Draft Decree of the Governing Council partially implementing Law 13/2022 of 21 December 2022 on Pharmaceutical Management and Care in the Community of Madrid, covering opening hours, out-of-hours and holiday services, personalised dosage systems, pharmaceutical care and dispensing with informed delivery to the home, and the transfer authorisation regime for retail pharmacies.

Article 43 of the Spanish Constitution recognises the right to health protection, establishing that the public authorities are responsible for organising and protecting public health by means of preventive measures and the necessary benefits and services.

Law 14/1986 of 25 April 1986, the General Health Law, as a basic law, responded to that constitutional requirement by proposing the creation of a National Health System, in which each autonomous community would establish a health service comprising all of the health centres, services and establishments managed by the autonomous community itself and authorising each of them to lay down implementing and supplementary regulations under the powers conferred upon them by their respective Statutes of Autonomy. By virtue of these powers, Law 13/2022 of 21 December on Pharmaceutical Management and Care in the Community of Madrid was approved, which is being partially implemented, addressing aspects such as the regulation of extended opening hours, out-of-hours and holiday services, requirements for preparing and delivering personalised dosage systems, pharmaceutical care and dispensing with informed delivery to the home and, finally, the dispatch authorisation regime for retail pharmacies in the Community of Madrid. This integration into a single regulation allows for clearer and more consistent regulation, facilitating its interpretation and application for citizens, pharmaceutical professionals and health authorities alike, while also helping to streamline the legislative process by addressing various aspects of the law comprehensively in a single regulatory document.

For its part, Law 16/1997 of 25 April 1997 on the Regulation of Retail Pharmacy Services establishes that the autonomous communities may regulate various aspects of pharmacies, such as: the minimum number of assistant pharmacists, in addition to the licence-holder, who must provide services in pharmacies; official opening hours; rules on out-of-hours duties, holidays, emergencies and other circumstances arising from the nature of their service.

It also recognises, among the basic services to be provided to the population, the following: information and monitoring of pharmacological treatments, collaboration in the control of the individualised use of medicinal products and collaboration in the programmes promoted by the health administrations on

quality assurance of pharmaceutical care and healthcare in general; the promotion and protection of health, prevention of disease and coordinated action with the health service care structures. In addition, it lays down specific provisions in Article 4 concerning dispatches from retail pharmacies.

On the other hand, Article 86 of the recast text of the Law on guarantees and rational use of medicinal products and medical devices approved by Royal Legislative Decree 1/2015 of 24 July 2015 is dedicated to the rational use of medicinal products and medical devices in retail pharmacies. In this regard, pharmacists, as those responsible for dispensing medicinal products, must ensure compliance with the guidelines established by the patient's doctor in the prescription, cooperate with the doctor in monitoring treatment through pharmaceutical care procedures and participate in activities aimed at rationalising the use of medicinal products, including informed dispensing to patients and the possibility of facilitating personalised dosage systems.

It is in the field of pharmaceutical care that Law 13/2022 of 21 December 2022 marks a milestone by addressing, firstly, personal dosage systems to improve pharmacotherapeutic compliance and prevent problems relating to medicinal products and, secondly, the regulation of pharmaceutical care and dispensing from the retail pharmacy with informed delivery to the home. It gives due recognition to the fundamental role of pharmacists in dispensing and reserves the delivery of medicinal products to the home to retail pharmacy staff, without neglecting the pharmaceutical care provided by hospital pharmacy services in the case of medicinal products whose dispensing is restricted to the hospital environment.

On the other hand, the same law addresses the regulation of dispatches from retail pharmacies, laying down specific conditions, requirements and limitations. This aspect represents a significant change, as it establishes that the transfer becomes effective through the legal act declaring it, once it has been documented before the competent authority in charge of pharmaceutical regulation. This contrasts with the previous procedure, which deferred its effectiveness to the time of receipt of notification of the administrative decision.

This decree is structured in 49 articles divided into 6 chapters, supplemented by 2 additional provisions, 3 transitional provisions, 1 repealing provision, 2 final provisions and 3 annexes. Its content addresses key aspects for the organisation and operation of retail pharmacies and pharmaceutical services, precisely developing the new models and requirements provided for by law.

Chapter I comprises the general provisions regulating the purpose and scope of application.

Chapter II, divided into three sections, regulates key aspects of the functioning of retail pharmacies. Thus, section 1. establishes the provisions relating to operating hours, including both extended hours with variable time slots and determination of the minimum number of pharmaceutical professionals required in order to ensure the constant and effective presence of at least one registered pharmacist during all hours of public service. Section 2 regulates the general criteria for the organisation of out-of-hours services, their provision, the manner of identifying out-of-hours duty pharmacies, possible modifications in health emergencies and the information that must be provided to the public. Finally, Section 3 is dedicated to the holidays of retail pharmacies and the criteria for ensuring continuity of service during those periods.

This regulation introduces, as a new feature, more flexible regulations on the opening hours of pharmacies, including variable time slots and extended hours, ensuring that at least one registered pharmacist is present at all times, a new organisation of the out-of-hours service, which provides for modalities adapted to territorial and population characteristics, as well as exceptional mechanisms in health emergencies and the organisation of holidays for retail pharmacies, guaranteeing continuity of service throughout the territory.

Chapter III is devoted to personalised dosage systems (PDS). Throughout its four sections, it outlines their regulation as a professional service aimed at improving therapeutic adherence and safety in the use of medicinal products. The conditions of provision, the technical and professional requirements, as well as the guarantees of quality, safety and traceability are set out in detail. Likewise, it is expressly stipulated that PDS must be prepared entirely and exclusively at the retail pharmacy that dispensed the medicinal products or, where applicable, in the authorised pharmacy service in the corresponding residential centre or in the pharmacy service linked to the residential centre's medicinal product storage facility, with the preparation of PDS by and for third parties being expressly prohibited.

On the other hand, as the main new aspect of the decree, Chapter IV is dedicated to regulating dispensing with informed delivery to the home by retail pharmacies, as well as non-face-to-face dispensing through hospital pharmacy services of medicinal products whose dispensing is restricted to the hospital environment. For the provision of this service by the retail pharmacy, the presentation of a prior sworn statement is required, as well as the express request of the patient. Specific guarantees are also established to ensure the traceability of the process, the quality of the service and the professional intervention of the pharmacist, all without any additional cost to the patient.

Chapter V regulates the transfer authorisation regime for retail pharmacies, simplifying it by reducing administrative burdens through the use of sworn statements, while ensuring the continuity of authorised services.

Finally, Chapter VI is dedicated to the penalties regime, with express reference to the basic and regional state regulations, building control capacity and legal certainty in the exercise of the pharmaceutical activity.

In its final part, the decree establishes mechanisms for the updating of standard models, regulates the application of inclusive language, establishes the transitional regime for procedures initiated prior to its entry into force and determines the effective date of application, the day after its official publication.

The content of this decree complies with the principles of good regulation laid down in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, and in Article 2 of Decree 52/2021 of 24 March 2021 of the Governing Council, which regulates and simplifies the procedure for drawing up the general regulatory provisions of the Community of Madrid.

The need for its approval addresses the general interest of guaranteeing the safety and quality of pharmaceutical care for the population of the Community of Madrid, meeting the demands of users and the sectors involved. This regulation makes it possible to achieve this objective by regulating the various aspects of pharmaceutical care described in the previous sections, thus complying with the principles of necessity and effectiveness.

This objective of integration is also in line with the principle of proportionality, as the decree contains the necessary regulation for achieving the aforementioned objectives, and by including the provisions essential to meet the needs to be covered, without the obligations imposed on the recipients going beyond those strictly necessary to guarantee the general interest pursued, which is that of protecting health and improving the quality and safety of the services provided by pharmacies.

It is also aligned with the principle of legal certainty, since it clearly defines the framework of the procedures applicable to regulated services and precisely establishes the list of obligations required of the persons responsible for such services. The implementation of the sworn statement, as well as the

requirement to prepare activity reports, facilitates the monitoring of compliance with the regulation by the parties concerned.

The principle of transparency is respected, since the public consultation and public hearing and information procedures have been carried out through the Transparency Portal, in accordance with the provisions of Article 60(1) and (2) of Law 10/2019 of 10 April 2019 on Transparency and Participation of the Community of Madrid, as well as Articles 4.2(a) and (d), 5 and 9 of Decree 52/2021 of 24 March 2021. Furthermore, once the regulation has been approved, it is published on the Transparency Portal.

On the other hand, the text contains precise regulation that is in line with its intended purpose and is considered the least intrusive measure, in accordance with the principle of efficiency. It avoids unnecessary or incidental administrative burdens by establishing procedures that are subject to notification or sworn statements instead of authorisations, allowing for more rational management of public resources. However, compliance with the requirements established in this decree entails a series of documentation and staffing obligations that could constitute an additional burden on pharmacies.

Finally, this decree respects the distribution of powers and is intended to endure over time in order to contribute to a stable and integrated regulatory framework.

During the processing of the regulation, the compulsory reports were issued on the following: coordination and normative quality; social impact analysis; public health impact; economic impact; and by the Consumer Council, the General Technical Secretariat of the Regional Ministry of Health and the General Attorney's Office.

The text of this regulation has been subject to the procedure for the provision of information to the European Commission in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

The Governing Council of the Community of Madrid is competent to issue this decree, in accordance with the provisions of Articles 18 and 21(g) of Law 1/1983 of 13 December 1983 on the Government and Administration of the Community of Madrid and the first final provision of Law 13/2022 of 21 December 2022.

Therefore, at the proposal of the head of the Regional Ministry of Health, heard/in agreement with the Legal Advisory Commission, the Governing Council, following deliberation at its meeting of the day,

HEREBY DECREES

CHAPTER I

General provisions

Article 1. Purpose.

The purpose of this decree is to regulate: the opening hours, out-of-hours and holiday services of retail pharmacies; the conditions and requirements for preparing and delivering personalised dosage systems; pharmaceutical care and the dispensing of medicinal products and medical devices to the home on behalf of retail pharmacies; non-face-to-face dispensing by hospital pharmacy services of medicinal products whose dispensing is restricted to the hospital environment; the procedure for authorising dispatches from retail pharmacies.

Article 2. Scope of application.

This decree applies to retail pharmacies and pharmacy services in the Community of Madrid.

CHAPTER II

Opening hours, out-of-hours services and holidays

SECTION 1. OPENING HOURS

Article 3. *Ordinary and official opening hours.*

1. The ordinary and official opening hours should be the same for all working days from Monday to Friday.

2. Saturday opening hours may be the same or different as those determined for the period from Monday to Friday and may extend above the fixed time slot.

3. In municipalities with fewer than two thousand inhabitants that do not have a health centre, the ordinary and official opening hours may be thirty-five hours

per week and be carried out continuously, and it must be open to the public every working day with the same hours.

Article 4. *Extended opening hours.*

1. Retail pharmacies may extend their ordinary and official opening hours of 40 hours a week to adapt to the needs of their basic health zone, choosing from the following options:

a) extension to 24 hours a day, every day of the year;

b) extension of ordinary and official opening hours between 6.00 and 23.00, uniformly from Monday to Friday.

2. On Saturdays, retail pharmacies can either maintain their extended opening hours from Monday to Friday, or set different opening hours.

3. Retail pharmacies that choose to remain open on Sundays and public holidays must maintain the same opening hours as on Saturdays throughout all Sundays and public holidays throughout the year.

4. Pharmacies that opt for extended opening hours in accordance with section 1 may establish alternative opening hours within the period 15 June to 15 September.

5. In exceptional situations or health emergencies, special opening hours may be established, which may be extended to such retail pharmacies as the health authorities deem appropriate, in order to meet the demand for extraordinary assistance while the situation persists.

Article 5. *Communication of opening hours.*

1. Before 1 November each year, the licence-holder of the retail pharmacy must notify the Official College of Pharmacists of Madrid of the chosen opening hours. The College must then forward this information to the regional ministry responsible for health matters before 15 December each year, indicating all of the opening hours notified by the retail pharmacies.

2. In the case of pharmacies with more than one licensed owner, it is sufficient that only one of them make the communication, in which case it must state that all the co-owners agree to it. If the retail pharmacy has a managing pharmacist, it shall be that pharmacist who makes the communication and, where appropriate, the replacement pharmacist if the communication is to be made during the replacement period.

3. Exceptionally, in the event of duly accredited unforeseeable circumstances or force majeure, changes to the timetable may be communicated outside the communication period established in the preceding paragraphs. Such changes shall only be possible where they do not affect the regular and official hours and should be maintained only for as long as the exceptional circumstances that led to their adoption persist.

4. In cases of new openings, relocations and transfers of pharmacies, the opening hours must be communicated before the start of activity as part of the

authorisation procedure for new openings, relocations or transfers. The Regional Ministry of Health forwards the schedules communicated to the Official College of Pharmacists of Madrid.

Article 6. *Requirements for pharmaceutical staff in extended hours and special circumstances.*

1. Pharmacies must have a sufficient number of pharmaceutical professionals to be able, depending on the opening hours, to ensure the constant and effective presence of at least one registered pharmacist, duly identified, throughout the entire time that the pharmacy is open to the public, whether during regular hours, extended hours, or out-of-hours service.

2. To ensure the presence of the pharmacist during the extended time slot, i.e. exceeding 40 hours per week, the following working time thresholds are established in which the recruitment of additional pharmaceutical staff will be necessary:

a) Up to 55 hours per week: the head pharmacist is sufficient, unless they are over the age of 70, in which case at least one full- or part-time assistant pharmacist must be appointed. Nor would it be necessary to hire an assistant in cases of co-ownership, where one of the owners is over 70 years of age and the other is under 70.

b) From 56 to 95 hours per week: at least two pharmacists are required, either two co-licence-holders or one licence-holder and one assistant pharmacist contracted according to the opening hours.

c) More than 95 hours per week: at least three pharmacists are required, including owners, co-owners and assistants, with contracts appropriate to the opening hours.

3. The provisions of paragraph 2 do not apply to pharmacies located in municipalities of fewer than 2 000 inhabitants, whose head pharmacist, manager or substitute is over the age of 70.

4. Where a retail pharmacy has a pharmaceutical clinic or medicinal product storage facility linked to it and the working hours of the retail pharmacy exceed 40 hours per week, or where those hours do not exceed 40 hours per week and coincide with the opening and working hours of the pharmaceutical clinic or storage unit, at least one assistant pharmacist must be designated, working full- or part-time, to ensure adequate pharmaceutical care during the working hours of the pharmaceutical clinic or storage unit and according to the workload it/they generate(s).

5. In cases where it is impossible to maintain the minimum number of pharmacists required, and provided that it is duly justified, the licence-holder of the retail pharmacy must notify the competent authority of a temporary reduction in opening hours, adapting them to the staffing requirements established in this article and, where appropriate, disassociate themselves from any pharmaceutical clinic or medicinal product storage unit associated with

them if, within three months, they do not have the necessary pharmaceutical staff.

SECTION 2. OUT-OF-HOURS SERVICES

Article 7. *Out-of-hours services for retail pharmacies.*

In order to ensure the continuity of pharmaceutical care, basic out-of-hours services are established outside normal and official opening hours. There are two types:

a) daytime out-of-hours service: this is provided by pharmacies continuously from 9.30 to 23.00.

b) Night-time out-of-hours service: this is provided by retail pharmacies continuously from 23.00 to 9.30 the following day.

Article 8. *Organisation of out-of-hours pharmaceutical services.*

1. Wherever there is a public health centre with an emergency medical service in a basic health zone, the out-of-hours services necessary to ensure continuity of pharmaceutical care should preferably be organised there.

2. In order to organise out-of-hours services in a given territory, pharmacies located in the same basic health zone may be grouped together with those located in neighbouring basic health zones in the following cases:

a) In municipalities with two or more basic health zones.

b) When the basic health zone coincides with the boundaries of a municipality, the out-of-hours service may be organised with other neighbouring basic health zones when there is no continuous care health centre in that zone or when the distance between urban centres does not exceed 15 km or 15 minutes' travel time.

c) When the basic health zone covers several municipalities, including at least one with fewer than two thousand inhabitants, the out-of-hours service may be organised jointly with other neighbouring basic health zones.

3. In basic health areas that do not have a public centre for continuous medical care or which include municipalities with fewer than two thousand inhabitants, a daytime out-of-hours service must be organised and a night-time out-of-hours service may be established at a distance no greater than that of the urban centre at which the nearest emergency medical service is located.

4. Out-of-hours services must be organised in accordance with health planning and may be established on a daily, weekly or other basis, in accordance with the needs of the service. Before 20 December of each year, the Official College of Pharmacists of Madrid must notify the regional ministry responsible for health matters of a proposal for the organisation of out-of-hours services for the following year, for assessment and, where appropriate, approval, without

prejudice to any amendments that may prove necessary in the light of care needs.

5. The regional ministry responsible for health matters may introduce specific and additional criteria in the organisation of out-of-hours services, within the framework laid down in the legislation in force and provided that they are justified by care needs relating to the accessibility of medicinal products and medical devices.

Article 9. *Localised out-of-hours service.*

1. Exceptionally, the night duty service for the dispensing of medicinal products and medical devices prescribed through the health services on a medical prescription may be carried out by the pharmacy on a localised basis, provided that the pharmacist's response time does not exceed 20 minutes from the time of the dispensing request. For this purpose, the contact details of the pharmacist must be displayed in the retail pharmacy in a place visible from the outside of the retail pharmacy.

2. The Official College of Pharmacists of Madrid must provide pharmacies offering this service with an identification sign to inform users.

Article 10. *Changes to out-of-hours services.*

1. Any changes to the out-of-hours service schedule must be communicated to the competent health authority by the Official College of Pharmacists of Madrid, justifying continuation of the conditions established in Article 8 for the organisation of the new out-of-hours service.

2. Accordingly, the regional ministry responsible for health matters may at any time call on the Official College of Pharmacists of Madrid to amend the shifts organised in the event of circumstances adversely affecting out-of-hours duty planning carried out in accordance with the criteria laid down in Article 8.

Article 11. *Out-of-hours services in health emergency situations.*

In exceptional or health emergency situations, extraordinary out-of-hours services may be established and extended to pharmacies deemed appropriate by the health administration to meet the demand for extraordinary care for as long as necessary due to the exceptional health situation.

Article 12. *Public information on out-of-hours services.*

1. Pharmacies are required to display in their premises a list of daytime and night-time duty pharmacies, both in their basic health zone and in neighbouring areas and municipalities, indicating the contact details of the pharmacist in the case of localised night duties.

2. The information on the out-of-hours services must be available and constantly updated in an area accessible to the public on the website of the Official College of Pharmacists of Madrid, as well as on the virtual health card of citizens of the Community of Madrid.

SECTION 3. HOLIDAYS

Article 13. *Holidays.*

1. Retail pharmacies must notify the Official College of Pharmacists of Madrid of their holiday period at least one month in advance. The College will organise holiday shifts for each basic health zone to ensure adequate pharmaceutical care for the population. The latter must in turn notify the regional ministry responsible for health matters of the proposed organisation of holiday periods determined for this purpose.

2. To ensure service during the holiday period, at least 50 % of the existing pharmacies in each basic health zone or grouped neighbouring areas must be kept open.

3. Pharmacies closing for authorised holidays must display a poster, in an area visible from the outside, announcing the holiday closure, the closure period and the nearest open pharmacies.

4. Pharmacies that have a pharmaceutical clinic or associated storage facility must guarantee service during the period in which these are in operation.

CHAPTER III

Personalised dosage systems

SECTION 1. GENERAL RULES

Article 14. *General conditions for provision of the service.*

1. The licensed pharmacist, manager or, where applicable, the head of the pharmacy service may offer a service preparing and delivering personalised dosage systems (hereinafter referred to as PDS). This pharmaceutical service involves a set of actions following dispensing, such as repackaging the medicinal products in a personalised dosage device with the aim of facilitating correct administration of the medicinal products and improving the patient's adherence to the prescribed treatment, through adequate information, preparation and supervision of the treatment.

2. Before commencing this activity, the licensed pharmacist, manager or, where applicable, the head of the pharmacy service must submit to the competent general directorate for pharmaceutical regulation the sworn statement provided for in Article 69 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations.

3. The activities involved in preparing PDS must be carried out entirely and exclusively in the same retail pharmacy or pharmacy service that has dispensed the corresponding medicinal products, by its contracted staff. Under no circumstances may preparation be delegated to another retail pharmacy, to another pharmacy service or to third parties, or carried out for third parties. PDS shall be delivered in accordance with the provisions of Articles 33 and 34.

4. PDS may only be prepared with medicinal products previously dispensed by the retail pharmacy or pharmacy service responsible for their preparation, thus ensuring control and traceability of the treatment.

5. PDS must be prepared exclusively by pharmaceutical professionals or by technical or auxiliary staff, always under the supervision of a pharmacist. The entire process must comply strictly with the standard operating procedure (hereinafter SOP) accompanying the relevant sworn statement.

6. Before delivering the personalised dosage system, the responsible pharmacist must check that all processes have been completed in accordance with the SOP and the applicable regulations, guaranteeing the safety and quality of the service provided.
7. The provisions of this Article apply both to PDS prepared for patients served in pharmacies and to those intended for persons dwelling in residential social service centres. In the latter case, the PDS must be prepared by the authorised pharmacy service of the residential centre itself or, failing that, by the retail pharmacy or pharmacy service to which the centre's medicinal product storage facility is linked.

Article 15. *Sworn statement.*

1. The sworn statement must be signed by the licence-holder(s) or manager of the retail pharmacy or, where applicable, by the head of the pharmacy service. It shall be submitted using the standard form in Annex I, available on the website

https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, and the standard form on the Digital Administration Portal (website).

2. The sworn statement must be updated in the event of any amendment of the regulations in force or changes in the conditions initially declared.

3. The General Directorate responsible for pharmaceutical regulation must be notified of the voluntary termination of service at least one month before the actual termination date, except in cases of force majeure justifying immediate termination.

4. In the event of transfer of the retail pharmacy to a new licence-holder, the latter must submit a new sworn statement within 10 days of the effective

transfer date if they wish to continue the service or, failing that, communicate their voluntary cessation of the activity.

5. The activity may start from the day of submission of the sworn statement, without prejudice to the control and inspection powers of the Administration to check compliance with the established conditions.

6. Failure to comply with the requirements laid down in Section 2 shall result, by decision of the General Directorate responsible for pharmaceutical regulation, in the impossibility of continuing the activity.

SECTION 2. REQUIREMENTS AND CRITERIA

Article 16. *Technical and organisational requirements for the provision of the PDS service.*

For the proper provision of the PDS service, retail pharmacies and pharmacy services must comply with the following technical and organisational requirements:

a) availability of pharmaceutical staff with knowledge of the applicable regulations, pharmaceutical activities linked to the service, procedures for the preparation of PDS, maintenance and cleaning of facilities and equipment, selection of medicinal products and pharmacotherapeutic monitoring; all of this is essential to ensure the safety of the procedure;

b) possession of the equipment and tools necessary for correct preparation of PDS in accordance with the provisions of Article 19;

c) the standard operating procedure (SOP) describing the workflow for preparing and delivering PDS;

d) quality evaluation; control and evaluation mechanisms must be established to ensure quality in the preparation and dispensing of PDS;

e) safekeeping and preservation of documentation relating to provision of the service, in accordance with applicable regulations on traceability and service quality;

f) documented delegation of duties: in the event that the licensed pharmacist, manager or head of pharmacy service delegates duties to an assistant pharmacist, such delegation must be expressly stated in the standard operating procedure, without this excluding the responsibility of the licensed pharmacist or head of service.

Article 17. *Requirements and standards for preparing and delivering PDS.*

In order to ensure safety and quality in preparing and delivering PDS, the pharmaceutical staff involved in this service must meet the following criteria:

a) PDS shall be prepared and delivered according to a documented procedure that ensures compliance with applicable quality standards;

b) the confidentiality of the patient's data must be respected at all times, in accordance with the data protection rules in force;

c) before a patient is included in the service, the suitability of the patient shall be assessed, taking into account the risks and benefits of using PDS;

d) the informed consent of the patient, their legal representative or, where applicable, the person in charge of the social and healthcare centre in which they reside, shall be obtained;

e) the physical, chemical and galenic characteristics of the medicinal products shall be analysed to determine their compatibility with the personalised dosage system;

f) a record shall be kept to ensure the traceability of the medicinal products included in the PDS devices;

g) the devices shall be prepared exclusively with previously dispensed medicinal products, in accordance with the applicable regulations;

h) the documentation relating to PDS activity shall be kept up to date and its preservation ensured in accordance with the provisions of Article 20;

i) measures shall be implemented to check the quality of the PDS, including the integrity of the associated records;

j) the patient, legal representative or, where applicable, the responsible healthcare professional shall be provided with adequate information on the use of PDS devices;

k) the patient's treatment shall be monitored in order to optimise therapeutic adherence and resolve any problems in relation to administration of the medicinal products;

l) each patient's medicinal products must be stored in separate, clearly labelled containers and in safe conditions.

SECTION 3. REQUIREMENTS FOR THE ACTIVITY OF PREPARING AND DELIVERING PDS.

Article 18. *Requirements for facilities.*

1. PDS must be prepared within the authorised premises of the retail pharmacy that dispensed the medicinal products or of the main authorised pharmacy service of the residential centre.

2. The preparation process should be organised sequentially to ensure a unidirectional workflow, minimising the risk of confusion and avoiding cross-contamination.

3. An area specifically dedicated to this activity must be set up, comprising the following zones:

a) Personalised service zone:

A separate space from the dispensing zone that guarantees confidentiality in individualised care, with the same area being used for other professional services.

b) PDS preparation zone:

1. this is a delimited space, preferably closed, without direct access to the outside or to the toilets;

2. it may be shared with the zone intended for the preparation of magistral formulas, provided that the activities are carried out separately by campaigns and that adequate cleaning is ensured at the end of each use, with the corresponding register.

3. it must have:

i. a smooth, impermeable, washable and disinfectable work surface.
ii. Walls made of smooth, washable and disinfectable materials.
iii. Controlled environmental conditions between 15 °C and 25 °C and a relative humidity between 40 % and 60 %.

c) Storage zone:

1. In retail pharmacies, the storage zone must be intended to store and preserve the medication dispensed in its original packaging, as well as the PDS prepared and organised for delivery in containers clearly identified for each patient. In the case of institutionalised patients, the identification of the corresponding residential centre should also be included.

2. In pharmacy services, this zone is intended to store and preserve the medicinal products necessary for the preparation of PDS, which, once prepared and organised for delivery, are placed in clearly identified containers for each patient and residential centre.

3. The storage area must be clearly indicated and separated from the area intended for the storage of other medicinal products.

4. Medicinal products and packaging material must be stored in accordance with the storage conditions established in their marketing authorisation. It shall be prohibited to store medicinal products on the floor or on surfaces that are difficult to clean and likely to promote contamination.

d) Documentation archive zone.

Article 19. *Equipment and tool requirements.*

1. The equipment and tools used in the preparation of PDS must be kept in perfect conditions of hygiene and preservation.

2. The packaging equipment consists of personalised dosage devices, which may be:

a) disposable multi-dose packs (blister or similar);

b) multi-compartmental (weekly pill boxes or compartmented trays).

3. At least the following instruments must be available:

a) Specific tools for splitting tablets: cutter, slicer, trays and tweezers.

b) Thermometer and hygrometer calibrated in accordance with national or international standards. The thermometer must also be subject to the metrological control of the State, in accordance with the regulations applicable in its specific field.

c) Clothing for exclusive use, such as masks, gowns, head coverings and disposable gloves.

d) Individually identified containers for safekeeping of the medication intended for each patient.

4. Automated systems, where available, as well as manual systems, should ensure the traceability of the medicinal products dispensed to each patient and of the devices prepared.

5. All equipment must be properly cleaned between each preparation, avoiding any risk of cross-contamination between medicinal products for the same patient or different patients.

Article 20. *Compulsory documentation.*

1. The retail pharmacy or pharmacy service must have the following documentation:

a) General documentation for assessing medicinal products suitable for inclusion in PDS.

b) Patient documentation, including:

(1) signed consent form;

(2) patient file;

(3) medication sheet, prescription or other similar document updated in physical or electronic format, containing the prescribed medicinal products.

(4) instruction sheet for the administration of medicinal products.

c) Documentation of the preparation process, including:

(1) the standard operating procedure;

(2) the records relating to the actions and controls described in the following articles.

2. The documentation generated by this activity, on any physical or digital medium, must be preserved for a period of at least one year. The patient file must be preserved for up to one year after leaving the service, ensuring the protection of personal data.

Article 21. *Standard working procedure.*

1. The PDS preparation and delivery service shall be provided according to a standard operating procedure approved, dated and signed by the licensed pharmacist(s), manager or, where applicable, by the head of the pharmacy service.

2. The procedure must provide for at least the following aspects:

a) objective and purpose of the procedure;

b) activities and tasks covered;

c) exclusion criteria for medicinal products not suitable for these systems, suitability of medicinal products to be included on the basis of the patient's risk assessment;

d) identification of medicinal products suitable for individual repackaging;

e) decision to include medicinal products susceptible to misuse or abuse (controlled drugs or psychotropic medicinal products);

f) decision on the inclusion of split units or on the need for individual packaging;

g) tasks assigned to each professional and those responsible for each phase of the procedure in order to ensure the proper organisation of the process;

h) hygiene and cleanliness requirements for facilities;

i) control of the environmental conditions of the preparation area;

j) reception, storage and preparation of devices;

k) details of the development, labelling and delivery phases of the systems;

l) method of communicating changes to prescriptions and action protocols.

m) registration and preservation of the generated documentation and protocol for its preservation and archiving.

3. The procedure must be clear, orderly and accessible to staff. It must be periodically reviewed and updated, preserving obsolete documents separately.

Article 22. *Register of actions.*

1. The retail pharmacy or pharmacy service must have documentary records that facilitate checking the conditions of preparation and the traceability of the medicinal products used.

2. The registers shall include:

a) cleaning register for facilities and tools;

b) register of environmental conditions in the preparation zone;

c) register of packaging materials used;

d) register of records of preparation, control and delivery to patients, or responsible professionals in the case of residential centres.

e) register of the suitability assessment of medicinal products, precautionary measures, special instructions and decisions taken by the responsible pharmacist and other decisions taken.

SECTION 4. DEVELOPMENT OF ACTIVITY

Article 23. *Medicinal products suitable for preparation in a personalised dosage system.*

1. Only medicinal products authorised by the Spanish Agency for Medicines and Health Products may be prepared in a PDS.

2. The core criteria for assessing the suitability of a medicinal product for preparation in PDS devices include: the physical, chemical and pharmaceutical stability of the medicinal product from the moment of its unpackaging, preparation, delivery and use; the toxicity of the medicinal product and potential for cross-contamination and potential for physical and chemical interaction with other medicinal products.

3. Medicinal products may be prepared in PDS provided that they are solid oral formulations and their physical, chemical and galenic characteristics ensure that they remain stable at room temperature outside their original packaging for the period covering extraction, preparation, delivery and use. PDS may not be prepared for a period exceeding 14 days.

4. The following are excluded from PDS:

a) oral or thermolabile non-solid medicinal products with storage requirements between 2 °C and 8 °C;

b) medicinal products for which there is information suggesting that they are unsuitable for PDS, unless precise data is available enabling them to be evaluated and justified;

c) medicinal products prescribed for occasional use, emergency use, or without a fixed schedule.

5. Where the marketing authorisation documentation for a medicinal product lacks information on its suitability for preparation in a PDS, it shall only be extracted from the manufacturer's original packaging for preparation in a PDS if sufficient accurate data is available to assess the risks and suitability of the medicinal product and the impact of the repackaging on its quality.

6. Only medicinal products presented in scored tablets for division into uniform doses or those with information provided by the marketing authorisation holder regarding their possible division may be divided for preparation in PDS. Split tablets should only be used when there are no authorised medicinal products available with the prescribed dosage or other alternatives available. Under no circumstances may surplus divided units be stored and kept for inclusion in the next personalised dosage preparation.

7. Medicinal products that share physical characteristics may not be packaged in the same pouch or container in such a way that it is difficult to distinguish between them. Those medicinal products that have to be individually repackaged shall be identified.

8. The inclusion of oral narcotic medicinal products shall be permitted only when their use complies with a fixed schedule prescribed by the practitioner. This inclusion must be properly documented, as must the control of open packages, which, where applicable, must be kept safe at the retail pharmacy.

Article 24. *Assessment of the patient's suitability for inclusion in the PDS scheme.*

1. The inclusion of a patient in an adherence programme with the use of PDS should be based on an individualised assessment, carried out by the pharmacist, with the patient present whenever possible, following a systematised review of their medication, taking into account objective criteria relating to therapeutic adherence, their capacity to handle the medication and the specific needs of the patient.

2. For this purpose, an interview is conducted with the patient, their legal representative or, where applicable, the responsible healthcare professional, in which the following aspects, inter alia, are assessed:

a) difficulties in therapeutic adherence, such as frequent forgetfulness or errors in the administration of medication;

b) presence of polymedication, meaning the administration of six or more medicinal products on a continuous basis;

c) physical or cognitive limitations that hinder autonomous management of medication;

d) specific treatment requirements whose complexity implies a high risk of error in their administration.

3. The results of the assessment must be reflected in a specific register at the retail pharmacy, ensuring the traceability of the decision taken and patient follow-up.

Article 25. *Informed patient consent.*

1. Patients included in the service must express their consent in a clear and credible manner before provision of the service begins. Such consent must be formalised in writing and must ensure that the patient or their legal representative has received clear, sufficient and understandable information about the service.

2. In the case of patients residing in a health and social care institution, consent may be granted by their legal representative. In the absence of the latter, it may be granted by the head of the centre, provided that prior written authorisation has been obtained from the patient or their legal representative.

3. The informed consent document must include at least the following aspects:

a) information about the PDS service and the repackaging of medicinal products by the retail pharmacy or by the pharmacy service responsible for the pharmaceutical provision;

b) the patient's right to stop receiving the service at any time;

c) the commitment of the patient or their representative to provide up-to-date information on their treatment and conditions of use of the PDS;

d) commitment of the patient to present prescriptions for the dispensing of medicinal products prior to preparation of the PDS;

e) commitment to report medication changes using the updated treatment sheet and to report hospital admissions or long temporary stays;

f) commitment to maintain the proper conditions of conservation and safety of the device delivered;

g) express indication of whether the retail pharmacy is authorised to keep safe any leftover medication;

h) commitment to collaborate with the pharmaceutical staff for the purposes of monitoring the treatment and checking adherence to the treatment, providing information on administration of the medicinal products and the return of the devices used, if applicable.

4. Informed consent must be formalised in duplicate, with one copy being given to the patient or their representative and another being preserved in the pharmacy or pharmacy department responsible, in accordance with the provisions of Article 20 and the data protection legislation in force.

Article 26. *Patient file.*

1. For each patient, a file must be created and updated containing the following information:

a) patient identification and contact details;

b) date of discharge from the service;

c) details of the doctor responsible (name, registration number and regional health code, if applicable);

d) medication sheet: trade name, active ingredient, dosage and duration of treatment;

e) list of medicinal products excluded from PDS and reason for exclusion;

f) medication suitable for individual repackaging;

g) changes in medication or administration schedule;

h) incidents occurring and their resolution;

i) monitoring of adherence to treatment;

j) pharmaceutical interventions carried out;

k) date and reason for leaving the service.

2. The patient file must be kept for a minimum period of one year after discharge from the service, ensuring the confidentiality of the data.

Article 27. *General requirements for the preparation of PDS.*

1. PDS must always be prepared under the supervision of the responsible pharmacist after checking for any problems relating to the medicinal products, duplications, incorrect dosage guidelines, duration of treatment and interactions.

2. Before each preparation, the pharmacist must check whether there are any changes to the prescribed medication and dispense only the necessary medicinal products.

3. The service must be suspended during the patient's hospital admission and resumed with updating of the pharmacological plan or updating of the patient's treatment once medication reconciliation has been carried out by the pharmacist.

4. For medicinal products that have been extracted from their primary packaging material, the PDS must be prepared immediately after extraction.

5. Preparation of PDS for periods longer than 14 days is exceptional and must be justified.

6. The preparation area must contain only the medicinal products dispensed to the patient, the necessary utensils and the supporting documentation.

Article 28. *Preparation and control sheet.*

A preparation and control sheet must be completed with the following information:

a) PDS internal registration number;

b) first name and surname(s) of the patient;

c) temperature and humidity conditions in the preparation area;

d) date of preparation;

e) packaged medicinal products: trade name, batch number and expiry date;

f) details of the device used: type and batch, where applicable;

g) period of validity of the PDS;

h) date and signature of the staff preparing the PDS and the pharmacist carrying out the quality control;

i) delivery date and signature;

j) any incidents recorded.

Article 29. *Packaging devices.*

1. Packaging shall be in approved multi-dose devices with the corresponding manufacturer's certificate of conformity for packaging containing medicinal products, which guarantees the suitability of the manufacturing materials in terms of avoiding interactions with the contents, as well as ensuring that the product meets the legal requirements to provide sufficient protection during storage and transport and allows for easy opening and removal by the patient. The devices shall be sealed or closed in accordance with the manufacturer's instructions, without their reuse being permitted under any circumstances.

2. Multi-compartment devices may under no circumstances contain medicinal products no longer in their primary packaging, in order to ensure their stability. These devices must undergo a strict cleaning and disinfection protocol after each use and their proper state of maintenance must be checked before reuse.

Article 30. *Safekeeping of surplus medication at the retail pharmacy and completion of the service.*

1. If the patient has authorised the retail pharmacy to keep safe the surplus units of the medicinal products used in the preparation of PDS, they must be stored in their original packaging, separately and with the identification of each patient. The quantity of these medicinal products stored should be proportionate to the quantity required for the preparation of each patient's personalised dosage system, taking into account the number of units contained in each original packaging of medicinal products. In any case, only packages containing medicinal products remaining from the last preparation of the devices currently in use may be stored in safekeeping. Therefore, before each preparation, it is

necessary to check whether or not it is necessary to dispense a package of medicinal products.

2. Once the patient, or their representative, decides to terminate the service, the retail pharmacy will return all open packages belonging to that patient.

Article 31. *Labelling.*

1. PDS must bear legible labelling that includes, as a minimum, the following information:

a) the patient's identification data;

b) identification of the retail pharmacy providing the service, with its code, the first name and surname(s) of the licence-holder(s) and the contact telephone number or, where appropriate, that of the pharmacy service responsible;

c) details of the doctor responsible: name, surname, professional association number and regional health code, if applicable;

d) the validity period of the PDS in a visible place;

e) the list of medicinal products included: trade name, batch and dosage schedule;

f) the internal registration number assigned to the PDS;

g) the administration and dosage instructions;

h) instructions for storage of the device, including any relevant warnings;

i) any additional information deemed necessary.

2. The labels are drawn up and checked against the data entered in the patient file.

3. If there is insufficient space on the label to include all of the information mentioned in sections f) to i), this information may be provided in a document accompanying the device.

Article 32. *Checking the PDS.*

1. Once the PDS has been prepared, and before it is dispensed, the pharmacist responsible shall carry out a final check and sign the preparation and control sheet.

2. The count of units in the device must be checked against the preparation sheet before the device is closed or sealed.

3. During checking, the following checks shall be performed:

a) the contents of the device are correct and contain the medicinal products indicated for the patient;

b) the device manufacturer's instructions for filling, sealing and labelling and the standard operating procedure have both been followed;

c) the device is correctly identified and labelled;

d) the validity period is clearly indicated;

e) the instruction sheet accompanying the device contains all of the necessary information in accordance with Article 34;

f) there are no visible alterations in the final prepared product.

Article 33. *Delivery of personalised dosage devices to the retail pharmacy.*

1. Delivery shall be made to the retail pharmacy or its affiliated medicinal product storage units, without prejudice to home delivery as regulated in Chapter IV.

2. Once the device has been checked it is delivered to the patient or their legal representative in accordance with the provisions of the standard working procedure.

3. Upon first delivery of the device, the patient is provided with the package leaflets of the medicinal products included in the PDS.

4. Upon each delivery of the device, an instruction sheet is provided that is issued in duplicate, signed by the person removing the PDS and filed with the pharmacy. This sheet must include:

a) the list of medicinal products included and not included;

b) identification of the doctor responsible for the prescription and the prescription dates or last change in the treatment, as well as the date of the medication sheet used;

c) instructions for the correct storage and handling of the device;

d) the name and telephone number of the retail pharmacy or pharmacy department responsible.

5. Upon each delivery, the pharmacist must collect information on the patient's adherence to the treatment, recording it in the patient's file.

6. Any surplus medicinal products that have not been included in the device and should not be kept by the retail pharmacy because they do not have the patient's authorisation are given to the patient. These medicinal products cannot be used in future PDS preparations.

Article 34. *Delivery of PDS to medicinal product storage facilities at residential social service centres.*

1. The delivery of PDS to residential social service centres shall be carried out by the retail pharmacy or by the pharmacy service responsible for the medicinal product storage facility in these centres. Both the retail pharmacy and, where applicable, the pharmacy service must ensure that:

a) The transportation of medicinal products in the PDS does not result in any alterations or loss of quality.

b) The correct products are delivered to the appropriate recipient, accompanied by the following information:

1. º delivery date;

2. º quantity delivered;

3. º duration of the medication period covered by the PDS;

4. º other identification details, as necessary.

Article 35. *Elimination of waste.*

Waste generated by PDS, as well as packaging returned by patients, must be deposited in the integrated waste management system container.

CHAPTER IV

Pharmaceutical care and dispensing with informed delivery to the home

Article 36. *Pharmaceutical care service and dispensing with informed delivery to the home by the retail pharmacy.*

1. The service may include delivery to the patient's home of:

a) medicinal products subject to medical prescription;

b) medicinal products not subject to medical prescription;

c) medical devices that do not require individual adaptation;

d) dietary therapeutic products;

e) PDS regulated in Chapter III.

2. Provision of this service is voluntary for pharmacies.

Article 37. *Sworn statement for the provision of services by the retail pharmacy.*

Retail pharmacies wishing to provide the pharmaceutical care service and dispensing with informed delivery to the patient's home must submit a sworn statement signed by the licence-holder(s) or manager to the General Directorate responsible for pharmaceutical regulation. Submission shall be made using the standard form in Annex II, available on the website at https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, and the standard form on the Digital Administration Portal (website).

1. In the event of a change of licence-holder of the retail pharmacy, the new licence-holder(s) must submit a new sworn statement within 10 days of the effective transfer date if they wish to continue the service or, failing that, communicate their voluntary cessation of the activity.

2. Provision of this service may start on the same day as submission of the sworn statement, without prejudice to the control and inspection powers to check compliance with the established requirements.

3. Cessation of provision of the service must be communicated to the General Directorate responsible for pharmaceutical regulation by the licence-holder(s) or the manager.

4. Before 28 February each year, the licence-holder(s) or manager(s) of the retail pharmacy that has provided the pharmaceutical care service and dispensing with informed delivery to the home shall submit an annual declaration to the general directorate responsible for pharmaceutical regulation detailing the number of patients to whom the service has been provided, indicating the number of deliveries made to each of them. Submission shall be made using the standard form in Annex III, available on the website at https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, and the standard form on the Digital Administration Portal (website).

5. Non-compliance with the declared conditions or the requirements laid down in this Article shall determine the impossibility of continuing with provision of the service, which shall be agreed by resolution of the General Directorate responsible for pharmaceutical regulation.

Article 38. *General conditions for provision of the pharmaceutical care service and dispensing with informed delivery to the home by the retail pharmacy.*

1. Preparation and dispensing of the pharmaceutical products requested must always be carried out by a pharmacist, who will ensure compliance with the guidelines established by the prescribing practitioner. This professional action must ensure correct dispensing, monitoring and adherence of the patient to the treatment with the medicinal products dispensed.

2. The service can only be provided from pharmacies that have previously dispensed the pharmaceutical products requested by the patient.

3. Any type of intermediation by third parties, entities or companies between the retail pharmacy and patients in the provision of this service is prohibited.

4. In accordance with the pharmaceutical planning criteria defined in Article 23.2 of Law 13/2022 of 21 December 2022 on Pharmaceutical Management and Care in the Community of Madrid, in order to ensure patient adherence to treatment and adequate pharmacotherapeutic follow-up, this service must be provided by retail pharmacies within the basic health zone or the nearest adjacent zone to the patient's home unless the patient exercises their right to choose a pharmacy.

5. In any case, the retail pharmacy is responsible for the pharmacotherapeutic follow-up of patients included in this scheme, ensuring continuous care and resolving problems relating to medication, using telematic means if necessary.

Article 39. *Application for provision of the pharmaceutical care service and dispensing with informed delivery to the home by the retail pharmacy.*

1. Patients in a situation of dependence or disability with a loss of functional autonomy, who have difficulty or face obstacles in travelling to the retail pharmacy of their choice, or their legal representatives, may request the service at the retail pharmacy of their choice, provided that it is offered there.

2. Upon receipt of the application, the retail pharmacy must inform the patient of the payment mechanisms available and complete a dispensing sheet including:

a) the name and surname(s) of the patient and, where appropriate, of the legal representative;

b) the circumstances giving rise to the request for the service;

c) the date of the service request;

d) the address to which delivery is to be made;

e) the individual health card code in the case of electronic prescription and the patient's identity number in the case of a prescription for narcotic or psychotropic medicinal products;

f) the details of the retail pharmacy providing the service;

g) the list of medicinal products and medical devices that the patient or their legal representative requests be dispensed.

3. The patient or their representative must sign the application, which will be valid for one year. In any case, the patient or their representative may terminate continuation of the service at any time. To do so, the patient need only sign a cessation document provided by the retail pharmacy, stating their express wish to terminate the service. This document must be filed with the patient's medical records.

4. The retail pharmacy must make this procedure available to the patient or their representative in an accessible manner, without the need to give reasons for the decision, ensuring that their request for deregistration is registered immediately and effected without undue delay.

Article 40. *Dispensing at the retail pharmacy and informed delivery of the requested pharmaceutical products to the home.*

1. Before dispensing the medicine, the pharmacist must verify the identity of the patient or, where applicable, their delegate. It must also ensure that access to the data necessary for correct informed dispensing and monitoring of the

treatment is carried out in accordance with the requirements and conditions laid down by law.

2. Dispensing must be carried out exclusively on the prescriptions pending dispensing requested by the patient or their legal representative.

3. The packaging of dispensed products must ensure their integrity and safety during transport.

4. Each package must be externally identified with the name and address of the patient and accompanied by a proof of delivery slip that should include:

a) the first name and surname(s) of the recipient;

b) the home delivery address;

c) identification of the pharmacy and the person making the delivery;

d) the list of medicinal products and healthcare products included in the delivery, indicating the name, quantity and any special storage conditions that might apply;

e) space for the recipient of the service to enter their name, signature and the delivery date.

5. The proof of delivery slip shall be issued in duplicate: one copy for the patient or their representative and another copy to be preserved at the retail pharmacy.

6. The delivery shall be made in such a way that the products do not suffer any deterioration in their quality or integrity.

7. Home delivery shall be carried out exclusively by the licensed pharmacists of the retail pharmacy, the pharmaceutical staff or pharmacy technicians of the same pharmacy, always under the supervision of the pharmacist and in accordance with the established standard operating procedures and applicable regulations.

8. If the service includes preparing and delivering personalised dosage systems, the retail pharmacy shall proceed in accordance with the provisions of Chapter III.

Article 41. *Payment to the retail pharmacy of the financial contribution for the pharmaceutical products.*

1. Payment of the financial contribution for dispensed pharmaceutical products shall be made using the available payment mechanisms, of which the interested party has been informed at the time of their request.

2. A receipt shall be issued upon payment pursuant to Article 15(4) of the recast text of the Law on guarantees and rational use of medicinal products and medical devices, approved by Royal Legislative Decree 1/2015 of 24 July 2015.

3. Under no circumstances may the provision of this service result in an increase in the price of the medicinal products or medical devices dispensed.

Article 42. *Obligations of the retail pharmacy in providing the service.*

1. The retail pharmacy must keep the originals of the proof of delivery slips for a period of at least two years and make them available to the health authorities upon request.

2. The documentation relating to provision of the service is subject to the registration and archiving requirements set out in Article 8.2(c) of Law 13/2022 of 21 December 2022.

3. Any use of information relating to the identification of patients or their treatments for purposes other than those laid down by law shall be prohibited.

4. The pharmacist must inform the health authorities of any incident occurring during provision of the service that might have clinical significance for patients.

Article 43. *Pharmaceutical care and non-face-to-face dispensing of hospital medicinal products from the hospital pharmacy service.*

1. The pharmaceutical care service may include telematic assistance developed by pharmacists specialising in hospital pharmacy aimed at ensuring safe, effective and accessible pharmacotherapy for patients requiring hospital-dispensed drugs. It may also include dispensing, on a non-face-to-face basis, with the delivery, if appropriate, of medicinal products to pharmaceutical establishments close to the patient's home authorised to dispense them, or to their own home.

2. The hospital pharmacy service must establish a specific protocol for the inclusion of patients in this care programme, providing for the following aspects:

a) identification of patients likely to benefit from the service;

b) procedure for ensuring the traceability and preservation of medicinal products during transport;

c) control measures to ensure that medicinal products reach their destination without deterioration or loss of quality.

3. In any case, the hospital pharmacy service is responsible for the pharmacotherapeutic follow-up of patients included in this scheme, ensuring continuous care and resolving problems relating to medication.

4. Non-compliance with the provisions of this Article shall determine the impossibility of continuing with provision of the service, which shall be agreed by resolution of the General Directorate responsible for pharmaceutical regulation.

CHAPTER V

Transfer of retail pharmacies

Article 44. *Authorisation of the transfer activity.*

1. The transfer of retail pharmacies, in accordance with the provisions of Article 31 of Law 13/2022 of 21 December 2022, may only be made in favour of one or more other pharmacists.

2. If the transfer is agreed upon by the co-licence-holders of the retail pharmacy in favour of a third party, an individual file is processed for each co-licence-holder involved in the transfer.

3. A transfer agreed by the licence-holder of a pharmacy in favour of two or more acquirers shall result in a single transfer file.

4. Should the owners of two pharmacies located in the Community of Madrid request to exchange their respective retail pharmacies, the request shall be processed in a single file.

5. Likewise, the application will be processed in a single file when the pharmacy that is intended to be exchanged has more than one licence-holder and undivided ownership shares are exchanged.

Article 45. *Authorisation application.*

1. The procedure is initiated at the request of the interested parties, who must submit a single application signed by both the transferor and the acquirer, in which they provide their personal details and identification of the retail pharmacy that is the subject of the legal transfer.

2. This application must be completed using the standard application form available on the website of the regional ministry responsible for health matters and the standard form on the Digital Administration Portal (electronic headquarters) and should be addressed to the general directorate responsible for pharmaceutical regulation.

3. The following documentation must be provided with the application:

a) a copy of the documents proving the identity of the pharmacists involved in the legal transaction of the transfer;

b) the plan of the premises occupied by the retail pharmacy to be transferred, on a standardised scale, updated to the date of transfer, specifying the distribution zones;

c) the transferor's sworn statement that they are not subject to the limitation set forth in Article 31(5) of Law 13/2022 of 21 December 2022;

d) if the pharmacy has any additional signage, this must be indicated, accompanied by a plan or photograph of its location;

e) the Licentiate or Bachelor's degree in pharmacy of the party acquiring the pharmacy office, together with the certificate of membership of the Official College of Pharmacists of Madrid;

f) the acquiring party's sworn statement that they meet the compatibility conditions referred to in current regulations and their commitment to comply

with them in the operation of the retail pharmacy, with an express statement that they are not in the process of transferring another retail pharmacy anywhere else on Spanish territory; the acquiring party's statement as to whether they will continue to provide the service of creating magistral formulations, PDS, or pharmaceutical care and dispensing with informed home delivery, if any of these were being provided by the pharmacy that is the subject of the transfer;

g) the declaration of the acquiring party of their intention to continue with the linked medicinal product storage facilities or sections that the pharmacy subject to transfer had had authorised;

h) communication of the opening hours of the retail pharmacy;

i) receipt of payment of the corresponding administration fee.

4. In cases of transfer to third parties due to the death of the head pharmacist, the heirs shall also provide the following documentation:

a) the death certificate of the deceased;

b) the will, if any, or, failing that, the notarial certificate of declaration of intestate heirs;

c) the public deed of partition and distribution of inheritance;

d) the declaration by all heirs of their intention to transfer ownership of the retail pharmacy;

e) if there are heirs who are minors or incapacitated, judicial authorisation for the transfer.

5. In cases of transfers to a co-licence-holder due to the death of another co-licence-holder of the same pharmacy, it will be sufficient to provide the documentation set out in section 4, as well as proof of payment of the corresponding fee.

6. In cases of transfer to one or more co-licence-holders of the part of the same pharmacy corresponding to another co-licence-holder, it will not be necessary to provide documentation that is already in the possession of the Administration, except for the updated sworn statements of the licence-holders and proof of payment of the corresponding fee.

7. During the course of the procedure, the Administration may require the interested parties to provide any other documents deemed essential for it to issue a decision.

Article 46. *Decision and effectiveness thereof.*

1. Once the application and accompanying documentation have been entered in the register of the General Directorate responsible for pharmaceutical regulation, the body responsible for making the decision, and once the checks and, where applicable, corresponding remedies have been made, said General Directorate shall issue a decision granting or refusing authorisation within three

months. If this period elapses without an express decision having been issued, the interested parties may consider their application to have been rejected, in accordance with the provisions of Law 1/2001 of 29 March 2001 regulating the maximum period and system of administrative silence in certain procedures.

2. The decision authorising the transfer is conditional on the presentation of the documentation referred to in Article 47 and shall produce its effects from the date of entry in the register of the body competent to decide. If this documentation has been provided at an earlier stage of the procedure, the authorisation decision shall become effective from the date of its notification to the interested parties.

3. If the documentation referred to in Article 47 is incomplete or defective, the interested party shall be required to rectify it within 10 days. Failure to remedy the situation within the time limit shall render the decision authorising the transfer null and void, which shall be formally communicated to the party concerned. The interested party shall also be notified if the requirement for remedy is deemed to have been met.

Article 47. *Documentation subsequent to the authorisation decision.*

1. In the resolution authorising the transfer, the interested parties are requested to provide the following documentation within 30 days of notification of the decision:

a) proof of the legal availability of the premises in the name of the acquiring party;

b) the notarial deed formalising the legal transaction of the transfer.

2. Once the above period has elapsed without the required documentation having been provided, the decision authorising the transfer shall be null and void.

Article 48. *Requirements to be met by the acquiring pharmacist.*

1. Once the transfer authorisation is effective, the new licence-holder(s) must submit the following documentation to the body that issued the decision, within 10 days:

a) the narcotics inventory signed by both parties involved in the transfer;

b) the minimum stock list signed and stamped by the new licence-holder(s);

c) the email address and contact telephone number of the retail pharmacy;

d) the communication of arrivals and departures of pharmaceutical personnel that have been made in connection with the transfer.

2. If the pharmacy being transferred is authorised to prepare magistral formulas and officinal preparations, provided that no modifications are made to the laboratory facilities, these activities may continue upon presentation, within

10 days of the effective date of the transfer, of a sworn statement confirming that the conditions of said authorisation are being maintained.

3. If the retail pharmacy subject to transfer is providing the services of PDS preparation or pharmaceutical care and dispensing with informed delivery to the home, these activities may be continued provided that, within 10 days of the effective transfer date, they submit the sworn statements required in each case.

4. In the case of medicinal product storage facilities linked to the transferred retail pharmacy, in order for the new owner(s) to be able to maintain them, they must, within 10 days of the effective transfer, submit the documents submitted for the last authorisation of those deposits signed by the licence-holder or the legal representative of the centre and by the new licence-holder(s).

5. If the transferred retail pharmacy has authorised sections, the new licence-holder(s) must, within 10 days of the effective transfer date, apply for the mandatory health authorisation for change of licence-holder from the competent body responsible for authorising pharmaceutical centres, services and establishments.

CHAPTER VI

Penalties regime

Article 49. *Penalties regime.*

Failure to comply with the provisions laid down in this decree shall be penalised in accordance with the offences and penalties regime provided for in Title IX of the recast text of the Law on guarantees and rational use of medicinal products and medical devices and in Title III of Law 13/2022 of 21 December 2022.

First additional provision. *Updating of standard forms.*

The standard forms applicable to the sworn statements regulated in this decree can be updated in order to keep them aligned with the regulations in force. To this end, it will be sufficient to publish the updated form on the website of the Community of Madrid at https://www.comunidad.madrid/servicios/salud/farmacias-farmacéuticos, where it will be permanently accessible to all interested persons, without the need for a new publication in the Official Gazette of the Community of Madrid.

Second additional provision. *Inclusive language.*

For reasons of economy of language and general technical difficulty of adaptation to the feminine and masculine gender, in all cases, any generic mentions using the masculine form that appear in the expository and operative

part of this decree are also understood to refer to their corresponding feminine, with strict equality in their legal effects.

First transitional provision. *Pharmaceutical professionals working extended hours and in special circumstances.*

Licence-holders and co-licence-holders of pharmacies shall have three months from the entry into force of this decree to adapt to the requirements for pharmaceutical professionals in the event of extended opening hours and special circumstances.

Second transitional provision. *Regime applicable to retail pharmacies and pharmacy services that were already providing the PDS service.*

Any retail pharmacies and pharmacy services already providing a PDS preparation and delivery service at the time of entry into force of this decree shall have six months to comply with its provisions.

Third transitional provision. *Pharmacy transfer authorisation applications in process.*
Transfer authorisation applications in respect of which no express decision has been made by the date of entry into force of this decree shall be processed in accordance with the regulations in force at the time of their submission.

Sole repealing provision. *Regulatory repeal.*

Any provisions of equal or lesser rank that contradict the provisions of this decree are hereby repealed; in particular, Decree 259/2001 of 15 November 2001 establishing opening hours, out-of-hours services and holidays for pharmacies in the Community of Madrid, are expressly repealed.

First final provision. *Regulatory enactment.*

The head of the regional ministry responsible for health matters is hereby empowered to issue any other provisions necessary for the implementation of this decree.

Second final provision. *Entry into force.*

This decree shall enter into force on the day after its publication in the Official Gazette of the Community of Madrid.

Dirección General de Inspección y Ordenación Sanitaria
CONSEJERÍA DE SANIDAD

Comunidad de Madrid

Entry register

ANNEX I

Sworn statement for personalised dosage systems (PDS)

○	Retail pharmacy	○	Pharmacy service

1.- Details of the retail pharmacy/pharmacy service:

No of retail pharmacy					
No of pharmacy service					
Road type		Road name		Number	
Postcode		Town			
email		Telephone 1		Telephone 2	

2.- Details of the Pharmacist(s) who is/are the Licence-holder(s)/Co-licence-holder(s)/Manager(s) of the retail pharmacy or pharmacist responsible for the pharmacy service:

NIF/NIE (tax/ID number)					
Name		Surname 1		Surname 2	
email		Telephone 1			

NIF/NIE (tax/ID number)					
Name		Surname 1		Surname 2	
email		Telephone 1			

3.- Details of the representative:

NIF/NIE (tax/ID number)			Company name/Entity		
Name		Surname 1		Surname 2	
email		Telephone 1		Telephone 2	
In the capacity of					

4.- Means of notification: ○ Interested party ○ Representative (please indicate to whom you would like the notification to be sent)

Notifications shall be made by **electronic means**; therefore, **prior to the submission of this application**, the person to be notified **must be registered in the Community of Madrid electronic notification system**. You can register by clicking on this link.

5.- Sworn statement:

Community of Madrid

I declare on my own responsibility:

- that I comply with the necessary technical sanitary requirements to provide the personalised dosage device (PDS) service;
- That I have adequate facilities, equipment and tools and the specific standard operating procedure for action, which will be kept available to the Administration at all times for subsequent control.

6.- Required documentation:

Documents to be submitted with the statement	
In the case of a declaration submitted by a representative, a document justifying the authorisation to carry out this process and the scope of this representation	☐
The Community of Madrid will consult the data contained in the following documents by electronic means(*):	
In the case of a natural person: the tax identification number(s) of the licence-holder(s) of the retail pharmacy	
In the case of a legal person: the NIF (tax number) of the representative	

(*) You may object to this consultation on grounds that you will need to justify. In this case, you must provide the documentation that you object to being consulted (Article 28(2) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations). All this without prejudice to the power of the Administration to check.

☐ I object to consultation of the following data for the reasons set out below:

In ……., on……... of……..…….. of……...

SIGNATURE

You can consult the information regarding the duty to inform about the protection of personal data on the following pages.

RECIPIENT	Regional Ministry of Health General Directorate for Health Inspection and Management

Information on data protection

1. Person responsible for processing your data

Community of Madrid

- **Data Controller:** REGIONAL MINISTRY OF HEALTH, G.D. FOR HEALTH INSPECTION and MANAGEMENT
- **Registered office:** Consult www.comunidad.madrid/centros
- **Data Protection Officer contact:** Data Protection Committee of the Regional Ministry of Health of the Community of Madrid protecciondedatos.sanidad@madrid.org.

2. In which processing activities are my personal data included and for what purposes will it be processed?

- MANAGEMENT OF ADMINISTRATIVE REQUESTS AND COMMUNICATIONS

In compliance with the provisions of the General Data Protection Regulation (EU) 2016/679 (GDPR), your data will be processed for the following purposes:

- management, processing and resolution of applications for authorisation, accreditation, certification, reports and evaluation, as well as

communications concerning: health and pharmaceutical centres, services and establishments; control of medicinal products for human and veterinary use; and control of medical devices and cosmetics.

3. What are the legitimate grounds for the lawfulness of the processing?

Law 13/2022 of 21 December 2022 on Pharmaceutical Management and Care in the Community of Madrid; Law 14/1986 of 25 April 1986, the General Health Law; Law 12/2001 of 21 December 2001 on Health Management of the Community of Madrid; Royal Legislative Decree 1/2015 of 24 July 2015 approving the recast text of the Law on guarantees and rational use of medicinal products and medical devices

GDPR 6(1)(e) the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the data controller.

4. How do you exercise your rights? What are your rights when you provide us with your data?

You may, if you wish, exercise the rights of access, rectification and deletion of data, as well as the right to request restriction of the processing of your personal data, object to its processing, or request portability of your data where appropriate; you also have the right not to be subject to an individual decision based solely on automated processing, including profiling.

In accordance with Law 39/2015, the GDPR (EU) and Organic Law 3/2018, you can exercise your rights by Electronic Register or in person, in both cases stating the reference 'Exercise of data protection rights'.

5. Processing involving automated decisions, including profiling, with legal or relevant effects

Not applicable

You have the right not to be subject to an individual decision based solely on automated processing, including profiling, which produces legal effects concerning you or significantly affects you in a similar way.

6. How long will we keep your personal data for?

The personal data provided will be retained for the following period:

Indefinite period

The data will be kept for as long as is necessary to fulfil the purpose for which it was collected and to determine the possible responsibilities arising in relation to this purpose and the processing of the data.

7. To which recipients will your data be communicated?

Interested parties to the proceedings. Other Public Administrations (Ministry of Health). Citizens via the website.

8. Right to withdraw consent to processing at any time

You have the right to withdraw your consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal, where the processing is based on consent or explicit consent for special data.

9. Right to lodge a complaint with the Control Authority

You have the right to lodge a complaint with the Spanish Data Protection Agency http://www.aepd.es if you do not agree with the processing of your personal data.

10. Category of data subject to processing

Identification data; academic and professional data; employment data.

11. Source of the data

Natural and legal persons required to obtain authorisation, accreditation, evaluation and to make the communication.

12. Additional Information

General Directorate for Health Inspection
and Management
REGIONAL MINISTRY OF HEALTH

Community of Madrid

Dirección General de Inspección y
Ordenación Sanitaria
CONSEJERÍA DE SANIDAD

Comunidad de Madrid

You can consult additional and detailed information and the applicable regulations on data protection on the website of the Spanish Data Protection Agency http://www.agpd.es, as well as information about the Record of Processing Activities of the Data Controller indicated above, via the following link: www.comunidad.madrid/protecciondedatos

Entry register

ANNEX II

Sworn Statement on Pharmaceutical Care and dispensing with informed delivery to the home for retail pharmacies

1.- Type of statement:

○	Registration	○	Change of licence-holder of the retail pharmacy	○	Cessation of service provision

2.- Details of the retail pharmacy:

No of retail pharmacy					
Road type		Road name		Number	
Postcode		Town			
email		Telephone 1		Telephone 2	

3.- Details of the Pharmacist(s) who is/are the Licence-holder(s)/Co-licence-holder(s)/Manager of the retail pharmacy:

NIF/NIE (tax/ID number)					
Name		Surname 1		Surname 2	
email		Telephone 1			

NIF/NIE (tax/ID number)					
Name		Surname 1		Surname 2	
email		Telephone 1			

4.- Details of the representative:

NIF/NIE (tax/ID number)			Company name/Entity		
Name		Surname 1		Surname 2	

email		Telephone 1		Telephone 2	
In the capacity of					

5.- Means of notification: ○ Interested party ○ Representative (please indicate to whom you would like the notification to be sent)

Notifications shall be made by **electronic means**; therefore, **prior to the submission of this application**, the person to be notified **must be registered in the Community of Madrid electronic notification system**. You can register by clicking on this link.

6.- Required documentation:

Documents to be submitted with the statement	
In the case of a declaration submitted by a representative, a document justifying the authorisation to carry out this process and the scope of this representation	☐
The Community of Madrid will consult the data contained in the following documents by electronic means(*):	
In the case of a natural person: the tax identification number(s) of the licence-holder(s) of the retail pharmacy	
In the case of a legal person: the NIF (tax number) of the representative	

(*) You may object to this consultation on grounds that you will need to justify. In this case, you must provide the documentation that you object to being consulted (Article 28(2) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations). All this without prejudice to the power of the Administration to check.

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SIGNATURE

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Information on data protection

1. Person responsible for processing your data

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In compliance with the provisions of the General Data Protection Regulation (EU) 2016/679 (GDPR), your data will be processed for the following purposes:

- management, processing and resolution of applications for authorisation, accreditation, certification, reports and evaluation, as well as

communications concerning: health and pharmaceutical centres, services and establishments; control of medicinal products for human and veterinary use; and control of medical devices and cosmetics.

3. What are the legitimate grounds for the lawfulness of the processing?

Law 13/2022 of 21 December 2022 on Pharmaceutical Management and Care in the Community of Madrid; Law 14/1986 of 25 April 1986, the General Health Law; Law 12/2001 of 21 December 2001 on Health Management of the Community of Madrid; Royal Legislative Decree 1/2015 of 24 July 2015 approving the recast text of the Law on guarantees and rational use of medicinal products and medical devices

GDPR 6(1)(e) the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the data controller.

4. How do you exercise your rights? What are your rights when you provide us with your data?

You may, if you wish, exercise the rights of access, rectification and deletion of data, as well as the right to request restriction of the processing of your personal data, object to its processing, or request portability of your data where appropriate; you also have the right not to be subject to an individual decision based solely on automated processing, including profiling.

In accordance with Law 39/2015, the GDPR (EU) and Organic Law 3/2018, you can exercise your rights by Electronic Register or in person, in both cases stating the reference 'Exercise of data protection rights'.

5. Processing involving automated decisions, including profiling, with legal or relevant effects

Not applicable

You have the right not to be subject to an individual decision based solely on automated processing, including profiling, which produces legal effects concerning you or significantly affects you in a similar way.

6. How long will we keep your personal data for?

The personal data provided will be retained for the following period:

Indefinite period

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8. Right to withdraw consent to processing at any time

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9. Right to lodge a complaint with the Control Authority

You have the right to lodge a complaint with the Spanish Data Protection Agency http://www.aepd.es if you do not agree with the processing of your personal data.

10. Category of data subject to processing

Identification data; academic and professional data; employment data.

11. Source of the data

Natural and legal persons required to obtain authorisation, accreditation, evaluation and to make the communication.

12. Additional Information

General Directorate for Health Inspection
and Management
REGIONAL MINISTRY OF HEALTH

Community of Madrid

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Entry register

ANNEX III

Annual declaration on Pharmaceutical Care and dispensing with informed delivery to the home for retail pharmacies

Annual declaration (No patients/No deliveries/patients):

	Retail pharmacy

Details of the retail pharmacy:

of retail pharmacy					
l type		Road name		Number	
code		Town			
l		Telephone 1		Telephone 2	

Details of the licensed pharmacist(s)/co-licensed pharmacist(s)/manager of the retail pharmacy

NIE D er)					
e		Surname 1		Surname 2	
		Telephone 1			

NIE D er)					
e		Surname 1		Surname 2	
		Telephone 1			

Details of the representative:

NIE D er)		Company name/Entity			
e		Surname 1		Surname 2	
		Telephone 1		Telephone 2	
e capacity of					

General Directorate for Health Inspection
and Management
REGIONAL MINISTRY OF HEALTH

Community of Madrid

Means of notification: ○ Interested party ○ Representative (please indicate to whom you would like the notification to be
nt)

fications shall be made by **electronic means**; therefore, **prior to the submission of this application**, the person to be ed **must be registered in the Community of Madrid electronic notification system**. You can register by clicking on this

Required documentation:

Documents to be submitted with the statement	
ual declaration of pharmaceutical care activities carried out, including the number of nts and number of deliveries/patients	☐
The Community of Madrid will consult the data contained in the following documents by electronic means(*):	
e case of a natural person: the tax identification number(s) of the licence-holder(s) of the retail pharmacy	
e case of a legal person: the NIF (tax number) of the representative	

You may object to this consultation on grounds that you will need to justify. In this case, you must provide the documentation that you object to being consulted cle 28(2) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations). All this without prejudice to the power of the inistration to check.

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RECIPIENT	Regional Ministry of Health General Directorate for Health Inspection and Management

General Directorate for Health Inspection
and Management
REGIONAL MINISTRY OF HEALTH

Community of Madrid

formation on data protection

Person responsible for processing your data

ata Controller: REGIONAL MINISTRY OF HEALTH, G.D. FOR HEALTH INSPECTION and MANAGEMENT

egistered office: Consult www.comunidad.madrid/centros

Data Protection Officer contact: Data Protection Committee of the Regional Ministry of Health of the Community of Madrid ecciondedatos.sanidad@madrid.org.

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ANAGEMENT OF ADMINISTRATIVE REQUESTS AND COMMUNICATIONS

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w 13/2022 of 21 December 2022 on Pharmaceutical Management and Care in the Community of Madrid; Law 14/1986 of 25 April 1986, the General Health w; Law 12/2001 of 21 December 2001 on Health Management of the Community of Madrid; Royal Legislative Decree 1/2015 of 24 July 2015 approving the ast text of the Law on guarantees and rational use of medicinal products and medical devices

PR 6(1)(e) the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the data troller.

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Processing involving automated decisions, including profiling, with legal or relevant effects

applicable

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Additional Information

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