EXECUTIVE SUMMARY

This study, *NHS hospital expenditure: pharmacy and investment in capital goods,* - is a continuation of the study conducted by AIReF in 2019 on *the Evaluation of public expenditure on medication dispensed through prescription,* analyses, reviews and evaluates hospital pharmaceutical spending and the spending and investment on high-tech capital goods in Spanish hospitals of the National Health System (NHS) between 2002 and 2018. The objective and final outcome of the study is **to make proposals** aimed at guaranteeing and improving the **sustainability and overall efficiency** of the public health system.

In budgetary terms, in 2018 the sum of the two items under evaluation, spending on medicines in the hospital sector and spending on high-tech capital goods accounted for **about €7bn** for the public purse.

However, the evaluation of these two budget items offers other aspects of interest that go beyond the budget size. **Hospital pharmaceutical expenditure** has increased steadily over recent years, from €2.324bn in 2003 to €6,613bn billion euros in 2018, rising from 21% of public pharmaceutical expenditure in 2003 to 39% in 2018.

In addition, all forecasts indicate that hospital pharmaceutical expenditure will continue **growing over the coming years**, mainly as a result of the introduction of innovative medicines with a high economic impact in the fields of oncology, new antidiabetic medication, drugs developed using synthetic biology, cell and genetic therapies and the expected growth in orphan drugs[1]. Another factor of interest is that there is **significant variability in the management of hospital pharmaceutical expenditure between autonomous regions and hospitals.** in addition, it is an area with limited transparency that has not been subject to extensive analysis.

Although **high-tech capital goods** are a less important spending item than pharmaceutical expenditure in budgetary terms, they have an important impact due to their high

[1] Orphan drugs are those intended for diseases which, because of their rarity, are not economically attractive to the pharmaceutical industry under normal market conditions, but are attractive for public health.

acquisition and operating costs and the potential savings they can generate in other items of hospital expenditure. They are also essential for providing **quality care**, with a high impact on health outcomes.

In addition, knowing the current state of the existing installed technology and the use that is made of high-technology health equipment is important as these are aspects which condition the operations and efficiency of the National Health System (NHS).

High-technology health equipment is mainly used in both diagnostic and therapeutic processes, but also in rehabilitation and life support. That is why the level of obsolescence and the per capita level of equipment are so critical when assessing the quality of care in the NHS.

It is a well-known problem that the autonomous regions have patient waiting lists for diagnostic imaging tests and the delay that these cause in relation to starting appropriate treatment with the consequent effect this situation may have on the worsening of the patient's condition.

The evaluation exercise for these two budget items has been conducted from an **economic perspective** and is based on **evidence and data analysis**, in the search for improvements in terms of **effectiveness** and **efficiency**. For this purpose, it has been essential to have quantitative and qualitative information from the following sources of information:

- **Databases**, both public and restricted.
- **Questionnaires**, designed for both the management of pharmaceutical expenditure and high-tech equipment, and those sent to NHS health services and hospitals.
- **Personal interviews,** various professionals have been interviewed face-to-face in hospitals for a duration of approximately 7-8 hours in a selection of 41 hospitals from all the autonomous regions, of different legal forms and with different management categories.
- **Meetings** held with **relevant stakeholders** and **working sessions with experts** in different subjects.
- **Review of literature and analysis of significant experiences**, both national and international.

Main conclusions of the evaluation in the field of hospital pharmacy

Decisions on financing and pricing of medicines

- **Decision-making on the financing of medicines and the setting of the financed price is a responsibility of Central Government exercised through the Interministerial Committee on Medicine and Healthcare Product Prices (CIPM).** Even though it is the autonomous regions that bear the pharmaceutical expenditure through their budgets and their involvement in this decision-making process has increased since 2019, the current model still grants the **autonomous regions** a **low level of decision-making power**, with only three of the 11 possible votes.

- In Spain, unlike in other countries, the current reference price system (RPS) is configured at the active ingredient level. It does not therefore allow an **overview** of the price of the medicines used in a given pathology. This leads to **significant differences in the prices of medicines with similar therapeutic value** for the same condition and **limits potential competition** between these medicines.

- With regard to the consideration of cost-effectiveness criteria in the pricing process, there is currently no systematic basis for evaluating cost-effectiveness studies and **the price for a significant proportion of the medicines is not linked to effectiveness**.

- With regard to the review and modification of the price of financed medicines, in May 2019 the CIPM started to include in its information notes the decisions to modify the price of financed presentations, as well as the resolutions to exclude medicines. Some of the upward price revisions have been aimed at avoiding the risk of medicine shortages resulting from excessively low prices (as of February 2020, the price of 23 financed presentations have risen, 3 of which correspond to medicines for hospital use). However, **these price revisions are sometimes made reactively and not systematically**, without using automatic warning mechanisms or clauses that prevent the price from falling below a certain threshold.

Evaluation and decisions for including medicines by pharmacy and therapeutics commissions (P&TCs) at a regional and centre level

- **At present, a multitude of evaluations are performed by P&TCs with room for improvement in coordination,** and they rarely work together in a network. This leads to **duplication** in the evaluation of medicines and a **lack of standardisation in the recommendations issued** by the different regions and by the different hospitals in the

same region.

- **The existence of different structures (regional and hospital P&TCs) and different levels of centralisation and decentralisation in the decision-making models for the pharmatherapeutical guides (PTGs) results in significant variability between regions in the governance and setting of the PTG.** These differences in turn largely translate into variability in medicine inclusion rates, i.e., the percentage of drugs that are included in hospitals' PTG.
- With regard to off-label medicines i.e., drugs that are used for different conditions than those set out in their data sheet, there are differences both in the governance and the management of requests for this type of drug and in the level of **applied protocols** in the request and approval processes between hospitals and regions. This variability, in turn, translates into **significant differences in the approval rate** between regions and inequity in access to treatments.

Rational use of medicines (RUM)

- **Biosimilar medicines** are one of the most important levers with regard to the strategy for the rational use of medicines in hospitals and in the search for sustainability of the healthcare system.
- **The level of penetration of biosimilars varies widely between regions, hospitals and clinical services.** In the case of the regions, the existing differences are of over 40 percentage points between region with the highest level of penetration in 2018 (Castile-La Mancha, with 46.8%) and that with the lowest (Basque Country, with 5.3%). Only Castile-La Mancha, Andalusia and Asturias record levels of over 40%.
- In comparative terms with similar countries, the penetration of biosimilars in Spain is **below the European average in three of the six active ingredients** for which European-wide data is available. There is therefore **room for improvement** in the use of biosimilars.
- **Differences** have also been noted **in the policies and strategies** used by health services and hospitals to encourage the use of biosimilars both in treatment-naïve patients and in the switch to biosimilars in patients who have already been treated with the reference biological medicine. These differences result in lower savings in those strategies in which the switch to biosimilars is limited to new patients and in the introduction of new medicines.
- It has been found that the use of **incentives** to encourage the use of biosimilars is not a common practice and the few hospitals that use them do so in a local and sporadic manner.
- In addition to biosimilars, another action related to the rational use of medicine is the **cooperation** of hospital **pharmacists** with the **clinical services and units** and their **integration into the medical team** as this offers advantages in terms of reducing errors

and problems relating to medication and optimising treatments. While it is true that this is a common practice in Spanish hospitals (it is carried out by 74% of NHS centres), there are different levels of development and areas for improvement, such as measuring the impact and outcomes achieved.

Public procurement and purchasing of medicines

- **In Spain, the levels of procurement for the supply of medicines under Act 9/2017, of 8 November, on Public Sector Contracts present worrying data, which demonstrates that there is significant room for improvement.** More specifically, in 2018 only **31% of the procurement of medicines** in hospitals has been **standardised**, i.e., almost 70% was implemented through smaller contracts and direct purchasing from pharmaceutical laboratories without using the contract awarding procedures set out in the Public Sector Procurement Act.
- **There is, however, a high degree of variability in the volume of standardised procurement between regions and hospitals.** For example, in 2018, while in Catalonia the percentage of standardised procurement stood at 98%, and in Andalusia and Murcia at 60%, in other regions, such as Galicia, Aragon or the Balearic Islands, it stood at below 10%. Moreover, even within the same region, the differences between hospitals are equally significant. Behind these differences in the level of standardised procurement in the supply of medicines lie, in turn, differences in the strategy and organisation of administrative procurement (e.g. aggregation of purchases).
- In practice, there are several obstacles that, to some extent, make it difficult for hospitals to achieve a higher percentage of medicines purchased subject to the provisions of the Public Sector Procurement Act. These include the lack of **human resources**, the **lack of training and professionalisation** of purchasing managers, the traditional **lack of a culture of compliance with public procurement legislation** in this area, **budgetary limitations**, the heterogeneity and limited flexibility of the **oversight function** and the difficulties in obtaining the **consensus and involvement** of professionals.
- Unlike other areas of administrative action, the process of purchasing medicines is characterised by a **lack of transparency** both in medicine prices and in the process of purchasing and concluding contracts. Greater use of the Public Sector Procurement Act in the procurement of medicines would at least promote a greater level of transparency in the process.
- In addition to this lack of transparency, there is also **significant variability in net purchase prices** between contracting authorities, i.e. excluding the commercial discounts offered by pharmaceutical laboratories. These differences, in turn, result in different levels of efficiency associated with purchasing, which among the regions

ranges between 6% and 23%.

There is insufficient use of strategic planning tools (annual and multi-year purchasing and procurement plans) by regional health services and hospitals to enable more effective and efficient organisation and implementation of medicine purchases. Only four of the 14 regions that have answered the questionnaire have a medicine purchasing and/or procurement plan at their hospitals.

Logistics and dispensing of medicines

- Medicine logistics management models: **practically all of these models are based or revolve around the hospital, with few or limited experiences of logistical integration of levels** - interhospital, inter-centre, care, provincial or regional. This medicine logistics integration would bring greater efficiency to the process (of the associated resources and the investment necessary for its automation), as part of a **strategy to integrate hospital pharmacy support processes**.

- Many hospitals in the NHS, particularly the larger ones, have **automated dispensing systems** in a large proportion of the **hospitalisation units**, although there are differences in the level of automation between hospitals.

- The logistics and dispensing management process has a **lower level of automation** for **out-patients** than for in-patients. There are significant differences in the level of automation between hospitals and in some hospitals the dispensing is carried out manually, which raises the likelihood of errors or suboptimal management of drug storage and stocks.

- Furthermore, in relation to **out-patient pharmaceutical care and dispensing**, one of the most noteworthy phenomena in hospital pharmacy services over recent years is the **continuous growth of the out-patient pharmacy.** This growth is also taking place in the number of patients dealt with (around 1 million patients in 2018). This situation has meant that expenditure on out-patient pharmacy services in many hospitals' accounts for almost 60% of total pharmacy spending.

- This sharp growth in the out-patient pharmacy has led to the saturation of numerous pharmacy services and to difficulties in dealing with patients in **suitable spaces**. Furthermore, it has led to inconvenience for patients by having to go to the hospital and **accessibility problems** in some regions.

- In order to address these difficulties, and in the context of the health crisis caused by COVID-19, most of the regions have reacted quickly to attempt to bring medication closer to patients, in many cases with telepharmacy-based solutions. However, there

is still no specific detail and standardised regulatory framework clearly regulating and delimiting the pharmaceutical service for out-patients and the terms, conditions and circumstances under which non-face-to-face drug dispensing (telepharmacy) can take place. Defining a common legal framework would allow for greater equity in out-patient pharmaceutical care and dispensing in the NHS.

- **Drug supply problems**, defined as the unavailability of medicines that are used and prescribed along the pharmaceutical supply circuit, are a **widespread and growing reality** in Spanish hospitals. In 2018, the average number of medicines with supply problems stood at 53.2 per hospital, with a total of 4,682 supply problems in that year. As a result, hospitals incur significant costs, both financially, due to the use of more expensive therapeutic alternatives, and in terms of staff, due to the resources that must be allocated to managing the drugs. With regard to the management of supply problems, **there is a general absence of protocols** and information systems for recording, notifying and managing supply shortages that would allow formal management of the problem by hospitals, implementation of early warning systems and inter-centre logistics networks that would mitigate the effects of the situations (particularly for essential medicines).

Main findings of the evaluation in the field of high-tech capital goods

Current status of the existing installed equipment

- Despite a 17% increase in the **per capita level of high-tech equipment** between 2010 and 2017, **Spain remains below the average for OECD countries** in five of the six high-tech equipment categories analysed. The level of high-tech equipment was also uneven and there were significant differences between the regions.
- The high-tech equipment installed in Spain has a **greater level of obsolescence** than in other neighbouring countries. Over 40% of the equipment installed at the end of 2018 is more than ten years old, far exceeding international standards or recommendations, which limit this figure to 10%. Furthermore, the situation has worsened over recent years and **the obsolescence is now greater than ten years ago.** There is also obsolescence across the board in the regions. Specifically, in all the regions, except the Balearic Islands, at least 20% of the equipment is over ten years old.
- A significant proportion of the high-tech equipment installed at both public and private Spanish hospitals has a **low intensity or level of use**, indicating that this

equipment is not operating at full capacity and that, in general, **the technological equipment is underused**.

Decision-making process for the incorporation of high-tech equipment

- The **planning and the needs assessment** is (or should be) the source of any purchase and investment decision. Despite its importance and strategic nature, most hospitals and/or health services have no technology acquisition and renewal plans and multi-year planning processes for strategic management of the acquisition and financing of high-tech equipment. In contrast, most hospitals do have a general equipment needs plan (aggregation of needs identified by the care services and management of services departments), that they review and update annually. These plans typically include priority levels (without specifying the criteria used for defining levels) which are dependent on annual budget availability.

  In addition, **it is not common** for the decision-making for acquiring equipment to use, on a systematic basis, **models or algorithms** based on objective criteria (technical, clinical, financial etc.) that make it possible to prioritise the different needs and which make the decision-making process for financing high-tech equipment more transparent and objective.

Rational use of high-tech equipment

- The rational use of high-tech equipment, defined as an equivalent concept to the rational use of medicine that aims for patients to have efficient access to high-tech health equipment according to their clinical needs, is a **virtually non-existent concept in this field.**

- Although it is true that some hospitals are working along these lines, with protocols for the **adaptation/validation of tests and oversight of their prescription** in order to promote the patient's safety and the optimal and efficient use of the equipment, it is not the usual practice and a significant proportion of hospitals and primary care teams conduct a low level of monitoring of these aspects.

Inventory management and maintenance of high-tech equipment

- The availability of an **inventory system** that provides reliable information on the level and features of the equipment and their status is essential for optimal management of high-tech health equipment. Although almost every hospital has an inventory system (94%), only in exceptional cases does the system also record the operational history, breakdowns, maintenance, use etc., which leads to highly dispersed information and which hinders optimal management of the equipment. In exceptional cases, this inventory is digitised and integrated into corporate information systems that allow such integration and interoperability with the care and logistics management information systems (purchasing, procurement etc.).

- An important figure in relation to **maintenance** are the **clinical engineering services/departments**, as they are usually responsible both for maintaining low and medium-technology equipment and for the first intervention in high-tech equipment and monitoring of the status of the equipment, inventory etc. Hospitals that have a clinical engineering service report around **35% fewer lost operating hours per year.** Despite their importance, there is a significant variability in the existence of these services in hospitals, as well as in their type (i.e., whether they are part of the hospital, outsourced or mixed).

- **The manufacturer is responsible for the maintenance of over half of the high-tech equipment** and, in most cases, both preventive and corrective maintenance is usually performed. In this regard, maintenance by the manufacturer **leads, on average, to 36% fewer operating hours lost per year.**

Main findings of the evaluation in cross-cutting aspects

Management tools

- One of the most effective tools for health management are programme contracts or management agreements entered into between the hospital management and the regional health service or ministry for a certain time period and which act as an instrument for framing the strategic lines, aligning actions and setting indicators. In the case of targets and indicators relating to the **rational use of medicine**, although they all have a similar structure, the content differs between regions with **very wide differences in indicators and metrics**, both in number and in the weight or scoring that they are given in the evaluation, which makes comparison between them difficult.

- The number of targets and indicators related to the management of high-tech equipment is much lower than those related to pharmacy services, with an **almost total absence of indicators** related to the ***r*ational use of equipment.**

- **There is significant variability between regions and hospitals in incentive schemes and mechanisms for professionals**. Some centres and/or regions only use financial incentives, while others also use non-financial compensation, such as training or career opportunities. Nevertheless, the perception is that the discriminatory capacity of the different centres among professionals is insufficient and they do not therefore fulfil their function and their **effectiveness is limited.**

- Despite their importance in evaluating the activity in terms of cost effectiveness and their implications for management from the point of view of monitoring expenditure

and outcomes achieved, **the measurement of health outcomes and the use of analytical accounting tools is insufficient** and there is significant room for improvement. The measurement of health outcomes is still underdeveloped and very much focused on a specific group of processes, pathologies and areas.

- As regards **analytical accounting systems**, their management functionalities are limited as a result of the lack of methodological standardisation, the problems of comparability or their high time lag.

Training and research

- The health sector is characterised by **insufficient resources allocated by hospitals, health services and the government** in general to the **ongoing training of its professionals.** This inadequate public funding is offset by funds earmarked for training by the pharmaceutical industry. However, this training does not meet the objectives and training needs of professionals identified by the Health Administration (which does not participate in defining them), and raises doubts about the criteria for access to such training. **In the research field, Spain is the leading European country and the fourth in the world in the number of clinical trials conducted and is therefore an international benchmark in research activity.** As a result, a significant proportion of hospitals conduct clinical trials, specifically 63%. However, not all centres have precise knowledge of the implications in terms of cost, revenue or tests that are performed in the context of these trials. In addition, few hospitals quantify the savings resulting from participation in clinical trials.

ICTs and information systems

- **The application of information and communication technologies (ICT) and digitisation are or should be one of the main levers for modernising the health system, as they contribute significantly to the management, decision-making and quality of health care.** In this field, the reality is that the regions are at very different points with regard to the level of integration, interoperability and sophistication of their information systems. **The strategy, lines of work and efforts in terms of investment in information and communication technologies (ICT) have been uneven** across regions and there has been no generalised increase in resources over recent years.

Proposed measures as a result of the evaluation

The analyses performed and the conclusions and findings obtained as a result of the evaluation allow us to make a series of proposals to the competent authorities and to the different agents involved in each one of the areas analysed in the study. The proposals are presented below, grouped into three main areas (hospital pharmacy, high-tech equipment and cross-cutting aspects), which are in turn classified according to areas and themes.

FIGURE 1 PROPOSALS IN THE FIELD OF HOSPITAL PHARMACY

Evaluation, access and review

Financing and pricing decisions

1. Review of the structure of the CIPM
2. Intensification of systematic review of prices and financing conditions
3. Adaptation of the current Reference Price System
4. Incorporation of cost-effectiveness criteria in pricing

Medicines pipeline

5. Development of a plan for the entry of new medicines

Pharmacy Commissions and PTG Decision

6. Creation of a P&TC Collaboration Network
7. Selection of the pharmatherapeutic al guide using a mixed decision-making model
8. Standardisation of the criteria for inclusion of off-label medicinal products

Rational use of medicine

Use of biosimilars

9. Promotion of the use of biosimilars, both at the start of treatment and in the switch.

Main measures:
- Legal framework
- Incentives model
- Training for practitioners
- Information for patients

Pharmaceutical care in the services

10. Promotion of the integration of pharmacists in multidisciplinary care services and teams

Optimisation of medicines

11. Progress in medicine redosing in pharmacy services

Procurement and

Public procurement

12. Use of formulas and procedures to speed up the processing of procedures in order to promote procurement under Public Sector Procurement Act
13. Consolidation of electronic procurement platforms and promotion of the use of dynamic purchasing systems
14. Involvemen t of all hospital professionals to increase procurement under the Public Sector Procurement Act

Purchase of medicines and price negotiation

15. Obligation of the regions to share the financed price with the procurement bodies
16. Prohibition of

Logistics and

Automation

17. Automation of the storage and dispensing of medicines for inpatients
18. Automation of medicine storage and dispensing for outpatients

Outpatients

19. Establishing a procedural and operational regulatory framework for the provision of pharmaceutic als to outpatients
20. Improving the humanisation of care and medicine dispensing for outpatients

Supply problems

21. Implementation of mechanisms for formal and more efficient management of medicine supply problems

ANALYTICS OF PHARMACEUTICAL EXPENDITURE DATA

National comparative analysis of expenditure on medicines

22. Improvement in the way information is collected to achieve greater data quality and standardisation

International comparative analysis of expenditure on medicines

23. Promoting the collection of standardised data to allow international comparisons

Source: Compiled by author.

FIGURE 2 PROPOSALS IN THE FIELD OF HIGH-TECH CAPITAL GOODS

Decision-making: renewal, expansion and innovation

Existing equipment

1. Development of a plan for investment in high-tech equipment that will allow Spain to converge towards the European average in terms of levels of equipment and obsolescence

Planning for the decision-making process

2. Strategic planning at the national and regional level on the incorporation and financing of the equipment
3. Implementation of models to systematise, objectify and prioritise decision-making for the acquisition and renewal of equipment

Procurement

4. Establishing specialised procurement teams and promoting networking among them

Rational use of equipment and maintenance

Equipment inventory and records

5. Establishment of integrated systems that allow joint management of equipment inventory, maintenance, agendas and use

Rational use of high-tech equipment

6. Review, control and validation of the suitability of diagnostic tests and the activity performed with the equipment
7. Implementation of attendance reminder and confirmation systems to manage absences

Maintenance of high-tech equipment

8. Recommendation for preventive and corrective maintenance of equipment, preferably with the manufacturer and having a clinical engineering team

Source: Compiled by author.

FIGURE 3 CROSS-CUTTING PROPOSALS

Management tools

Setting the target and incentive model

1. Review of the target and incentive model for professionals

Health outcomes

2. Establishment of medicine and high-tech equipment management systems based on health outcomes

Analytical accounting

3. Implementation and/or readjustment of analytical accounting systems to enable them to be used for management

Training and research

Training

4. Creation of an independent training plan, managed and supervised by the NHS offering the possibility of indirect collaboration of the industry

Clinical trials

5. Definition of a protocol for recording clinical trial activity and financial implications for the centre

INTEGRATION OF INFORMATION SYSTEMS

ICTs and information systems

6. Development of integrated and interoperable information systems that will facilitate networking and the exchange of information

Source: Compiled by author.

Of all of these, the most important proposals due to the size of the problem or field they affect, their potential **impact in budgetary terms and their capacity to transform and improve the sustainability of the system and the quality of care** are those listed and described below.

Firstly, with regard to **the rational use of medicine**, the most significant proposal is the **promotion of the use of biosimilar medicines in place of reference biological medicines**, both at the start of treatment in new patients and in the switch in patients already treated with the reference product. In order to achieve this, a set of measures is proposed that must be implemented in a complementary and coordinated manner and which consist in:

- Introduction of incentives to prescribe and use biosimilar medicines (e.g., profit-sharing).
- Greater legal certainty for professionals in decisions to switch and/or replace reference biological medicines with biosimilar medicines.
- Appropriate information for patients (experience of other patients, leaflets and infographics).
- Information and training for practitioners through sessions given by clinical leaders on the opportunities of releasing resources.
- Work with clinical leaders and practitioners on measuring outcomes and providing evidence.
- Tendering through open procedures (framework agreements, etc.) for the supply of biological medicines, starting from the loss of validity of the patent of the reference medicines and the emergence of biosimilar medicines.

Promoting the use of biosimilars would have a very significant impact in terms of savings and releasing resources for the NHS. According to the study[2] carried out by the Universidad Complutense de Madrid, led by Professor Manuel García Goñi and commissioned by the Spanish Biosimilar Medicines Association, the use of the biosimilars already marketed and the entry of the expected new ones and their use are expected to generate hypothetical savings of €872m in 2020, €937m in 2021 and € 1.047bn in 2022 (compared with a scenario without biosimilars). In other words, if the actions defined in the proposal to promote the use of biosimilars are implemented, an **average gross annual hypothetical saving of €952m could be achieved over the next**

[2] *Análisis de impacto presupuestario de los medicamentos biosimilares en el Sistema Nacional de Salud de España (2009-2020) [budgetary impact analysis of biosimilar drugs in the Spanish National Health System (2009-2020)].* This study has been provided by BioSim. It will be published in November 2020.

three years.

Secondly, with regard to the decision-making process for financing and pricing, a **review of the structure of the CIPM** is proposed based around giving greater weight to the regions in decision-making. It is also proposed that two separate bodies or divisions be created within the CIPM, for investigation (technical analysis) and resolution (decision maker), which will ensure independence. Finally, the role currently played in this process by certain agents, such as the Ministry of Industry, Trade and Tourism, which should only be part of the investigation body/division under the proposed new scheme, should be reconsidered.

In addition, it is also recommended **to incorporate cost-effectiveness criteria in setting the price of medicines** in line with current practice in some medicines (such as *Chimeric Antigen Receptor T-Cells (CAR-T) therapies*), so that medicines are classified according to their therapeutic value based on cost effectiveness studies and their incremental clinical benefit is adequately supported.

Alongside these measures, an **adjustment of the current RPS** is also recommended taking into account the ATC4[3] (therapeutic equivalent) and ATC5 (active ingredient) levels for pricing in those medicines classified as "of choice" or therapeutically equivalent alternative (TEA).

Finally, closing the circuit of the financing and pricing process, it is recommended **that the systematic review of prices and financing conditions be intensified**, especially when there are price drops in benchmark countries or when the approved financing conditions (efficiency, sales estimates, etc.) are not met.

Thirdly, with regard to the evaluation by the P&TCs, it is recommended **to create a network for cooperation between the different P&TCs** for networking at a national level, coordinated by the Ministry of Health, independently and with its own budget, issuing binding recommendations for certain drugs (e.g. those with a high economic and/or health impact).

This measure is complemented by **the establishment of a mixed decision-making model** for selecting the medicines that form part of the PTG in such a way that the decision will be centralised (national/regional) for some medicines, while for others the decision will be taken by the hospital.

Fourthly, with regard to public procurement, **progress must be made towards a greater volume of medicine procurement under the provisions of the Public Sector Procurement Act.** The proposals for achieving this objective consist of the use of

[3] *Anatomical, Therapeutic, Chemical* (ATC).

formulas and procedures that allow quicker processing of the proceedings and **consolidation of electronic procurement and promotion of the use of dynamic purchasing systems**. It would also be necessary in this area to make progress in **integrating public procurement management** (reducing the number of procurement bodies, increasing joint tender processes etc.) as it has been noted how some regions with a strategy for integrating these management processes (with a scope of regional, provincial, inter-centre, specialised bodies etc. level) have higher levels of standardised procurement.

More specifically, it is proposed that the medicines in which there is no competition and free-market (exclusive medicines), the Public Sector Procurement Act be adapted to incorporate procurement formulas. These should consider the administrative resolution entailed in the favourable financing decision of the CIPM and should reduce the bureaucratic burden currently involved in the processing of procurement proceedings negotiated on the basis of exclusivity. Similarly, it is also proposed that this adaptation of the Public Sector Procurement Act be carried out for medicines in special situations (orphan drugs, foreign drugs, etc.).

In the case of medicines in which there is competition and a free market, it is proposed, firstly, that the purchasing be aggregated using criteria such as volume of contracts that the contracting authority intends to award or the geographic area to which these contracts refer. Secondly, it is proposed that the procurement be speeded up by materialising the proceedings by means of framework agreements and strengthening the preparation of standard contracts by health services and/or contracting authorities.

Another measure proposes promoting competition through tendering by therapeutic applications or conditions, so that the medicines that make up each of the batches are intended for the same pathology and therefore included in the same therapeutic sub-group of the *Anatomical, Therapeutic, Chemical* (ATC) classification.

The lines of action proposed in this study, in the area of public procurement for the supply of medicines and the incorporation of innovation, should be included in the **National Public Procurement Strategy** provided for in the Public Sector Procurement Act, which is a legally binding instrument for the public sector.

Fifthly, with regard to the purchase of medicines and price negotiation, **it is recommended that the regions should share the net purchase price with the contracting authorities**. More specifically, with the aim of facilitating the sharing of information, it is recommended that a **national net price registration** system or tool be set up with access at least for the contracting authorities.

On a supplementary basis, it is also proposed that rules be laid down **prohibiting**

pharmaceutical laboratories from **giving discounts that are not transparent, assignable to the medicine on which they are offered, transferable to its price and included in the contract documents.**

Sixthly, and finally, as a result of the continuous growth in out-patient pharmaceutical care over recent years, we propose the **definition and establishment of a specific regulatory framework for the procedure and operations of out-patient pharmaceutical care**, as well as a clear protocol for face-to-face and non-face-to-face dispensing (telepharmacy) and bringing medication closer to out-patients.

In line with this idea, **it is proposed that the humanisation of care and dispensing of medicines to out-patients be improved** through two routes: firstly, guaranteeing adequate care in the visits that the patient makes to the hospital (first consultations, periodic monitoring and follow-up consultations, changes in medication, etc.) and, on the other hand, bringing medication closer to certain groups of patients (patients that are adherent, clinically stable, with mobility problems or who reside far from the hospital, etc.). This measure would result in the NHS making a **significant investment in improving accessibility** and it is proposed that this should be done through the alternative that best suits each case (dispensing at home, in public health centres or retail pharmacies).

With regard to the area of high-tech equipment, and in relation to the existing level of equipment, it is **firstly** proposed that **a national strategy be developed for investment in high-tech equipment in order to converge with the European average in terms of level of equipment and obsolescence**, taking into account the current level of intensity of use of the equipment.

This strategy should be implemented in a coordinated manner at a national level and would entail a very significant investment for the NHS.

More specifically, it has been estimated that the **renewal** of public equipment whose age exceeds its useful life, taking into account its level of use (intensity of use), would have required investment in 2019 for the NHS of **between €243m and €356m.**

Convergence towards **the levels of equipment** per million inhabitants of the average for **OECD countries,** bearing in mind the level of use of the equipment, would have meant in 2018 an investment need for the NHS of **between €203m and €282m**, or **between €313m and €437m** if it were to converge towards the average levels of equipment of **Western European** countries.

Overall, the needs for renewal and expansion of the existing equipment would have **meant an investment of around €608m over these two years** on average.

Secondly, decision-making for the incorporation of equipment must be supported by objective and verifiable data. We therefore propose the **implementation of models/algorithms to systematise, objectify and prioritise decision-making for the purchasing and renewal of equipment**.

Finally, and at a more cross-cutting level, it is recommended that progress be made on the digital transformation of the public health system, adopting and developing **integrated and interoperable information systems that allow full traceability of processes, facilitate networking and the integration and sharing of information** between clinical services, hospitals and health services.

Implementation of this measure would achieve greater efficiency in health management thanks to greater availability and accessibility of information. For this purpose, taking into account the current situation, the NHS would need to make a **significant investment**. According to 2017 data from the SEIS Index study prepared by the Spanish Society of Health Informatics (SEIS), the budget for information and communication technologies (ICT) of all the regions stands at approximately 1.22% (€695m) of the Health Spending Budget of the entire NHS of that year (€57.231bn). According to the report *Towards Digital Transformation of the Health Sector*, prepared by the SEIS, the Spanish Federation of Healthcare Technology Companies (FENIN) and the Association of Electronics, Information and Communications Technologies, Telecommunications and Digital Content Companies (AMETIC), the average ICT expenditure of European countries stands at between 2% and 3% of their total expenditure on health. Therefore, if we want to converge to these percentages, from 1.22%, we should invest between **€449m** (2%) and **€ 1.021bn** (3%) in addition to the current budget.