

## POSITION STATEMENT ON TELEPHARMACY SPANISH SOCIETY OF HOSPITAL PHARMACISTS (SEFH)

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### SEFH's Position Statement on Telepharmacy

SEFH believes that telepharmacy is a useful and necessary complementary tool for the delivery of specialized pharmaceutical care in areas such as patient follow-up; patient education, providing them with truthful professional information; coordination of clinical teams to promote continuity of healthcare and a multidisciplinary approach; and efficient drug delivery ensuring easy accessibility. All these activities should be geared toward the ultimate goal of improving health outcomes and maximizing patient safety.

SEFH considers that the delivery of telepharmacy is fully warranted provided that it is set within a clearly defined pharmaceutical care model governed by quality and safety-driven criteria. Telepharmacy should also meet the existing laws and regulations concerning health and pharmaceutical care, abide by the ethical principles inherent in healthcare, and follow the humanization-of-care strategy and the code of conduct adopted by the pharmacy profession.

SEFH urges healthcare authorities at the different levels of government as well as lawmakers, members of professional healthcare associations, leaders of hospital pharmacy departments, and representatives of patient associations to undertake such initiatives to ensure an efficient, safe and humane use of telepharmacy, both for patients and for professionals, and to promote research into the ways telepharmacy can be applied to improve health outcomes.

### Definition

Although the term *telepharmacy* is widely used both in Spain and abroad, it tends to be associated to a variety of goals, methods and applications. For that reason, SEFH would like to propose the following definition:(1)

***Telepharmacy involves the delivery of pharmaceutical services at a distance through the use of information and telecommunication technologies***

Considering the definition above, telepharmacy can be considered to encompass the main tasks usually conducted by hospital pharmacy departments: therapeutic validation, review of clinical documentation, pharmaceutical care, patient follow-up, adherence monitoring,

education and information on the drugs to be administered, coordination with other healthcare professionals (from the same or other hospitals), and evaluation of health outcomes.

Like on-site pharmaceutical care, telepharmacy may or may not be accompanied by dispensation and informed delivery of treatments, whether pharmacological, dietary, or other therapies, including investigational drugs.

## Background

The incorporation of information and communication technologies (ICTs) to telemedicine over the last few decades has brought about a veritable explosion in healthcare.(2) At the same time, patients have become more proactive, demanding greater access to information and a more participative role in the digital transformation of healthcare.(3) In this respect, European, national and regional authorities have long promoted the use of telemedicine as a tool to boost the quality of healthcare by way of both new legislation and new strategic policies.(4-6)

Specialist hospital pharmacists have also incorporated ICTs to their everyday professional practice. Indeed, in line with other international pharmacist associations,(7-10) SEFH has long promoted the use of such technologies with a view to improving the quality of the entire pharmacotherapeutic process, with patient safety and the improvement of patient outcomes as the main priorities.(11-13) Moreover, SEFH has since 2014 been working on the creation of a Strategic Outpatient Pharmaceutical Care Map (MAPEX project). Among other initiatives this project includes the development of the so-called “Capacity-Motivation-Opportunity” pharmaceutical care model, intended to incorporate telepharmacy to the clinical setting. (14-16) More recently, in 2020, SEFH published the *Marco Estratégico de Telefarmacia* (Strategic telepharmacy Framework), which constitutes the groundwork for this Position Statement.(1)

As a matter of fact, telepharmacy is already in use in several spheres both in Spain and the rest of the world, and its effectiveness has been analyzed in numerous studies with highly satisfactory results, from the point of view of health outcomes, patient perceived quality, and clinical efficiency.(17-20)

The success achieved by hospital pharmacy departments in urgently implementing telepharmacy services in the context of the Covid-19 pandemic attests to the technical competency of pharmacy professionals and to the existence of an appropriate legal framework. This success could lead to the widespread implementation of telepharmacy services beyond the context of the current state of emergency.

## Telepharmacy procedures

The implementation of telepharmacy services should be based on a standardized procedure defined by hospital pharmacy departments wishing to undertake such implementation. The approval of the hospital's management and/or the relevant region's health authorities is also required. The process must meet all the required quality standards.

For the implementation to be successful, a multidisciplinary team must be put together to take responsibility for the coordination and planning of the work. The roles and responsibilities of team members must be appropriately assigned and constant communication between the team and the different clinical stakeholders is essential.

**Inclusion of patients in a telepharmacy program must be based on the principle of equity and should not be restricted to specific conditions or medications. Inclusion criteria must only take into consideration patients' individual clinical, pharmacotherapeutic or personal needs** (autonomy, technological expertise, risk of social exclusion, technological barriers, socioeconomic barriers, availability of a caregiver, personal preferences). SEFH's *Modelos de Estratificación y Atención Farmacéutica* (Pharmaceutical stratification and care models) may be used as a guideline.(21)

The patients' electronic medical record (EMR) should be the centerpiece in telepharmacy delivery. The ECR must reflect the details of the patient's evaluation, it must be used as a source of information when preparing the different administrative and clinical documents required, and it must contain any recommendations or indications formulated by the specialist pharmacist.

As regards pharmaceutical care, telepharmacy mainly involves the following tasks: pharmacotherapeutic monitoring; educating patients and giving them information on the drugs prescribed to them; clinical coordination; and dispensing and informed delivery of drugs.

- **Pharmacotherapeutic monitoring**

It is considered that telepharmacy **allows specialist hospital pharmacists to carry out a remote clinical-therapeutic evaluation** of the patient. This contributes towards the main goal of pharmacotherapeutic monitoring, i.e. achieving the pharmacotherapeutic goals established for each patient. Therefore, as a general rule, **the therapeutic evaluation of both in- and outpatients must scrupulously follow a specific standardized pharmaceutical care procedure**. Pharmacotherapeutic monitoring should be performed jointly by the specialist hospital pharmacist and the other members of the multidisciplinary team, who should work in a coordinated and carefully planned manner, involving the patient and/or their caregiver at all times.

When carried out through telepharmacy, pharmacotherapeutic follow-up must include a re-stratification of patients' priorities; an assessment of their eligibility for remote monitoring; a determination of whether the treatment prescribed can be administered remotely; an evaluation of the patients' understanding of how and why they should be treated; the monitoring of adherence; and constant communication with the attending medical team in case difficulties are encountered in achieving the desired pharmacotherapeutic goals.

Patients must be provided with information on how to contact the pharmacy service to clarify doubts about their treatment or report emergencies, in which case joint decisions will have to be made in real time. To this effect, telemedicine-specific technologies and bidirectional synchronous (phone calls, video calls) and asynchronous (email, apps, instant messaging) communication tools are required to stay in touch with the patients.

- **Educating and providing information to patients and their caregivers**

Telepharmacy is a tool that makes it possible to educate patients and provide them with rigorous, truthful and up-to-date information. It is in fact a valuable tool to disseminate information, increase patients' knowledge and facilitate the development of e-learning, providing comprehensive fully-remote patient education, which optimizes time and saves healthcare resources. It is expected that telepharmacy will create communication, discussion and analysis spaces, help improve communication with patients and allow a better understanding of the latter's needs regarding their health and their treatment. Moreover, it will enable real-time measurement of health outcomes thanks to the incorporation of cutting-edge technological solutions to that effect. As a result, hospital pharmacists will be able to develop individualized follow-up and monitoring strategies.

- **Coordination with the multidisciplinary team**

**Telepharmacy is considered a safe and efficient tool to ensure proper coordination between the work of the hospital pharmacist and that of the other members of the multidisciplinary team.** The information transmission system should be integrated into the information systems of the health centers involved, and the procedures and activities should be agreed upon among the different teams.

At each pharmacy intervention or consultation, whether face-to-face or otherwise, hospital pharmacists must enter the relevant information into the patient's EMR to allow a multidisciplinary evaluation of the therapeutic strategies and follow-up plans to be carried out in the different clinical domains.

- **Dispensing and informed delivery of drugs**

**Telepharmacy ensures that remote dispensing and informed delivery of drugs is conducted in a safe manner. This requires careful planning and organization of the delivery circuit**, in accordance with the possibilities, infrastructure and material means available to each specific hospital. To facilitate coordination and thereby optimize the delivery of telepharmacy, single clinical acts will be favored, making face-to-face appointments to the pharmacy department coincide with other hospital appointments. In addition, scheduled appointments and a register of remote consultations will be required.

A validation procedure must invariably be followed prior to the delivery of a prescribed drug. **A remote consultation with a specialist hospital pharmacist will obligatorily take place whenever a drug is delivered to a patient** in order to perform the required pharmacotherapeutic monitoring and enter a record into the patient's EMR. It is essential to ensure the confidentiality, safety and traceability of the whole process (dispatch, custody, preservation, delivery and reception). The patient's consent must also be obtained.

#### **Research, innovation, indicators**

The encouragement of research and innovation, and the measurement of their impact, should be a priority for any hospital pharmacy providing telepharmacy services. Close monitoring of the work done permits an appraisal of the standard of service provided. Such appraisals should be conducted using indicators suited to the characteristics of the specific telepharmacy project implemented, which should allow a joint evaluation of efficiency, health impact, technological efficacy and return on investment.

To this effect, a custom scorecard should be developed, integrated within the hospital's own scorecard, which contains indicators for follow-up, activity, quality, satisfaction, costs, patient reported information and overall outcomes. This will make it possible to analyze, compare and measure the impact of the specific telepharmacy service implemented.

#### **Necessary resources**

The relevant government bodies must make available the means required for the proper provision of telepharmacy services.

- **Human resources**

All the stakeholders involved in the provision of telepharmacy services, both healthcare providers (pharmacists, physicians, nursing staff and others) and the patients receiving such services, should be appropriately educated regarding the use of telepharmacy tools so as to ensure that the service provided is of the expected standard. In this respect, an education program should be established that includes technological capacity-building and contents

related to appropriate service provision, procedures, quality and safety standards and communication strategies.

In this respect, a helpdesk should be established to provide users with technical support and assist them with their training, clarifying any doubts they may have. It should also help them with the functional maintenance of the technologies developed, ensuring that the service is provided appropriately.

Any agreement entered with telepharmacy service providers should adhere to the policies, procedures and work standards established.

Finally, once a telepharmacy program has been implemented, it is essential that it should be developed appropriately over time. That is why **it is necessary to implement a plan that ensures that telepharmacy services can efficiently cope with the stipulated demand with appropriate quality and safety standards.** Also, a risk assessment program should be established, accompanied by a contingency plan, so that any difficulty arising while telepharmacy services are provided can be swiftly addressed.

- **Material resources. Technology**

Material resources, particularly those of a technological nature, are also essential for a successful implementation of telepharmacy. Apart from providing the groundwork for appropriate pharmaceutical care, such tools must be integrated into the healthcare information systems and the telemedicine systems already in place in the relevant hospital or regional healthcare system. Interoperability among the different tools implemented, and the security and integrity of patient data and information systems should be guaranteed.

Institutions and government agencies must establish a standard methodology to evaluate telepharmacy or telemedicine tools in such a way as to ensure their quality and usefulness, as well as their attunement to the patients' needs. Moreover, a set of minimum technological requirements or components must be defined for the proper development and implementation of telepharmacy tools.

**All implemented telepharmacy tools must ensure the security and confidentiality of information, as well as the protection of all user data.**

#### Legal framework

- **National and regional regulations**

There are currently very few regulations in Spain regarding the provision of telepharmacy services, all of them adopted by regional authorities. One such norm is Instruction 6/2018 of

the Regional Secretariat for Universal and Public Health of the Valencia Region, issued on 7 January 2019,(22) which regulates the way drugs must be home dispensed to outpatients. Another example is Galicia's Law 3/2019 on the organization of pharmacy services (published on 2 July 2019), which authorizes informed delivery of hospital-dispensed drugs at the patient's home.(23). The scarcity of regulation in this area **means that both state and regional authorities should introduce a clear and robust legal framework for telepharmacy suited to the patients' needs and the realities of the current healthcare scenario.**

At any event, any initiative taken in the realm of telepharmacy must ensure compliance with other norms required for their implementation such as those related to information on the patient's clinical status and degree of autonomy, with the limits and powers pursuant to Law 41/2002 (24) and the corresponding regional regulations on the subject.(25-28). At the same time, strict compliance is required with the requirements established in the relevant privacy laws and regulations, particularly the General Data Protection Regulation, Organic Law 3/2018 (LOPDgdd) and the *Esquema Nacional de Seguridad* (Spanish Security Framework).(29-30)

- **Emergency regulations following the COVID-19 outbreak**

Following the outbreak of the COVID-19 pandemic, the Spanish Ministry of Health published a series of emergency regulations including ordinance SND/293/2020 (25 March 2020), which establishes the conditions for dispensing and administering drugs within the Spanish National Health System.(31) This document declares that every autonomous region may introduce the measures they consider most appropriate to guarantee delivery of hospital-dispensed drugs. It also regulates home delivery of investigational drugs to patients on clinical trials. Further to the introduction of this emergency measure, all autonomous regions have adopted resolutions allowing and ensuring drug delivery at the patient's doorstep. These decisions have been accompanied by the establishment of remote pharmaceutical care procedures to allow the continuity of pharmaceutical care, ensuring maximum levels of effectiveness, safety and adherence.

### **Ethical responsibilities**

The practice of telepharmacy should be guided by the search of professional excellence proposed in the latest version of the Spanish Code of Ethics for Pharmacists (2015) and the four principles of Biomedical Ethics.(32-33)

The principle of autonomy requires patients to indicate that they are willing to and in agreement with participating in the telepharmacy program and to fill in an informed consent form acknowledging their co-responsibility in the use of the prescribed drugs. Patients also have the right to withdraw their permission at any time.

Pharmacotherapeutic monitoring based on the use of ICTs, remote dispensing and informed delivery of drugs allows patients to manage their time more flexibly, provides a more individualized service, and promotes the bioethical principle of beneficence, striving to preserve the patient's wellbeing.

The development of any telepharmacy procedure should be guided by ethics, non-discrimination, solidarity, proportionality and transparency, all of them essential ingredients in the pursuit of equity.

It is the specialist hospital pharmacist's duty to ensure an appropriate use of technology to complement and enhance the specialized pharmaceutical care provided, offering alternatives, promoting humaneness in care and giving patients and their caregivers the support they need in monitoring their disease in the outpatient setting.

*This position statement of the Spanish Society of Hospital Pharmacists is based on a document titled Marco Estratégico en Telefarmacia (Strategic telepharmacy framework) prepared as part of the above-mentioned MAPEX project. The purpose of the MAPEX project was to establish an outpatient care framework for specialist hospital pharmacists. This work was reviewed by the Board of Trustees of the Spanish Society of Hospital Pharmacists in May 2020.*

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