CNMC

COMISIÓN NACIONAL DE LOS MERCADOS Y LA COMPETENCIA

IPN/CNMC/023/15 DRAFT ROYAL DECREE REGULATING THE FINANCING AND PRICING OF MEDICINES AND SANITARY PRODUCTS AND THEIR INCLUSION IN THE SPANISH NATIONAL HEALTH SYSTEM'S PHARMACEUTICAL PROVISION

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During its meeting of 19 November 2015, the Competition Chamber of Spain's National Authority for Competition and Markets Council (CNMC) approved this report on the **Draft Royal Decree regulating the financing and pricing of medicines and sanitary products and their inclusion in the Spanish National Health System's pharmaceutical provision** (henceforth, DRD). For these purposes, the link to the draft regulations and their Regulatory Impact Analysis Report (RIAR) were referred. This report examines the implications of these draft regulations from the point of view of effective competition in the markets and efficient economic regulation.

This report has been approved at the request of the **Ministry of Health, Social Services and Equality** within the consultative remit of the CNMC with regard to the process of drawing up regulations which affect its area of jurisdiction in the sectors which it supervises, under Article 5(2) (a) of Act 3/2013, of 4 June, creating Spain's National Authority for Competition and Markets.

I. BACKGROUND

The DRD constitutes the **implementing regulation** of the Consolidated Text of the Act on guarantees and rational use of medicines and sanitary products, approved by Royal Legislative Decree 1/2015, of 24 July (henceforth, CT), which was also the subject of a report by this CNMC[1].

This regulation has been pending since 2006 and covers issues of particular economic significance as it affects operators, users of these services and taxpayers (as this represents a very significant component of public expenditure).

In particular, the implementing regulations concerning the criteria and procedure governing the decision on the financing and pricing of newly marketed medicines had been repeatedly demanded[2]. Both aspects (decision on financing and pricing), developed in this DRD, are established in the same procedure and the same joint resolution by the competent body of the MHSSE (Directorate-General of the Basic Services Portfolio of the Spanish National Health System and Pharmacy) [3].

[1] IPN/CNMC/005/15 REPORT ON THE ROYAL LEGISLATIVE DECREE APPROVING THE CONSOLIDATED TEXT OF THE ACT ON GUARANTEES AND RATIONAL USE OF MEDICINES AND SANITARY PRODUCTS (henceforth, Report on the TRLG)

[2] Both by the academic doctrine, sector operators and this CNMC in its aforementioned Report on the TRLG.

[3] Notwithstanding the above, the authority/competence for setting prices is hold by the Inter-Ministerial Price Commission.

Due to the complexity of the sector and regulations and prior to the analysis of the content and considerations of this DRD, it would be wise to provide a brief outline of the different types of medicines and their economic specificities and of the basis for price intervention and the various existing pricing schemes.

Regarding the categories of products (medicines), differentiated sub-markets are determined according to certain variables:

i) Recent marketing and patent protection: the termed "**innovative"** medicines versus those marketed for at least 10 years or with **generic**[4] competition.

ii) Subject to medical prescription ("**prescription**") or otherwise (usually called "**advertising**" medicines). In the latter case there is no public funding due to the fact that they are not subject to prescription.

iii) Inclusion in the pharmaceutical provision (**funded** by the Spanish National Health System, NHS) or otherwise.

iv) Depending on the distribution channel it is possible to distinguish between medicines dispensed by pharmacies and those dispensed by hospitals ("**hospital** medicines").

Among the possible market segmentations that would result from the combinations of the above variables, and of particular relevance for this DRD, is the market segmentation of medicines subject to medical prescription and public funding because: i) on account of their own uniqueness they are subject to intense intervention, particularly in terms of prices; and ii) they represent a high percentage of the pharmaceutical industry with respect to the rest.

[4] An *innovative* medicine is characterised by the fact that it contains a new active ingredient on which research has been conducted and which has been comprehensively developed, from chemical synthesis to clinical use. It is therefore the first and sometimes the only one which provides data on its safety and therapeutic effectiveness of the particular pharmaceutical product. It is usually marketed in different countries by the same operator, even under the same name, and sometimes its brand becomes considered by prescribers as synonymous with the active ingredient. Generic medicines are medicines with the same health characteristics which are interchangeable with the corresponding original medicines ("reference medicines") and are marketed once the patents thereof have expired. E/CNMC/003/15 Study on the medicine retail distribution market in Spain (page 19).

The pharmaceutical sector is subject to **intense regulation** in most of the countries in our region, the rationale being: a) the special safeguard required by the legal right protected: the health of people; b) the existence of market failures in the sector, which also hinder equitable access to health protection; and c) the strategic importance of the sector in the economy, its innovative strength and, especially, the impact on public finances of pharmaceutical provision.

Price regulation is especially **intense** in most neighbouring countries. These administrative price interventions are justified by the economic peculiarities of the pharmaceutical sector[5], especially in the case of medicines subject to medical prescription due to their impact in public funding. We should also consider the positive externalities of medicines and their importance to public health, desirable equitable access to the pharmaceutical provision and, especially in recent years, the strong impact of the pharmaceutical bill of the Spanish NHS.

The **CT** constitutes the regulatory framework that this DRD develops, in particular Title VIII (on the public funding of medicines and sanitary products, Art. 91-107. That legal instrument states these main lines:

- Medicines and sanitary products, once approved for marketing by the Spanish Agency for Medicines and Sanitary Products (AEMPS)[6], can be included in pharmaceutical provision (i.e. funded by the Spanish NHS). The CT regulates the criteria and procedure, both for inclusion of the product (funding) and exclusion (non-funding) in its Arts. 92 and 93. The decision corresponds to the MHSSE[7] by express resolution in which funding and price conditions will be established.

[5] **In terms of demand,** i) the final consumer does not make the buying decision, but rather it is a matter of the termed "credence goods", where the decision rests with the prescriber (doctor). Nor does the consumer assume responsibility for payment (at least not entirely) of the medicine, nor the prescriber. Consequently, demand is very price inelastic and moral hazard problems arise; ii) there are significant information asymmetries between patients/consumers and prescribers, on one hand, and between producers (laboratories) and prescribers, on the other. Consequently, if the incentives of prescribers (doctors) and patients are not aligned, it is possible to alter the choice and other asymmetric information problems. With regard to **supply**, there are specificities such as: i) patent protection produces a temporary monopoly on the market of the medicine in question; ii) high fixed and input costs, very high costs in terms of R&D and advertising and promotion, low marginal costs and high margins; iii) partly as a consequence of the above, high levels of concentration.

[6] Either authorised by the European Medicines Agency (or generally in accordance with the provisions of European regulations establishing Community procedures for the authorisation and control of medicines for human and veterinary use).

[7] In particular, to Director-General of the Basic Services Portfolio of the National Health System and Pharmacy.

- Price regulation, which is particularly complex, is established in Arts. 94 ff. of the CT and may be briefly summarised as follows:

First, there is an **intervention at several levels**: the laboratory selling price (also called LSP, industrial price or production price) is taken as the base. To that laboratory retail price must be added the margins[8] set by the Authority under a dual margin – partly fixed and partly proportional – for both wholesale distributors and retailers (pharmacies). Adding VAT to all the above items we obtain the retail price (RP)[9]. That is to say:

LSP (laboratory selling price) + **wholesale margin** (store retail price) + **pharmacy margin** = **RP** (super-reduced 4% VAT)

Secondly, **the LSP intervention system** differs depending on the type of medicine based on two variables that combine: a) whether or not it is funded; b) whether or not it is an innovative medicine (less than 10 years on the market) or a generic medicine.

Pricing schemes, already provided for in the CT, but which this DRD clarifies are as follows:

- **Price fixed** by the Inter-ministerial Price Administration/Commission for Medicines for "innovative" medicines (newly marketed) which request their inclusion in the portfolio.
- **System for reference pricing and homogeneous groups**: for "non-innovative" medicines (i.e., which have been marketed for at least 10 years and there is a generic or biosimilar medicine).
- **Free price**: in principle for all non-funded medicines.
- **Price reported** with possible opposition from the Authority: for medicines that have recently become non-funded. Other non-funded medicines can also be included in this system.
- **Selected price**: possible implementation for non-innovative medicines (subject to the system for reference pricing and homogeneous groups) and for non-funded medicines but that may be considered of interest to public health under the terms of General Act 33/2011, of 4 October, on Public Health.

[8] Art. 94.9 CT. See Royal Decree 823/2008, of 16 May, establishing the margins, deductions and discounts related to the distribution and dispensing of medicines for human use.

[9] Art. 94.10 CT.

As regards **applicable European regulations**[10], it leaves a wide margin of freedom to the Member States in their financing and pricing decisions. However, it establishes two significant requirements: i) deadlines for financing and pricing decisions; and ii) administrative decisions must be **justified**, based on **objective** and **verifiable** criteria.

Finally, other recent regulatory initiatives with a direct impact on the pharmaceutical sector, especially in economic terms, must be considered. In particular:

- The **recent amendment to General Act 14/1986, of 25 April**, **on Health** (LGS)[11]. On the one hand, it strengthens transparency and obligations regarding the provision of information on the pharmaceutical expenditure of the autonomous communities. On the other, it introduces for those autonomous communities that have acceded to an instrument to support the sustainability of pharmaceutical and healthcare spending, a rule for pharmaceutical spending and spending on sanitary products, limiting it to the medium-term reference GDP growth rate of the Spanish economy[12].

- Updating of the reference price system by Order SSI/2160/2015, of 14 October.

- **Modification of the CT through final provisions by way of amendments to the Act on the General State Budgets for 2016**, recently approved and published in the Official State Gazette[13]. In particular, it notes that: i) it eliminates the limitation of discounts (for prompt payment or volume of purchases) to the pharmacies; ii) it modifies dispensing rules (the so-called "substitution requirement" of the pharmacist of the medicine with the same active ingredient but a lower price); and iii) the exclusive identification of generics by the acronym EFG. Given the importance of these measures introduced in the LPGE for 2016 will receive a special mention in this report.

[10] Directive 89/105/EEC on the transparency of measures regulating the pricing of medicines for human use and their inclusion in the scope of national health insurance systems**,** known as the "Transparency Directive".

[11] Amendment of the LGS through FP 1 of Framework Act 6/2015, of 12 June, amending Framework Act 8/1980, of 22 September, on the financing of the Autonomous Communities and Framework Act 2/2012, of 27 April, on Budget Stability and Financial Stability. According to the National Reform Programme of the Kingdom of Spain for 2015, it constitutes a response to the specific recommendation to the previous NRP for 2014, "*Further strengthen the efficiency of the health system, especially increasing the rationalisation of pharmaceutical expenditure, also in hospitals*"

[12] The measure, reflected in the amendment of the LGS, is a response to the specific recommendation to the National Reform Programme (NRP) of the Kingdom of Spain for 2014 and included in the NRP for 2015, "Further *strengthen the efficiency of the health system, in particular increasing the rationalisation of pharmaceutical expenditure, also in hospitals"*

[13] Act 48/2015, of 29 October, on General State Budgets for 2016.

II. CONTENT

The DRD is applicable to **a wide range of medicines and sanitary products**. That is:

i) **medicines** funded and dispensed by pharmacies, hospitals and primary care centres ("hospital medicines");
ii) those **sanitary products** included in pharmaceutical provision (such as gauzes and healing materials, products necessary for the application of medicines and others[14]);
iii) **medicines that are dispensed in special situations**; and
iv) medicines and sanitary products marketed outside the Spanish NHS under free or reported prices.

Consequently, and as the RIAR itself acknowledges, the DRD affects each and every one of the elements that make up the chain of medicines and sanitary products. It is **a regulation with a far-reaching impact** on the different links and actors since: i) it affects all operators of the various links of the pharmaceutical and sanitary product sector: laboratories, manufacturers and suppliers of sanitary products, distribution entities and pharmacies; ii) it directly influences the different health authorities of the autonomous communities and other bodies managing the Spanish NHS; iii) it directly affects citizens such as users of medicines and sanitary products; and iv) Last but not least, public funds[15].

The DRD is **primarily intended** to regulate, among others, two crucial aspects of medicines and sanitary products: medicines **funding** by the NHS **and pricing** of such funded medicines. The criteria and procedure are developed under the mandate of the CT. However, the content of the DRD is broader. It consists of 71 items, grouped into 11 chapters, 9 additional provisions, 4 transitional provisions, 1 derogatory provision, 5 final provisions and 2 annexes:

- Chapter I: object, scope and general principles on the public funding of medicines and sanitary products and the inclusion thereof in the Spanish NHS pharmaceutical provision.

- Chapter II: general criteria for public funding of medicines, the fixing of medicine prices in the Spanish NHS and the procedure for the inclusion of medicines in the Spanish NHS pharmaceutical provision.

[14] In particular, those provided in Art. 49(6) of the DRD: Healing materials; sanitary products intended for applying medicines; sanitary products for collection of excreta and secretions; and utensils for the protection or reduction of wounds or internal malformations.

[15] It is a considerable element of the healthcare provision (around 18%) and the GDP (around 1.5%), according to OECD estimates already mentioned in E/CNMC/003/15 Study on the medicine retail distribution market in Spain.

- Chapter III: legal regime for specific reservations and special conditions for funding medicines.

- Chapter IV: medicines' prices special regimes: reported prices, free price and selected prices (the reference price system and the homogeneous group system regulated by Royal Decree 177/2014, of 21 March, are omitted).

- Chapter V: medicine price review, on its own initiative or at the request of a party, procedure to be followed and deadlines for implementation of revised industrial prices.

- Chapter VI: inclusion in the Spanish NHS pharmaceutical provision of new medicine instructions.

- Chapter VII: exclusion of medicines from the Spanish National Health System pharmaceutical provision ("defunding").

- Chapter VIII regulates the funding of medicines in special situations.

- Chapter IX: supply of medicines to the Spanish NHS.

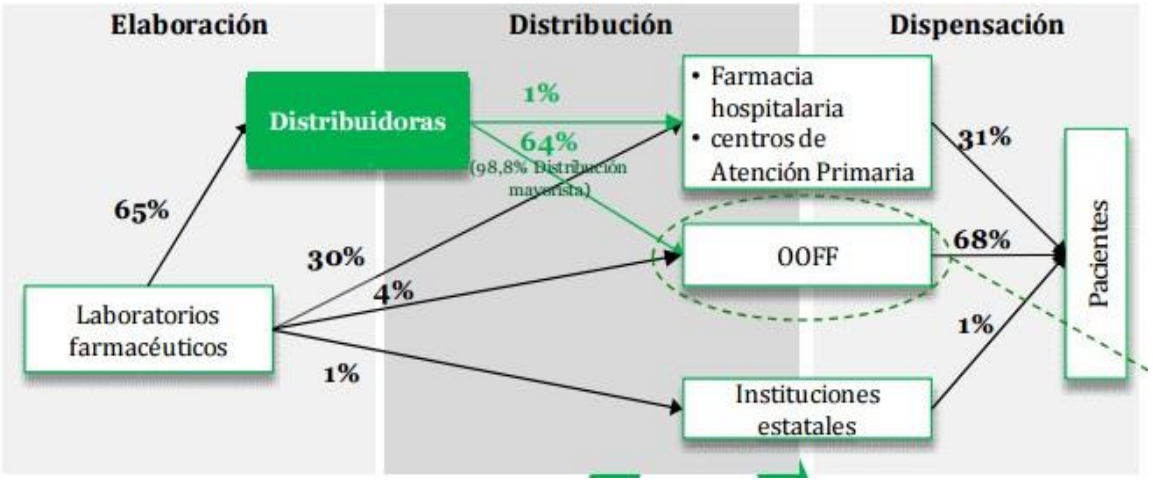
- Chapter X: systems of information on medicine supply and monitoring of its funding by the Spanish NHS.

- Chapter XI: provisions on sanitary products largely similar to that made with medicines whose regulation is continuously referred to. In particular it provides for: financing, pricing, margin settings, procedure for inclusion in pharmaceutical provision, dispensing, contribution of users, specific reservations and special funding conditions, exclusion of products from those offered, special pricing schemes and price review.

- Regarding the remaining provisions, the reduction of the contribution by sales volume (AP 3), the application of deductions (AP 4 and 5) and the transitional provision on the application of reported medicine prices (TP 4) are, inter alia, to be highlighted.

III. GENERAL FEATURES OF SPANISH MARKET

Within the Spanish pharmaceutical sector various **links and actors in the production chain** can be distinguished: i) production (laboratories); ii) wholesale distribution (medicine distribution entities and laboratories themselves);
iii) retail distribution (pharmacies, which dispense 68% of medicines and hospital pharmacy services[16] and health centres, which dispense 31%).



Medicine chain in Spain 2012. Source: FEDIFAR, Analysis of pharmaceutical distribution in Spain

The **Spanish pharmaceutical industry** market is characterised by the existence of high barriers to entry[17], largely generated by high fixed costs and investment in R&D and regulation itself; the presence and leadership of multinational pharmaceutical companies; and concentration[18] with frequent business operations being made in order to its market position.

[16] Hospital pharmacy: dispenses more complex products, with special instructions and generally through parental dispensing. This market sub-sector is characterised by: its very significant weight, when compared with other countries in the region and its considerable growth in recent years.

[17] *Policy Roundtables: Competition and Regulation Issues in the Pharmaceutical Industry*, OCDE (2000).

[18] There are about 250 pharmaceutical companies in Spain, of which 75% are foreign. Most are small and medium enterprises, of which 35% employ 100-250 people and only about 2% employ more than 1000 employees. *"Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States"*, published by the European Commission in 2006.

In this regard, it is noteworthy that in 2011 the five largest pharmaceutical companies accounted for a market share of 25% if we take into account all distribution channels, and 32% if only sales through pharmacies[19] are taken into consideration. In this link, two types of operators may be discerned[20]:

On the one hand, the laboratories termed "innovative" which produce original medicines under patent protection. In general, they compete in innovation (development of new therapeutic alternatives or improvements with respect to those already existing), a high percentage is allocated to R&D&I and marketing and promotional activities. They represent 53.5% of total medicine units dispensed by pharmacies and 79% of total turnover. The vast majority of the latest recently marketed innovative medicines approved are hospital and, in particular, biotechnological medicines[21].

On the other hand, we have the generic medicine manufacturers, who sell medicines equivalent to the originals once their patent has expired. Large companies that sell a wide range of medicines and small operators with a limited portfolio of medicines co-exist. In general, they compete mainly on price. They allocate a limited amount of resources to R&D&i and maintain high levels of spending on marketing. Generic medicines accounted for 46.5% of total medicine units dispensed by pharmacies and 21% of market turnover in 2013[22].

In the **wholesale distribution** sector, practically the whole market share corresponds to the 52 companies grouped into 9 associations and, in turn, the Federation of Pharmaceutical Distributors – FEDIFAR. Some operators maintain high market shares that are very significant in certain geographical areas, which contributes to the fragmentation of this market[23]. They distribute 94% of all medicines dispensed by pharmacies. Regarding the concentration in this market, it should be noted that the cumulative market share of the five largest operators amounts to 61%[24].

[19] *Dossier on the value of Pharmaceutical Distribution in Spain.* Antares Consulting S.A. Bio-industries and pharmacy. 2011.

[20] "*Pharmaceutical Sector Inquiry Final Report*". European Commission 2009.

[21] According to the Report on the Pharmaceutical Sector by the Medical Association (2014).

[22] E/CNMC/003/15 Study on the medicine retail distribution market in Spain (page 63).

[23] Files N-05086 ALLIANCE UNICHEM/CERF CATALONIA and N-05095 FAES FARMA/IPSEN, as well as *"Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States"*, published by the European Commission in 2006.

[24] *Dossier on the value of Pharmaceutical Distribution in Spain.* Antares Consulting S.A. Bio-industries and pharmacy. 2011.

In the **retail distribution**[25] sector, two main channels can be distinguished:

a) Retail distribution through **pharmacies**, accounting for 68% of total medicine sales in 2012. It is a heavily regulated industry with restrictions on competition which this CNMC recently revealed in its Study on the medicine retail distribution market in Spain, to whose conclusions this Report refers to.

b) Distribution in **hospital pharmacy services and health centres**, whose volume accounted for 31% of sales in 2012[26]. These medicines have been almost entirely provided by laboratories. The share of hospitals in the medicine retail distribution market in Spain has increased considerably in recent years, exceeding 33% of the total share. There is a significant lack of transparency and information, which must be provided by the autonomous communities, on the prices of hospital medicines and the total cost thereof.

IV. GENERAL ASSESSMENT

The pharmaceutical and sanitary product sector has been given **special attention by the competition defence authorities**, both by this CNMC[27] and even by the European Commission[28]. Within the framework of competences of this CNMC, action has been taken both in terms of promoting competition and efficient economic regulation and enquiries into anti-competitive and business concentration conducts.

[25] FEDIFAR, Analysis of pharmaceutical distribution in Spain (2012), according to the 2012 Pharmaceutical Industry Report and IMS Health estimates.

[26] According to the same source (2014 Pharmaceutical Industry Report with data provided by IMS Health), the billing and proportion of hospital medicines is increasing, accounting for 33.6% of total medicine sales in 2014.

[27] There have been numerous disciplinary proceedings in relation to the defence of competition ruled on by the national authority. Without being exhaustive, it is worth citing Proceeding No. S/0014/07, Medical Waste Management, in which an agreement was approved to distribute the public customers of the medical waste management market and other non-competition agreements between companies in the sector; Proceedings 649/08, Generic Pharmaceutical Products, in which the CNC punished several pharmaceutical associations for collective recommendations in the generic medicine market, subject to medical prescription and the reference price system that were intended to standardise the conduct of pharmacies; Proceeding No. 395/97, Influenza vaccines, in which price-fixing agreements for influenza vaccines were approved with which various pharmaceutical laboratories participated in public tenders.

[28] In 2008 it launched a sector enquiry after detecting poor functioning of the market and possible anti-competitive practices. See the Analytical Report Summary of the sector enquiry into the pharmaceutical sector (2009). From the standpoint of the files, see, for example, Resolution in Case COMP/A. 37.507/F3 – AstraZeneca.

From the perspective of promoting competition and efficient economic regulation, various regulatory projects[29] have been reported on, notably the Report on the CT which conducted an analysis and in which recommendations were consequently made on the regulation of medicines in our country. In addition, the recent Study on the medicine retail distribution market in Spain was published, comprehensively analysing the most significant regulatory restrictions detected in the current management of pharmacies, with the resulting recommendations being made.

From the standpoint of supervision and sanctioning, this CNMC has mainly analysed proceedings relating to the so-called "dual pricing agreements" between laboratories and the cancellation of distribution agreements with wholesalers, as well as boycotts on generic medicine producers[30]. In addition, with respect to proceedings conducted in relation to business concentrations, this CNMC has ruled on operations related primarily to laboratories and distributors[31].

Based on this knowledge of the market from the different perspectives mentioned, the following general observations (IV.1) and individual observations (IV.2) are intended to be transmitted to the proposing body.

[29] IPN 081/12 DB AMENDING THE ACT ON GUARANTEES AND MEDICINES, IPN 105/13 ON THE RD REGULATING THE SYSTEM FOR REFERENCE PRICING AND HOMOGENEOUS GROUPS IN THE SPANISH NATIONAL HEALTH SYSTEM; IPN 085/13 DRD ON THE DISTRIBUTION OF MEDICINES FOR HUMAN USE; IPN 105/13 RD REGULATING THE SYSTEM FOR REFERENCE PRICING AND HOMOGENEOUS GROUPS IN THE SPANISH NATIONAL HEALTH SYSTEM

[30] By way of example, to cite the cases that are currently in the proposed resolution stage, on 30 September 2014 disciplinary proceeding S/0472/13 was initiated in relation to practices restricting competition, which are prohibited by Article 1 of the LDC (Act on the Defence of Competition), consisting of exchanges of information and agreements on the fixing of prices and other commercial conditions in the distribution and sale of test strips for determining blood glucose by several pharmaceutical companies and the Spanish Federation of Sanitary Technology Companies (*Federación Española de Empresas de Tecnología Sanitaria*). Similarly, in September 2014, the CNMC decided to initiate another proceeding, after performing inspections in various laboratories, distributors, professional associations and industry associations in relation to a possible agreement to fix prices and other commercial conditions in the distribution and sale of sanitary and dietary products.

[31] The main causes behind these concentrations related to: the tendency of the regulator to reduce medicine prices, and consequently the corresponding reduction in the distributor's margins; the existence of an unfavourable economic and financial environment; and the possibility of the laboratories providing directly to the retailer.

IV.1 General observations

Any regulatory intervention measure must conform to the **principles of efficient economic regulation and competition promotion**[32]: in particular, those relating to justification of its **necessity, proportionality and minimum competitive distortion**[33].

There is some consensus on **public priority objectives** in **pharmaceutical policy**: i) ensuring access to medicines under equal conditions at affordable prices; ii) ensuring the efficacy, safety, quality and cost-effectiveness of medicines; iii) providing an appropriate framework for innovation; iv) promoting competition in the sector; v) ensuring the sustainability of public spending; and vi) industrial policy objectives – promoting GDP growth, employment and exports in the sector.

This CNMC is fully aware of the need to protect the health of citizens and especially of the need to preserve access to safe, effective and quality medicines under equitable conditions at affordable prices. It is relevant to note that the **principles of efficient economic regulation, which are conducive to competition** are not only an end in themselves of the pharmaceutical policy but a valuable **tool for achieving the objectives of public interest at stake**, especially in the access of the population to medicines and the best therapeutic solutions, as well as the promotion of innovation[34].

This is because increased competition contributes to access to medicines at prices which are lower (particularly among generic medicines and medicines whose patents have expired) and sustainable for public finances[35], while it encourages innovation (the so-called "innovative" medicines do not compete so much on price as on innovation and providing the best solutions to patients).

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[32] CNC recommendations to public authorities for a regulation of markets which is more efficient and promotes competition (2008) and the Guidelines for the preparation of reports on competition of regulatory projects.

[33] These principles are enshrined in Article 4 of Act 2/2011, of 4 March, on Sustainable Economy; Art. 5 ff. of Act 20/2013, of 9 December, on the Guarantee of Market Unity and Art. 129 of Act 39/2015, of 1 October, on the Common Administrative Procedure of the Public Authorities which will replace the aforementioned provision of the Act on Sustainable Economy from its entry into force (October 2016).

[34] "*Recent developments in competition policy in the pharmaceutical sector: more competition for greater investment in innovation and better access to medicines*". SAURI. Spanish Economy Paper No. 145 (2015).

[35] See the Analytical Report Summary sector enquiry into the pharmaceutical sector conducted by the European Commission (2009)

It must also be taken into account that the competitive operation of the **pharmaceutical sector has considerable room for improvement**. The European Commission already found in its investigation deficiencies in the competitive functioning of the market[36]. Among the causes, it highlights regulatory problems and potentially anti-competitive business practices[37]. It concluded by recommending that any action taken by public authorities in the pharmaceutical sector should aim to establish a competitive environment that ensures European citizens access to innovative, safe and affordable medicines without undue delays.

On the other hand, it might be advisable to adopt a **programmatic instrument** setting out the objectives of the pharmaceutical economic policy[38] and a comprehensive analysis of the set of potential tools and intervention measures[39]. This, in addition to adopting an optimal mix and carefully designed policy, will facilitate a consistent, predictable and transparent legal framework that provides legal certainty. Actions in this regard are recommended. In particular, from the regulatory point of view, specification and improvement of the impact analyses of the RIAR on regulatory projects while strengthening transparency are encouraged.

[36] In particular, delays observed in the launching of generic medicines on the market and the apparent decline in innovation, measured by the number of new medicines.

[37] Within the regulatory causes the need to ensure the brevity of the authorisation processes for new generic medicines, ensure the speed of the pricing processes and reimbursement conditions and the need to adopt policies to facilitate the penetration of generic medicines were proposed. Business practices potentially restricting generic medicine competition focused on pay-for-delay agreements in which the innovative laboratory can induce the generic medicine company to delay its entry into the market in exchange for a share of the exclusive income.

[38] The possibilities and **intervention measures** are very diverse and can be grouped into supply and demand measures:

Supply policies	**Demand policies**
Price regulation: Initial price decision (different systems), updates, freezes and cuts	Measures aimed at prescribers (doctors): education, prescription guidelines, monitoring guidelines, prescription quotas, medicine budget, financial incentives
Expenditure control: rebates, returns, payback, price/quantity agreements	Measures aimed at dispensers (pharmacies): generic substitution, financial incentives, returns on discounts (clawback)
Regulation of the industry: control of benefits, tax benefits	Measures aimed at patients: information and education, shared costs
Funding and reimbursement: based on economic evaluation, reference pricing system, positive and negative lists	

F. Lobo (2014), based on "*Analysis of differences and commonalities in pricing and reimbursement systems in Europe*" ROVIRA and ESPIN (2007).

[39] The 2004 Pharmaceutical Policy Strategic Plan for the Spanish NHS was the last recent comprehensive document of the public pharmaceutical policy.

We should remember the reflections of this CNMC[40] on the **regulation on medicine prices.** In particular:

- While European legislation ("Transparency Directive")[41] maintains the sovereignty of the Member States, with modulations and specific minimum requirements[42] on the **pricing** of medicines, this intervention constitutes a **limitation of the constitutionally recognised principle of free enterprise (**Art. 38 Const. 78). As such, both the need for intervention and its justification, proportionality and benefits of the chosen mechanism should be duly justified.

- Notwithstanding the foregoing, the economic literature and empirical evidence[43] does not substantiate that **price intervention is i) either the only or the best option made available by the Authority; ii) or the need to intervene as intensely** as in the Spanish regulation where such intervention leads to the direct fixing of prices and margins.
  Particularly serious, moreover, is the extension of these especially intense regulatory measures to sanitary products, of a totally different nature to the medicines.

- In the case of Spain, it can be stated that price intervention certainly creates, among others, two **perverse incentives[44]** that are contrary to efficient economic regulation:

  i) the incentive to launch newly marketed products, although they do not represent a significant innovation or a substantial therapeutic improvement in order to substantiate the rise in prices;
  ii) the incentive for companies to promote consumption (and thus compensate for the lowering of prices and maintain billing), against the principle of rational use and containment of public spending.

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[40] IPN 005/2015 CT.

[41] Directive 89/105/EEC on the transparency of measures regulating the pricing of medicines for human use and their inclusion in the scope of national health insurance systems**.**

[42] Specifically, deadlines are set for decisions regarding financing and pricing, and every decision is required to be justified, based on objective and verifiable criteria. Also, the applicant companies must be provided with appropriate legal remedies.

[43] A thorough review of all this literature and empirical evidence can be found in "*Políticas actuales de precios de medicamentos en Europa*" ("Current medicine pricing policies in Europe"). F. LOBO 2015.

[44] *Vid.* for example in "*La regulación de los medicamentos, teoría y práctica"* ("*The regulation of medicines, theory and practice*"), ZARA YAHNI et al, Healthcare Gazette vol. 12 no. 1, 1998. (page, 43); "*Regulación y competencia de precios en el mercado farmacéutico" ("Regulation of and competition in prices in the pharmaceutical market")* PUIG -JUNOY, Spanish Economy Papers No. 76, 1998. More recently, see "*Launch prices for new pharmaceuticals in the heavily regulated and subsidized Spanish market*, *1995-2007"*, PUIG-JUNOY, Health Policy, 2014, no. 116, page 170-181 or F. LOBO (2014), page 139.

- The recommendation is to encourage i) **measures other than price intervention such as those adopted for demand purposes**, with appropriate scope[45], which have a strong pro-competitive component and have proved to be effective in reducing pharmaceutical public spending[46]; ii) if price intervention is maintained, it should be less intense[47] and with a narrower scope, and the intervention mechanisms should be carefully designed, with special consideration for microeconomic foundations in the sphere of medicine economics; iii) the **evaluation of pharmacoeconomics** factors in the pricing decision; iv) **increasing transparency**, since no reasoned decisions on fixed prices are published.

Based on these benchmarks, it would seem a necessary implementing regulation[48] to establish lines of action, especially with regard to the funding and pricing of new medicines. However, the margin of discretion offered by this DRD remains high in an aspect of extraordinary importance. The detail of the DRD regarding deadlines and procedures is broad, but minimal with respect to specific criteria that limit administrative discretion and exploit the full potential of the principles of efficient economic regulation.

In short, **there is room for improvement in a set of areas from the point of view of promoting competition and efficient economic regulation** (the need for specificity, use and improvement of economic evaluation, adaptation to the principles of efficient economic regulation, which are conducive to competition, improving transparency and reducing the margin of discretion of the Authority and eliminating the inappropriate extension of the regulatory regime to sanitary products) which will be subject to specific assessment in the following specific observations.

[45] Demand-side measures includes all those aimed at prescribers (doctors), dispensers (pharmacists) and patients (end users). The articulation of the principle of rational use of medicines (and its implementation in the regulation of the obligation to replace the pharmacist, prescription by active ingredient, encouraging prescribing guidelines and awareness and information campaigns) is an example of the extent of demand, although there are other examples.

[46] Specifically, measures which apply the principle of rational medicine use. Particularly, deepening and extending rationalisation measures and appropriate prescription of medicines and monitoring thereof. Attention should be drawn to the high consumption in units of medicines in our country and the consequences, not only from an economic viewpoint (due to their public funding) but also in terms of public health (repeatedly warned about by health authorities) and from an environmental perspective.

[47] The intensity and scope refer to the fact that the prices of each link in the production chain are regulated and also fixed. For example, the current configuration of the reference pricing system.

[48] Here the sector operators, doctrine (specialists in Health Economics and specifically in medicine economics) and the CNMC itself, in addition to the RIAR, coincide: this regulatory development is *"timely and appropriate in order to ensure the necessary transparency in procedures for the financing*

and pricing of medicines and sanitary products and legal safety in the sectors concerned".

IV.2 Specific observations

IV.2.1 Criteria and procedure for the financing and pricing of medicines, in particular newly marketed medicines

Once the medicine is authorised for marketing by the Spanish State Agency for Medicines and Sanitary Products[49], manufacturers-suppliers of medicines can apply for funding from the Spanish NHS ("inclusion in the Spanish NHS pharmaceutical provision").

This DRD implements this procedure in its Art. 5 ff. In the procedure, a joint decision is taken on its inclusion as a medicine funded by the Spanish NHS and its maximum industrial price is thereby fixed. The competent body for doing so is currently[50] the Directorate-General of the Basic Services Portfolio of the Spanish National Health System (henceforth, DG Pharmacy) of the MHSSE. The pricing decision, without prejudice to the provision of the single and joint resolution on the financing and pricing decision, corresponds to the Inter-ministerial Price Commission for Medicines (Art. 4 of DRD and AP 1 of RD on structure of the MHSSE).

The elements providing the basis of the decision on financing and pricing are **inadequate** since:

i) In relation to the criteria for the financing decision (Art. 3 DRD), the implementing regulations in this regard are null and void as there is merely a reference to those provided in the CTLG[51] and a reiteration of the clauses of

[49] Either authorised by the European Medicines Agency (or generally in accordance with the provisions of European regulations establishing Community procedures for the authorisation and control of medicines for human and veterinary use).

[50] Royal Decree 200/2012, of 23 January, establishing the basic organisational structure of the Ministry of Health, Social Services and Equality and amending Royal Decree 1887/2011, of 30 December, which establishes the basic organisational structure of the ministerial departments.

[51] There is a regulatory reference to the funding criteria "[...] *selective, not indiscriminate funding, taking into account general, objective and published criteria and, specifically, the following: a) Severity, duration and consequences of the various diseases for which they are indicated. b) Specific needs of certain groups. c) Therapeutic and social value of the medicine and incremental clinical benefit thereof, taking into account its* ***cost-effectiveness****. d)* ***Rationalisation of public spending intended for pharmaceutical provision and budgetary impact in the Spanish National Health System****. e) Existence of medicines or other therapeutic alternatives for the same conditions at a lower price or lower cost of treatment. f) Degree of innovation in medicine*." "*For the financing decision for new medicines, in addition to the corresponding* ***cost-effectiveness and budgetary impact analysis****, the innovation component will be taken into account for indisputable therapeutic advances as it modifies or improves the course of the disease, the prognosis and therapeutic outcome of the intervention and its contribution towards the sustainability of the Spanish National Health System if, for the same health outcome, it contributes positively to Gross Domestic Product (Art. 92(1) and 92(8) CT)*.

the non-funding clauses[52]. This CNMC again warns of (i) the excessive discretion as to the decision to how the set of pre-selected criteria will be applied and the possible preference of some over others (ii) the reference to the consideration of the contribution of the medicine to gross domestic product introduces possible discriminations due to the origin of the products with an uncertain trajectory and complex conformity with the transparency Directive.

ii) As for the principles and criteria for the **decisions on the pricing** of newly marketed medicines and **their inclusion in the Spanish NHS** (Art. 4 ff. DRD), the DRD apparently develops the criteria for pricing decisions in its Art. 8. According to the RIAR[53], the criteria for the decisions on the pricing of medicines follows the practice by the Inter-ministerial Price Commission for Medicines of the MHSSE (IPCM). These include, inter alia, cost-benefit analysis, sales forecasts, pharmaco-economic studies, medicines' prices levels and financing conditions in other EU MS, relevance of the medicine for certain sub-populations, information on R&D&I activities, contribution to GDP and the trade balance. It should be noted that:

- This is only information and documentation required from operators that are going to market medicines. The problem is that the decision-making criteria are strictly speaking those set out in Arts. 3 and 4 DRD and, as it has been stated, are not sufficiently defined. And above all, **there is no guarantee of justification[54], transparency or publicity**. The technical evaluation report[55] is **not binding** for the proposed decision of the IPCM ("it will serve as support"[56]) **nor is publicity required. Nor are the IPCM resolutions**, based on which the Directorate-General of Pharmacy of the MHSSE hands down the final decision, **binding, nor do they have to be made public or justified**.

[52] "medicines whose funding **is not deemed necessary** to cover the basic healthcare needs of the Spanish population will not be funded by the Spanish NHS", "nor will medicines indicated in the treatment of syndromes and/or ***less serious*** symptoms", etc. (Art. 3(2))

[53] Page 120.

[54] There are only a few references to justification without specifying what specific points have to be reasoned. For example, it is required that the technical evaluation Report is to be prepared by the competent body of the MHSSE and needs to be justified, but there is no further particular specification (Art.10 (2)).

[55] Art. 10 DRD. It is a kind of draft resolution in which the documentation is evaluated and the positioning of the medicine in therapeutic terms, the degree of innovation, cost effectiveness and budgetary impact are analysed.

[56] Art. 10(3) DRD.

- Even though there is a guarantee of the application of the criteria which have been used in practice and supposedly protect this DRD, **they are criteria that are not recommended from the point of view of good economic regulation and promotion of competition**. Specifically: a) they maintain obsolete methodologies such as *cost-plus*, as detailed below; b) they may lead to discrimination due to the origin of products – contribution to GDP and trade balance; c) they do not detail the type of studies required and part of the documentation is left to the discretion of the Authority (expressions like "where appropriate", "at the request of the competent body" and alike).

iii) The DRD seems to continue having recourse, at least partially, to the methodology for determining the laboratory selling price (LSP) based on the **addition of costs**[57] on the basis of information provided by the manufacturer, which the Authority checks for the purposes of final pricing ("cost-plus method"). Therefore, it should be deduced that a *"justified maximum industrial price for funding in the Spanish NHS [MP] incorporating an analysis of* ***recognised*** *costs and benefits to form the price proposal (Art. 8.1.c) is required of the laboratory or supplier*. In addition, the DRD does not expressly repeal the Royal Decree 271/1990, of 23 February, on the reorganisation of intervention in the prices of pharmaceutical products for human use, covered by this mechanism. It should be noted that this method of adding costs is contrary to efficient economic regulation and competition promotion. It introduces a risk of asymmetric information between laboratories and the Authority and has also been criticised by doctrine[58] and abandoned by most benchmark health systems.

iv) The **principle of cost-effectiveness**, provided for in the CT and whose development and effective implementation has been demanded by different operators[59], especially by this CNMC[60], has not been developed. That is, the analysis and

[57] This RD establishes a mechanism for determining MP prices based on the addition of costs on the basis of information provided by the manufacturer, which the Authority checks for the purposes of final pricing. That is, the Laboratory Selling Price (LSP) = cost price + Expenditure on R&D + Business profit. To this LSP are added the distribution margins of wholesalers and the dispensing margins of pharmacies to obtain the RP, to which indirect taxes are then applied.

[58] The method has been phased out in most neighbouring countries due to its many limitations such as: it reduces incentives for productive efficiency; it is difficult to verify and involves high transaction costs; asymmetries of information on the actual costs between laboratories and the administration, which leads to costs greater than the actual costs being allocated; and the difficulty of recognising R&D expenses, etc. per product) F. LOBO (2015)

[59] http://directivos.publicacionmedica.com/spip.php?article235. In particular, the Medical Association, in its Report on the pharmaceutical sector in 2014.

Guarantee that the cost of pharmaceutical provision is offset by the benefits to the health of citizens (pricing based on value[61] for money). This is a key principle of health economics in benchmark public health systems – United Kingdom, Germany, Sweden, among others-, for decisions regarding financing and pricing. It involves the explicit application of economic evaluation in decisions regarding the financing and pricing of medicines, in addition to the traditional conditions of effectiveness, safety and quality[62].

This economic evaluation and application of the principle of cost-effectiveness was attributed in Art. 95 of the CT to the Advisory Committee of the IPCM, whose constitution has been pending for more than three years, and which this DRD does not develop.

v) Additional areas for improvement are noted in the **procedure** itself, both concerning marketing authorisation by the Spanish Agency for Medicines and Sanitary Products (AEMPS)[63] – provided for in the CT and implementing regulations – and that stated in this DRD. The procedure is too lengthy and complex. It should be clarified and simplified and its useful life should be shortened as possible, thereby reducing its consideration as a possible barrier to entry.

Finally, it should be remembered that although the above observations were related to newly marketed medicines, any of those observations (absence of rigorous economic evaluation and precision of criteria by mere reference to or reproduction of the CT) are equally applicable to the decision on price review and exclusion of medicines from pharmaceutical provision ("defunding").

Based on the above, the following is recommended:

[60] The IPN 05/2015 on the CT stated that "structural changes should be considered in price intervention, aimed at mechanisms that take into account in particular cost-effectiveness considerations, in addition to the therapeutic contribution or innovation of the medicine"

[61] Paris, V. and A. Belloni (2013), "*Value in Pharmaceutical Pricing*", OECD Health Working Papers, No. 63, OECD Publishing.

[62] Therefore, it is usually described as the "fourth guarantee" and has been incorporated into a growing number of national systems.

[63] The European Commission has identified delays of more than 9 months on average in Spain in the authorisation of the marketing of the medicines of the chosen sample. "*Pharmaceutical Sector Inquiry Final Report*". European Commission 2009 (page 325)

- A precise and effective implementing regulations regarding elements already provided for in the CT, which this DRD merely reproduces, focusing its justification from the standpoint of the principles of efficient economic regulation and promotion of effective competition. In these implementing regulations a **comprehensive analysis of intervention alternatives** should be carried out and **a broad debate** with due transparency[64], according to the repeated recommendations of international best practices, **should be encouraged**.

- The principle of **cost-effectiveness**, a feature of the economic evaluation of medicines must be developed, and measures for its effective implementation must be articulated, both for decisions regarding the funding of medicines (inclusion in the portfolio of provisions) and for determining medicine prices, especially for newly marketed innovative medicines. The assessment of new schemes, such as pricing based on value, is recommended. The principle of cost-effectiveness should also be used for the proper monitoring and possible review of the assessment of the medicine financing and pricing decisions. As a necessary condition to this recommendation, the necessary technical training of the personnel performing these functions is advised.

  It may be an interesting option to explore financing systems for results and joint venture contracts in which financial risk is divided between the Spanish NHS and laboratories in particularly complex cases. Especially whether payments could be made conditional to the attainment of previously agreed therapeutic targets or results or improvement of the state of health of patients and incorporate penalties should the targets are not met and introduce incentives if results improve the overall established system[65], incorporate penalties should the targets are not met and introduce incentives if results improve the overall established system

- Inclusion in any case of **sufficient guarantees of justification, publicity and transparency of decisions**.

- **Ensuring independence of criteria and technical training of decision-making bodies, especially in health economics and pharmacoeconomics.** This technical expertise would be desirable in the Inter-ministerial Price Commission for Medicines itself. For this purpose it is suggested to assess the extent to which an additional body (Advisory Committee) is required. If it is considered, however, that the complexity of the matter requires technical support specific to the work of the Inter-ministerial Commission

[64] As an example of good practice, it would be appropriate to consider a similar consultation process, in terms of form and content, to that recently conducted in the United Kingdom in its amendment of the financing and price intervention system with a thorough analysis of impacts (see The Pharmaceutical Price Regulation Scheme 2014 and all subsequent documents).

[65] See Pharmaceutical Pricing Policies in a Global Market, OECD 2008 (p.107), F. LOBO (2015) or *Aplicación de los contratos de riesgo compartido a la financiación de nuevos medicamentos (Application of joint venture contracts to finance new medicines)* PUIG-JUNOY and MENEU (2005)

and, therefore, the creation of the Advisory Committee, maximum care should be taken regarding its composition to ensure the technical capacity of its members and avoid possible conflicts of interest.

- **Simplification and reduction of procedural deadlines**. Both the marketing authorisation of the AEMPS (although not regulated in this DRD) and the inclusion of the medicine in pharmaceutical provision (financing and pricing).

IV.2.2 Extension of the regulation on the financing and pricing of medicines to certain sanitary products

The DRD issues to a large extent (Arts. 49(a) (71)), although with its own peculiarities, regulation on financing and price intervention for certain sanitary products included in pharmaceutical provision (Art. 49(6) DRD): *healing materials; sanitary products intended for applying medicines; sanitary products for collection of excreta and secretions; and utensils for the protection or reduction of wounds or internal malformations.*

The measure is negatively considered since, in general, **it is very questionable to apply such an intense and exceptional intervention system to products of a substantially different nature[66] to the medicines** and, therefore, this intervention must be based on the existence of a market failure or specificities.

The Supreme Court itself has ruled in this regard with respect to some of the products included in pharmaceutical provision and which are regulated by the DRD (absorbent nappies) which *"are not medicines or pharmaceutical (or sanitary) products and whose use does not involve health hazards, nor requires previous advice on how to use them, nor public control or supervision due to their potential risk in marketing and distribution[67]*".

Consequently, all the observations made in this Report on the regulation of prices and medicine funding decisions, with even greater justification given the limited specificities of most sanitary products included in pharmaceutical provision, are repeated.

In particular, **certain regulatory restrictions should be reconsidered**:

[66] Such is the case of healing materials, such as cotton wool, gauze or products used for the collection of excreta and secretions, such as nappies.

[67] Judgments handed down by the Supreme Court on 26 October 2004 and 12 March 2008.

- **The reservation for dispensing these products to pharmacies.** Dispense and supply of these products should be allowed in other establishments. This is an unjustified reservation of activity. Although they may exceptionally be justified in some specific cases, for the vast majority (cotton wool, gauze, bandages, absorbent incontinence products for the collection of excreta and secretions, etc.) there is no need for the intervention of a skilled technician for the act of dispensing[68]. In addition, if it were exceptionally appropriate, it should not be limited to pharmacists and even less so only to pharmacy managers.

  Nor can this activity reservation be justified because it involves a product *funded* for the management of the process of reimbursement as the generalisation of electronic prescriptions and broad access to technology simplifies management of reimbursement, which is not onerous and is accessible to any operator. In addition, the current mechanism for intermediation between pharmacies and the Spanish NHS through Pharmacists' Associations for billing and collection of prescriptions poses significant risks in terms of coordination, since the CNMC recently recommended eliminating this reservation of activity attributed to Pharmacists' Associations. All these issues should be reconsidered.

- **Introducing** for the first time in the regulation, without basis or justification, **margins for distribution and dispensing of sanitary products** included in the Spanish NHS pharmaceutical provision (Arts. 51 and 52 of the DRD). These margins **should be eliminated**. They pose a limitation on competition in the retail distribution of these products. They eliminate the incentive, through competitive pressure, for there to exist price reductions, improvements in quality or service in establishments. The regulation represents a step backwards that is even conducive to possible restrictive practices (pricing) detected in the sector[69]. Moreover, it even seems to be more permissive than the regulation of

[68] The Pharmaceutical Care Forum in Community Pharmacy defines dispensing as "the professional service provided by the pharmacist aimed at ensuring, after an individual evaluation, that patients receive and use medicines in a way appropriate to their clinical needs, in the doses appropriate to their individual requirements, for the appropriate period of time, with the information for the proper usage procedure in accordance with regulations".

[69] See the proceeding relating to practices that restrict competition in the Spanish market for manufacturing, distribution and dispensing of absorbent products for severe urinary incontinence in adults (AIO) Proceeding No. S/DC/0504/14 AIO initiated by this CNMC and currently being conducted. The 18 companies investigated (THE PROCTER & GAMBLE COMPANY, PROCTER & GAMBLE ESPAÑA, S.A, ARBORA & AUSONIA, S.L.U, DOMTAR LUX HOLDINGS, SARL, LABORATORIOS INDAS, S.A.U, SCA GROUP HOLDING B.V, SCA HYGIENE PRODUCTS, S.L., PAUL HARTMANN ESPAÑA, S.L.U, LABORATORIOS HARTMANN, S.A., BARNA IMPORT MEDICA, S.A., ONTEX ES HOLDCO, S.A, ONTEX PENINSULAR, S.A.U, ONTEX ID, S.A.U, TEXTIL PLANAS OLIVERAS, S.A., ALGODONES DEL BAGES, S.A.U. and the SPANISH FEDERATION OF SANITARY TECHNOLOGY COMPANIES (FEDERACIÓN ESPAÑOLA DE EMPRESAS DE TECNOLOGÍA SANITARIA, FENIN) account for an AIO market share of around 95%.

medicines in some respects already mentioned as negative[70]. All the following issues should be reconsidered.

- Extending and broadening **mechanisms for the acquisition** of these products through **public tenders** on a competitive basis.

- Extending the scope of the homogeneous group system to more categories of products than the current ones.

IV.2.3 Lack of information, monitoring and evaluation. The particular case of hospital medicines.

Although in Arts. 46-48 of the DRD references are given to an information system on medicine supply and monitoring of funding, the provisions are insufficient. Spanish NHS shortcomings in this regard, especially regarding spending on hospital medicines, are considerable. Despite the greater specificity introduced in the recent amendment of General Health Act 14/1986, of 25 April, in its Title VI "Transparency and sustainability of healthcare spending" and other mandates already provided for in the current regulation[71], it is considered appropriate to stress the lack of aggregate information and monitoring on this important expenditure chapter. It represents more than 33% of total expenditure of the provision and shows a growing trend. Other institutions, from the EU[72] and the healthcare sector[73] itself, have made pronouncements to the same effect. This is a relatively small group of medicines and therapeutic groups, which constitutes an obvious strength for the purposes of improved control.

[70] For example, with regard to the requirement for the incorporation of an analysis of recognised costs and benefits to form the price proposal.

[71] Royal Decree 177/2014, of 21 March, regulating the system for reference pricing and homogeneous groups of medicines in the Spanish National Health System, and certain information systems on financing and pricing of medicines and sanitary products.

[72] *"remains essential to control rising pharmaceutical costs and, in particular, to monitor the pharmaceutical costs of hospitals"* COUNCIL RECOMMENDATION of 14 July 2015 on the National Reform Programme for Spain for 2015, through which an opinion was issued by the Council on the Stability Programme for Spain for 2015.

[73] *"Analysis and transparency in hospital dispensing becomes essential. The characteristics of the use of medicines in this area is in actual fact unknown, although they are readily available at hospital and/or Management level, through Pharmacy Services, and although it is mandatory to provide aggregated and disaggregated information at prescription and hospital level".* Report on the Pharmaceutical Sector by the Medical Association (2014), pages 40 and 41.

The following is recommended:

- Draw up mandates for the provision of billing information on hospital medicines. Not only the volume of units consumed but their price and volume of total expenditure, which is currently unknown.

- Include an ongoing and ex-post evaluation of pricing and financing decisions thereon in line with indications in previous sections

IV.2.4 Margins for dispensing and limiting discounts

Pricing maintains the **addition of margins** to the laboratory selling price (LSP, Art. 4.3. DRD and referral to the current Regulation which requires the determination and amount thereof)[74]. The margin applied most commonly in dispensing by pharmacies, for medicines with MP of up to €91.63[75], consists of 27.9% of the MP excluding tax. While this may be legally provided for in the CT, it is questionable in terms of its justification and the fact that it does nothing to promote efficiency, as well as its proportionality[76] regarding its amount and configuration, in line with what was recently alerted to by this CNMC[77] in the study published.

The following is recommended:

- evaluating alternative remuneration systems, such as the possibility of a mixed system combining a fixed dispensing rate[78] with the partial or total refund of the price of the medicine by the Spanish NHS[79] and the remuneration of certain services defined by the Spanish NHS.

[74] Royal Decree 823/2008, of 16 May, establishing the margins, deductions and discounts related to the distribution and dispensing of medicines for human use.

[75] Note that the average price of the medicine dispensed by pharmacies is €7.75.

[76] With regard to proportionality, one might question whether the price increase which it represents (25.9% on average) for the user or more frequently the taxpayer corresponds to the service received. Moreover, the fixed margin is substantially higher than in other European countries (19.2% on average in Europe compared with an average of 25.9% in Spain.

[77] Study on the medicine retail distribution market in Spain (2015).

[78] This system has the advantage that it remunerates the act of dispensing (regardless of the price of the medicine) but, on the other hand, does not provide incentives for improving service quality.

[79] The partial refund of the price (maximum) of the medicine is called clawback and is applied in countries like the United Kingdom. The Spanish NHS returns to pharmacies the price paid by them to laboratories and wholesale distributors, so that the discounts obtained by pharmacies are transferred to the Spanish NHS and patients.

- notwithstanding the fact that they are fixed in the CT and their amendment is not possible through this DRD but through a regulation having the force of law, it is recommended once again to eliminate any limitation on discounts by pharmacies for users on OTC medicines (thereby removing the current 10%).

IV.2.5 Special pricing schemes (I) reported prices

This scheme is compulsory for (i) medicines excluded ("non-funded") from the Spanish NHS pharmaceutical provision and (ii) medicines included in the Spanish NHS pharmaceutical provision but intended to be marketed outside that scope with a different price to that set by the Spanish NHS. It is voluntary for (iii) medicines not funded by the Spanish NHS.

It should be borne in mind that the reported price scheme goes beyond a mere notification as it may be opposed by the Authority, but there is no guiding criterion that substantiates the opposition of the Authority, nor is the criteria on which the IPCM bases its decision known.

In this respect the following **is recommended**:

- **Maintain the scope**, subject to specification of the criteria for opposition and subsequent decision on the fixed price, **only in the first case** (non-funded medicines), in line with recommendations by this CNMC in its report on the CT.

- Limit the application of the price reported in the second case (ii) and **when the market price is higher** than the price funded by the Spanish NHS. Marketing should be promoted at lower prices outside the Spanish NHS without involving any burden on operators and without further intervention by the Authority being required.

- **Remove the condition for voluntary adherence to the reported price scheme.**
  Its justification is not understood. The price intervention of prescription medicines, even if they are not funded by the Spanish NHS based on existing market shortcomings[80], but there should not be a voluntary scheme apart from the general one (it involves adding dispersion to the existing heterogeneous pricing system), especially not a scheme with little precision in terms of its operation and criteria to consider, such as that of reported prices. Finally, non-prescription medicines (OTC) must follow a free pricing system.

[80] Purchase decision delegated by the prescriber, not the patient, guaranteed access to health protection at affordable prices, medicine as an essential good with positive externalities, information asymmetries, etc.

IV.2.6 Special pricing schemes (II): Selected prices

The selected price scheme (Arts. 24 to 28 of the DRD) was initially envisaged in the CT in Art. 99. It is a system that can possibly be implemented for medicines subject to the reference pricing system (i.e. those that have been marketed for more than 10 years and there is a generic or biosimilar medicine) given certain circumstances provided for in Art. 99.4 CT[81]. It seemed to indicate that it was a pro-competitive supply mechanism in which the MHSSE suggests a maximum funding price, communicates it to suppliers so that they can express their intentions and, according to the communications received, proposes to the Inter-ministerial Price Commission for Medicines a maximum price, for approval. That is, there is a competitive pressure between bidders regarding the price, a kind of auction[82].

However, **the regulation established by the DRD (Arts. 24 ff.) is removed from the pro-competitive philosophy** that may be inferred from the CT. It is a pricing system without bidders competing on price. The Authority sets the selected price (Art. 25.2) and operators express their intention to adhere without proposing an alternative lower price. It is therefore objectionable from the point of view of promoting competition and efficient economic regulation since i) it is not a market mechanism, but rather direct pricing by the Authority (Art. 25.2).; ii) it is not specified under what conditions it might be applicable; iii) there is no detail of the criterion that substantiates the resolution of the Authority (it refers only to "legally established criteria" in Art. 25.4 DRD).

It should also be added that this CNMC has been aware of **the existence of an earlier version of this DRD in which the system was configured in a completely different way**. There was a public call to tender for the selection of medicines with due transparency on the MHSSE website open to the participation of all Spanish NHS bidders. Since there was hardly any competition in the market in a sector as highly regulated as the pharmaceutical industry, the system would at least introduce competition into the market with potential efficiency gains[83].

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[81] Consumption on the whole, budgetary impact, the existence of at least three medicines on the whole and no risk of shortages.

[82] For this reason, this CNMC assessed this mechanism, in a preliminary manner and after warning of the lack of awareness of its future practical configuration, positively in the report on the CT, stating that: *"In principle, it is a pro-competitive mechanism in which there does not exist price intervention and use is made of market mechanisms. Therefore, its consideration is positively valued. While it has not yet been implemented, special care should be taken when implementing it so as not to introduce any restrictions on access to the tender".*

[83] The Andalusian Agency for Competition and the Secretariat of the Market Unity Council (within the Ministry of Economy and Competitiveness) have also made pronouncements in this regard in respective reports.

Therefore, the following **is recommended**:

- exploring market mechanisms such as auctions and centralised public purchases so as to generate price competition (and its consequent budgetary reduction and savings), greater transparency and improved administrative efficiency[84]. However, their design should be based on principles guaranteeing effective competition, including: i) facilitating freedom of access to the tender, ii) avoiding discrimination between operators, iii) reducing the risks of concentration of the number of operators, and iv) offsetting the risk of collusive behaviour.

IV.2.7 Sharing, centralisation and coordination of commercially sensitive information between Pharmacists' Associations and the Pharmaceutical Industry

The DRD establishes in its AP 4 and 5 a procedure for applying and distributing deductions among all actors in the pharmaceutical chain (reduction of the prices of medicines billed to the Spanish NHS by 7.5%), introduced by Royal Decree-Act 8/2010. The aforementioned RD Act provides that such deduction of 7.5% must be divided among the different actors (laboratories and pharmacies).

In implementing the provision[85] and with the idea of preventing pharmacies from having to make advance payments of the deductions that correspond to pharmaceutical companies and distributors, the following mechanism is provided in AP 5:

- *Farmaindustria*[86] is an integrated fund for the total amount of deductions applied in the billing of Spanish NHS prescriptions from the previous month.
- Each month the Provincial Pharmacists' Associations submit to the *Farmaindustria* billing data broken down by pharmaceutical company.
- *Farmaindustria* makes available to the Provincial Pharmacists' Associations the resulting proportional amount.
- The Directorate-General of the Basic Services Portfolio of the Spanish NHS (MHSSE) provides pharmaceutical companies that request it the necessary information so that they can compare the billing data.

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[84] Report by the State Industrial Holding Corporation (*Sociedad Estatal de Participaciones Industriales, SEPI*) on central purchasing bodies and applying them to a possible centralised platform for the purchase of medicines and sanitary products for the Spanish NHS (2012).

[85] Implementing regulations of the RD Act had still not existed, but rather documents or letters in which the Director-General of Pharmacy of the MHSSE gave instructions on the implementation of this distribution. Such documents or letters have been cancelled by the SC in its judgment of 12 June 2015.

[86] National Business Association of the Pharmaceutical Industry which groups the majority of innovative pharmaceutical companies

The procedure provided by the participants (provincial pharmacists' associations, association representing the laboratories and the Ministry itself) and by the type of information exchanged (billing data by company submitted by the provincial pharmacists' associations, "necessary information" without limit or precision, that the MHSSE can provide to the laboratories) raises serious **questions regarding adaptation to competition regulations as it facilitates possible collusive conducts[87].**

It is recommended that it be removed and that an alternative procedure be put in place which fully respects competition regulations.

V. ASSESSMENT OF THE LEGAL AMENDMENT INTRODUCED BY THE ACT ON GENERAL STATE BUDGETS FOR 2016

Given the close connection with the subject of this Report and notwithstanding the fact that it involves amendments to laws made through a regulatory instrument on which a report had not been requested, this CNMC deems it appropriate, given their relevance, to make a pronouncement on recent amendments to the CT introduced by Act 48/2015, of 29 October, on the General State Budgets for 2016 (final provision twenty). In particular, the changes made affect the following:

i. **It removes the 10% limit on discounts for early payment or volume of purchases that distributors can give to pharmacies** (FP 20. One amending Art. 4.6 of the CT).

ii. Identification by the **initials EFG** (generic pharmaceutical equivalent) is **exclusively carried out for generic medicines** (FP 20 two amending Art. 14.2 of the CT).

iii. It modifies the **obligation of substitution by the pharmacist**. That is, the rule still prevails that in the case of prescription (either by active ingredient or trade name) the pharmacist must dispense the medicine with the lowest price in its homogeneous group. But the reference to supply **the generic medicine** in the case of equal prices is removed. (FP 20 three and four amending Arts. 87.4 and 89.5 of the CT).

[87] It imposes the exchange and centralisation of very sensitive information (products, prices and quantities), both submitted by pharmacies to the respective Official Provincial Pharmacists' Association and that which the Official Provincial Pharmacists' Association submits to the Pharmaceutical Industry. Both the Official Provincial Pharmacists' Association and the Pharmaceutical Industry constitute associations representing operators from the sector in two links: production and distribution. What is more, provisions are in place for the MHSSE to provide the laboratories with the "necessary information" without safeguards or limitation, to contrast billing information.

iv. It amends the regulation for the **fixing of the price of** medicines **funded** by the Spanish NHS. Until now, it was established that the funded price must be lower than the industrial price (LSP) when it is dispensed outside the Spanish NHS. Now it is allowed to be **lower than or equal** (FP 20 five amending Art. 94.7 CT).

Notwithstanding the analysis of these amendments that may, where appropriate, be performed, and bearing in mind the formal disadvantages[88] that such a decision entails, it is considered appropriate to draw attention to the amendment of the regulation of discounts given to pharmacies.

This CNMC has generally been in favour of reconsidering the limits on discounts, not only those which laboratories can afford to give to pharmacies but also those that pharmacies can afford to give to users. In this regard, it welcomes the removal of the 10% limit on discounts for prompt payment or volume of purchases given by distributors to pharmacies, since they are conducive to greater competitive pressure and efficiency gains for operators. However, it should be noted that it is desirable **that that greater competitive pressure and its benefits** (in the form of lower prices and better products and services) **impacts not only operators** (pharmacies and distributors[89]), **but also on the consumer/user and the taxpayer**. Otherwise it would result in revenue being misappropriated by the former[90].

For this purpose, the following **is recommended**:

- Incorporating appropriate mechanisms[91] to ensure their impact on consumers and public finances, already pointed out and recommended in the past by this CNMC with the aim of i) promoting competition in terms of the level of retail prices (benefiting the consumer); and ii) improving the efficiency of the public health system and its financial health.

[88] When processed through a regulation with such heterogeneous content as the LPGE for 2016 and not through a specific and substantive industry regulation.

[89] By facilitating the improvement of their stock policy and commercial strategies.

[90] There is empirical evidence that when there was no limit on discounts given by distributors to pharmacies, the distributors recorded figures of 40% with no benefit for the user or the taxpayer. *"Impact of the regulation of medicine prices on competition in the generic medicine market: assessment of the effects and need for reform"* J. PUIG-JUNOY. 2009.

[91] In particular, the partial refund of the price (maximum) of the medicine, known as clawback, and applied in countries like the United Kingdom.

VI. CONCLUSIONS AND RECOMMENDATIONS

- The DRD consists of implementing regulations that are necessary from a theoretical point of view, especially with regard to the funding and pricing of new medicines. However, it contains aspects which could be improved **from the perspective of efficient economic regulation and promoting competition**.

- These principles, especially the principles of necessity, proportionality and minimum competitive distortion, are not only an end in themselves of the pharmaceutical policy itself, but rather **a valuable tool for achieving the objectives of public interest at stake**. Increased competition contributes to access to medicines at lower prices which are sustainable for finances, while encouraging innovation. There is considerable scope for regulatory improvement in this regard.

- Regarding the **decision on the financing and pricing** of new medicines, the DRD: i) does not specify criteria or reduce the excessive **discretion** of the Authority; ii) Does not provide any development on the mentioned economic evaluations in the decisions; iii) its consistency with the **principles of efficient economic regulation and promoting competition is significantly deficient**, partly because its conformity is not analysed; and iv) the existing **lack of transparency** is maintained. This CNMC recommends in this regard:

  - The **precise and effective development of the criteria** for funding and pricing already provided for in the CT. Such development must be carried out within the framework of a comprehensive analysis of intervention alternatives and a broad debate with due transparency should be encouraged.

  - The **generalisation of rigorous economic evaluation** in decision-making (both initial and follow-up and review). In particular, the **principle of cost-effectiveness** should be developed and the introduction of the pricing method based on value should be assessed.

  - **Ensure the independence and technical training**, especially in health economics and pharmacoeconomics, of decision-making bodies.

  - Inclusion in any case of sufficient **guarantees of justification, publicity and transparency of decisions**.

  - Simplification and reduction, unless there are justified reasons, of **procedural deadlines**, avoiding their configuration as a barrier to entry.

- The **price regulation scheme provided for sanitary products** included in pharmaceutical provision is objectionable. It entails extending the intense scheme for the regulation of medicine prices to products (gauze, bandages, absorbent incontinence products and others) without such features or specificities. It is recommended to remove the scheme introduced, especially the regulation of margins and the reservation of dispensing in pharmacies. Instead competitive supply mechanisms should be extended and the homogeneous group system expanded.

- It is recommended that mandates be drawn up for the provision of billing information on **hospital medicines** and that this be monitored and evaluated. Not only the volume of units consumed but their price and volume of total expenditure, which is currently unknown.

- The **margins to which the DRD refers** are questionable on account of their justification, configuration, the fact that they do nothing to promote the efficiency of operators and their proportionality. It is recommended to evaluate alternative remuneration systems.

- It **is recommended to remove the limitation on discounts** on the price of advertised medicines aimed at the public and not subject to medical prescription.

- The **reported price scheme** is not a mere advance notice, but rather the possibility exists that the Authority might be opposed without sufficient specification of criteria for opposition or pricing. It is recommended that such criteria be specified, that the scope be limited only to medicines that have been excluded from pharmaceutical provision, that the remaining conditions for mandatory application be reconsidered and that their application to non-prescription medicines be removed, as well as the condition for voluntary adherence to this scheme.

- The **selected price** scheme is removed from the pro-competitive philosophy that could be inferred from CT and previous drafts of the DRD. The current version entails direct pricing by the Authority without specifying the conditions for application or decision-making criteria. Consequently, it is objectionable from the perspective of efficient economic regulation and competition promotion. It is recommended to redirect the scheme towards the initial philosophy.

- The **information exchange procedure** for the application and distribution of deductions among all actors in the pharmaceutical chain raises doubts regarding its adaptation to competition regulations as it facilitates possible collusive conducts. **It is recommended that it be removed and that an alternative procedure** be put in place which fully respects competition regulations.

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