurement, receiving, storage, dispensing/distribution, follow-up, control, surveillance, and training concerning medical products.

In conclusion, MP are a professional area governed by strict regulations which requires the participation of HP in multidisciplinary teams in public and private centers, as they have the technical competence needed for the custody and use of MP, which guarantees an effective and safe use.

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