CNMC
COMISIÓN NACIONAL DE LOS MERCADOS Y LA COMPETENCIA

IPN/CNMC/005/15 REPORT ON THE DRAFT ROYAL LEGISLATIVE DECREE APPROVING THE CONSOLIDATED TEXT OF THE ACT ON GUARANTEES AND RATIONAL USE OF MEDICINES AND HEALTHCARE PRODUCTS

12 March 2015

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The Competition Chamber of the National Authority for Competition and Markets Authority (henceforth CNMC), in its meeting of the 12 March 2015, approved this Report on the Draft Royal Legislative Decree approving the Consolidated Text of the Act on Guarantees and Rational Use of Medicines and Healthcare Products (henceforth DRLD), analysing its implications from an effective market competition and efficient economic regulation point of view.

The request for report was received in this Commission on 16 February 2015. The documentation received consists of the draft DRLD, together with the Memorandum of Regulatory Impact Analysis (RIA).

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 that affect its setting of competition in the sectors it supervises, under Article 5(2) a) of *Act 3/2013 of 4 June on the creation of Spain's National Authority for Markets and Competition*.

I. BACKGROUND

The **main objective** of the DRLD is the compilation of a **unique text including all amendments to Act 29/2006,** of 26 July, on Guarantees and the Rational Use of Medicines and Healthcare Products, since it first entered into force (henceforth "Guarantees Act")**.** The legislative delegation for the compilation of this Consolidated Text is found in the final provision of Act 10/2013 of 24 July[1].

Since its publication, Act 29/2006 of 26 July has suffered **numerous amendments in the last years** that basically reflect the cost adjustments and streamlining of pharmaceutical expenditure measures, as well as the transposition of EU regulations. The RIA memorandum identifies up to ten guidelines modified from the original draft of Act 29/2006, of which it is worth noting the successive Royal Decrees[2] approved between

[1] Act 10/2013 of 24 July, incorporating into the Spanish legal system Directives 2010/84/EU of the EP and the Council of 15 December 2010, on pharmacovigilance and 2011/62/EU of the EP and the Council of 08 June 2011 regarding the prevention of the entry of medical counterfeits into the legal supply chain, and amending Act 29/2006 of 26 July established in its 4th Final Provision. [...] "This authorisation includes the powers to **regulate, clarify and harmonise** the legal texts that shall be consolidated".

[2] Royal Decree Act 4/2010 of 26 March, on the rationalisation of pharmaceutical expenditure in the National Health System; Royal Decree Act 8/2010 of 20 May, adopting extraordinary measures for the reduction of public deficit; Royal Decree Act 9/2011 of 19 August on measures for improving the quality and cohesion of the National Health System, on contributing to tax consolidation and increasing the maximum amount of State guarantees for 2011; and Royal Decree Act 16/2012 of 20 April on urgent measures to guarantee the sustainability of the National Health System and improve the quality and security of its provisions.

2010 and 2012. These introduced major changes, especially in pricing, reimbursement and other economic issues related to medicines and sanitary products[3].

The DRLD constitutes a recasting - with relevant clarifications and harmonisation - of the current valid legislation. Even though the DRLD does not in any way constitute the transposition of the new EU regulation, it should be noted that part of the Act 29/2006 had as its objective the transposition of community regulation: Directive 2001/83/CE of 06 November 2001, on a community code relating to medicinal products for human use, and its various amendments.

Within the Spanish pharmaceutical sector, these **links and agents may be identified in the production chain**: the laboratories take care of production. Regarding wholesale distribution, it is drug distribution entities that are responsible[4]. Lastly, retail distribution is managed by pharmacies[5] (which dispense 68% of medicines) and pharmacy services at hospitals[6] and health centres (the remaining 32%).

In addition, it is important to distinguish the different **product categories** that determine different markets according to: a) whether they are recently marketed medicines (with patent protection); b) whether they are subject to medical prescription; and c) whether they are financed by the Spanish National Health System (NHS)[7].

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[3] Although the 4 Royal Decree Acts are not the only amendments made, it is appropriate to mention them owing to i) their particular impact and substantial amendment to the regulation; and ii) the lack of amendments made by the CNMC, in large part due to the urgency of the proceedings.

[4] Laboratories distribute directly to hospital and health centre pharmacies (30% of all medicines) and seldomly to pharmacies. They operate more than 52 companies, largely grouped into 6 co-operatives that represent more than 75% of the market. In addition, 97% of the wholesale distributors are members of the Affiliated Union of Pharmaceutical Distributors (FEDIFAR)

[5] Pharmacies are subject to wide-reaching regulation and to scarce competition at this level (authorisation only to collegiate pharmacists and timetable and place of business regulations, just to mention but a few). Since 2010, for the first time in recent history, there was a reduction in turnover - up to 5% in 2012, although by January 2015 this was already reversed. . "Spanish Market Trends" IMS Health. November 2013

[6] Hospital pharmacy: dispenses more complex products with special medical indications and generally dispensed via parenteral. This sub-sector of the market is characterised by: its extremely high weight in comparison to other neighbouring countries; its high growth experienced since 2007; and deceleration -now stabilised- since 2010.

[7] Since the reform introduced by Royal Decree Act 16/2012, the NHS only funds prescription medicines.

The pharmaceutical sector is subject to **intense regulation** in the majority of our neighbouring countries based on: the special safeguards required by the legal interest protected: people's health; b) the existence of market failures in the sector that hinder access to health protection under equity conditions; and c) strategic relevance of the sector to the economy, its innovative intensity and specially, the impact of pharmaceutical provisions on public finances.

Price regulation is particularly intense in the majority of our neighbouring countries. Administrative intervention on prices is justified by the economic singularities[9] of the pharmaceutical sector, in particular of prescribed medicines and publicly funded medicines. Also the following should be considered: the nature of the public good and positive external effects on health, the desirable accessibility to service provisions under equity conditions and particularly in recent years, the high impact of pharmaceutical provisions on the NHS.

It is also a sector in which the competition authority has exercised different actions, from business concentrations to sanction proceedings for violation prohibitions included in national[10] and EU[11] competition rules.

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[8] The analysis of different segmentations such as competency in innovation amongst patented medicines.

[9] **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.

[10] Without being exhaustive and citing **recent open document files** that are still in the investigation phase, on 2 September 2014, the CNMC decided to initiate a file sanction S/DC/0504/14 to 15 production, distribution and dispensing companies dealing with absorbent products for serious urinary incontinence in adults (AIO), and to the Spanish Federation of Healthcare Technology Companies (FENIN) after indications of possible anticompetitive behaviours. In particular, possible price fixing, commercial condition settings and the waivers prohibited under Article 1 of the LDC. On 30 September 2014 disciplinary proceedings S/0472/13 were commenced, for restrictive practices banned under Article 1 of the LDC, consisting of exchanges of information and arrangements for pricing and other commercial conditions for the distribution and sale of test strips for determining glucose levels in the blood, by various pharmaceutical laboratories and FENIN.

[11] See for example, Decision on the COMP/A Case. 37,507/F3 - AstraZeneca, or the EU investigation on competition in the pharmaceutical sector (2008/2009): Analytical summary of the Sectorial Investigation Report on the pharmaceutical sector

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/citizens_summary_es.pdf

II. CONTENT

The DRLD consists of a preamble and a main body with one sole article (approving the consolidated text), an additional provision (regulatory references to the new consolidated text instead of to the Act 29/2006), a derogatory provision (implicit and explicit in Act 29/2006) and a final provision (entry into force).

The sole Article approves the consolidated text and comprises 127 articles divided into 11 titles and their respective chapters, fifteen additional provisions, six transitory provisions and four final provisions.

- Title I **General Provisions** includes, in the first place, the **scope** of the Act. It is defined extraordinarily broadly as it includes each and every process that affects the development of medicines (for human and veterinary use) and sanitary products[12]. It encompasses all the agents involved in their industrial, commercial, prescription and dispensing circulation. It also includes the **definitions** and a set of demonstrations of the intense administrative intervention in the matter, in the form of guarantees and **obligations** to the agents involved and to the Administration itself[13].

- Title II[14] **on medicines**, defines the concept of a legally recognised drug; it establishes the guarantees expected of industrially produced medicines and the conditions for prescribing and dispensing via an intense authorisation and registration scheme. It also regulates the set of sanitary guarantees and monitoring (pharmacovigilance).

- Title III on **investigation** of medicines for human use and their guarantees: clinical tests and their administrative regime (subject to authorisation, sanitary administration faculties, various obligations and guarantees carried out as part of the test).

- Title IV establishes the **requirements of prior authorisation and fulfilment of technical obligations**, while Titles V and VI respectively deal with the registration[15] and sanitary guarantees for the medicines' international trade.

[12] Their clinical investigation, evaluation, authorisation, registration, production, processing, quality control, storage, distribution, circulation, traceability, marketing, information and publicity, import and export, prescription and dispensing, monitoring the benefit-risk relation, organising its rational use and procedures for, when applicable, financing with public funds.

[13] Debentures and guarantees: on replenishing and dispensing; on independence and prevention of conflicts of interest; defending public health; and that of the Authority, including the obligation to guarantee the maximum transparency in decision-making (Art 3 to 7).

[14] Title substantially modified, although not in the economic side but rather on the technical watershed (efficiency, security and quality guarantees) by Act n. 10/2013 of 24 July

[15] Both the registration of pharmaceutical laboratories and of producers, importers and distributors of main assets are managed by the Spanish Agency for Medicines and Healthcare products AEMPS.

- Title VII deals with the **principle of rational use of medicines** for human use and covers aspects such as guarantees of objectivity and quality of information, promotion and publicity; with doctor's and hospital prescription regulation and a set of measures and obligations on traceability.

- Title VIII, establishes the **public funding** procedure of medicines and healthcare products: the rules on pricing, price reference and selected prices systems, patients' obligations to pay for certain medical provisions (co-payment) and information management systems for official prescriptions and in general, the consumption of consumables directly under the control of pharmaceutical provision.

- The last three Titles (IX, X and XI), regulate the **sanctions scheme**, the act of publicity ceasing for medicines and the fees for the provision of services and completion of the General Administration activities regarding medicines, healthcare products and cosmetics and personal care products.

- Of the **additional provisions**, the regulation of the total or partial exclusion of medicines from NHS' pharmaceutical provision (5th additional provision) and contributions by volume of sales imposed on producers, importers or providers of medicines and/or healthcare products to the NHS (6th additional provision) stand out.

III. ASSESSMENT

Without prejudice to the recognition that the proposing organ has scarce margin of manoeuvre when dealing with the task of preparing a Consolidated Text, the **global assessment** made from the point of view of competition advocacy and efficient economic regulation is double: (i) from a **formal** point of view **(III.1),** the act of creating a consolidated text merits a positive assessment that shall improve the legal clarity and security. However, observations can be made about some of the options taken; (ii) from the **substantive** point of view (III.2), there are recommendations that, while exceeding the available margin of manoeuvre in the creation of a consolidated text, call for their consideration in future regulations.

Notwithstanding the above, additional recommendations may be made by the CNMC once the Study of the retail medicine distribution market in Spain is concluded.

III.1. Formal observations: more ambitious approach to the recasting

The aim of the DRLD is to consolidate, in one sole text, the amendments that have been made to the Guarantees Act of 2006 since its entry into force. This authorisation to compile a consolidated text does not need to be limited to a mere "recasting", but it shall rather "regulate, clarify and harmonise" the legal texts that need consolidation, in accordance with the delegating Act (4th Final Provision of Act 10/2013 of 24 July and in particular, under Article 82(5) of the Spanish Constitution).

The doctrine of the Spanish Constitutional Court has interpreted this function in broad terms, specifying that the scope of the consolidation or recasting includes i) the elimination of discrepancies and conflicts; and ii) the introduction of additional regulations complementary to those that are strictly subject to consolidation, assuming it is necessary to close loopholes, specify intent or, ultimately, create coherence and systematise the sole consolidated text[16].

In this sense it is worth noting that i) the DRLD is extremely complex to understand -even for a legal expert-; ii) its system and coherence can be improved; and iii) it is worth taking advantage to improve the clarification and harmonisation of the resulting text.

Due to its impact in competition promotion and efficient economic regulation, and notwithstanding the additional substantive observations that will be mentioned afterwards, - the text of Title VIII is particularly complex and worthy of improvement,

[16] STC 166/2007 of 4 July, reiterating the contents of STC 13/1992 of 6 February.

regarding the public funding of medicines and sanitary products and specifically, the applicability of different categories of price systems.

In particular: i) understanding the scope and the different assumptions under which each price scheme operates; ii) the intervention mechanism for each scheme; iii) the confusion over the use of terms such as "discount", "rebates" or "reductions" addressed to different agents in the chain, different prices (producer consumer prices) and their different meanings; iv) not inconsiderable contradictions and ambiguities (such as reported[17] price scheme, among others)

In this respect, it is therefore recommended that more clarity be introduced into the text in order to expressly specify the scope and definition of each price scheme, reference terminology be used more precisely (discount, rebates, reductions, etc.) and apparent contradictions be eliminated.

III.2. Substantive observations that may be taken into account in future legal reforms

From a general perspective, the regulation analysed presents some controversies from the point of view of efficient competition advocacy and economic regulation.

On one hand, certain aspects are **positively assessed**, such as the specific provisions for the development of competition and competitiveness (Art. 101) to stimulate them amongst suppliers of pharmaceutical consumables; the existence of a more economic approach[18] in the assessment of medicines (Art. 96); references to transparency in the adoption of decisions by Public Authorities (Art.7 and 16.4), assuming that operators do not have access to commercially sensitive information; the depiction of development schemes for competition promotion in prices on the demand side, such as the development of generics, substitution of pharmacists or prescription by active ingredient[19].

[17] Art. 95(1) *in fine* states that "for the purposes foreseen in this Act, it shall be understood that non-funded medicines shall be part of **free market price schemes**" and it continues by introducing in its section 4 that "**notified prices**", which are those that are truly used ("holders of distribution authorisations for the same may distribute the medicines dispensed within the Spanish territory under notified price schemes, on the understanding that the price be communicated to the Ministry of Health, Social Services and Equality, so that the department may have the opportunity to object for Public Interests reasons.")

[18] By way of a technical committee - Advisory Committee for Pharmaceutical Provision to the NHS- to advice the Inter-ministerial Commission on medicines' prices although it is yet to be constituted.

[19] Measures also adopted in our setting, as stated in "Price interventions on medicines in Spain" Félix Lobo. Springer Healthcare 2014

In contrast, through this report, appraisals have been made by the competition authority, with respect to traditional aspects of regulation, such as its intensity, complexity, lack of justification and the resulting design of the different medicines' pricing systems; the limitations of discounts made by operators; excessive regulation affecting pharmacies and other establishments; the restriction on distribution operators through certain marketing channels different than the traditional ones (distance or internet sales[20]); specific aspects of behaviour subject to disciplinary proceedings (replenishment guarantee).

These restrictions limit the possibilities for operators to follow price differentiation strategies in order to compete in the market, with short term effects from a dynamic point of view, as well as reconciliation issues regarding the free enterprise principle established in the Constitution (Art. 38). This is developed further below.

III.2.1. Public funding and price intervention schemes

III.2.1.1 Procedures and criterion for public funding (Art. 93 TR)

Once they are authorised for distribution by the Spanish Agency for Medicines and Sanitary Products (AEMPS), medicines and sanitary products may be included in NHS funding. Article 93 TR covers the procedure, which establishes that for them to be included within the pharmaceutical provision, there must be an explicit resolution by the Ministry of Health, Social Services and Equality (henceforth "MSSSI"), where it shall establish the funding and pricing conditions.

This inclusion of cost-effectiveness references[21] belonging to pharmacoeconomics and of the regulation of an Advisory Committee for the Inter-ministerial committee on prices of specialist medicinal products references are deemed positive.

[20] Community regulation requiring the condition that the natural or legal person offering the medicinal products is authorised or entitled to supply medicines to the public must be considered, even at distance, in accordance with national legislation of the Member State in which that person is established" (Art. 85(c) of Directive 2001/83 -" on the Community code relating to medicines for human use)

[21] [...] The inclusion of medicines in the National Health System funding is made possible through selective (not indiscriminated) funding, taking into account general, objective and published and specifically, the following: a) Seriousness, duration and repercussions of the different pathologies for which they are included; b) Specific needs of certain collectives; c) Therapeutic and social value of the medicine and its incremental clinical benefit, taking into account its cost-effectiveness relation; d) Rationalisation of public spending destined for the pharmaceutical provision and its budgetary impact on the National Health System; e) Existence of medicines or other alternative therapies for the same medical condition at a lesser price or cheaper than the cost of treatment. f) Degree of innovation of the medicine.

However, given the relevance for one medicine to be included in the NHS funding, the inclusion procedure provides: (i) **excessive discretion** regarding the decision on how to apply the set of preselected criterion and the possible preference of one over another; (ii) a reference to taking into consideration the medicine's contribution to gross domestic product, introducing possible **discrimination due to the origin of products**, with concerns also on future and uncertain developments..

III.2.1.2 Price intervention schemes: explanation and general consideration

The DRLD maintains the traditional intensity of pricing regulation –it sometimes even consists of an actual price fixing. The complex[22] regulation established through Article 92 and subsections can be briefly summarised as:

Firstly, intervention exists at different levels starting with the laboratory selling price (also called LSP, industrial price or production price). Margins must be added to this laboratory selling price[23], which is fixed by the Authority under a dual rate -fixed part and proportional part- for both wholesale distributors and retailers (pharmacies). Once VAT is added to all the previous concepts, the retail price is reached (RP)[24].

Secondly, the MSL intervention scheme differs according to the medicine or sanitary product: a) if it is non-funded: a free prices scheme is theoretically followed as declared in the TR but, in reality, it consists of a notified prices scheme with the possibility of opposition by the Authority; b) if it is funded (and requires prescription): The Authority fixes the MSL[25] (Art. 95 TR). In this case it varies if b.1.) the medicine is newly marketed, then the Authority - Inter-ministerial Commission for Medicine Prices- fixes the price; b.2.) it has been on the market for more than ten years or there is a generic alternative version (reference price system and homogeneous groups.

[22] The complexity of the regulation has already been noted in the formal observation: the text and systematics are confusing and it is almost impossible to understand, even by legal operators who make a significant intellectual effort, and so are the scope of each scheme, and the intervention and setting mechanisms. It is recommended that the text and the systematics be generally simplified, and the legal technique improved as it is a complex legal framework that does not provide legal security for operators and ultimately neither does it for the public or contributors in general.

[23] Art. 95(9) TR. See the margins medicinal products for human use.

[24] Art. 95(10) TR.

[25] And ultimately, the RP is no more than the sum of the LSP and the margins.

Within the various possible methods of regulation, the Spanish Health Authority has been gradually showing its preference with particular intensity for price intervention. Account must be taken that even if Member States hold the authority to set medicines' prices[26], under specific regulations, this intervention constitutes a limitation to the constitutionally recognised free enterprise right (Art. 38) and, as such, its intervention necessity, justification, proportionality and benefits must be made explicit.

Notwithstanding the above, it is worth noting that neither economic literature nor empirical evidence[27] suggest that price intervention is i) neither the only nor the best option available to the Administration; ii) should be as heavily regulated as it is, to the extent that such intervention results in in price and margin fixing.

In the case of Spain, it can be seen that the price intervention produces, *de facto,* two perverse incentives, contrary to the efficient economic regulation:

- Incentive to launch new products even though they do not represent an innovation or present a substantial therapeutic improvement in order to update prices.
- Incentive for companies to promote medicines consumption (in order to compensate for a decrease in prices and maintain turnover), in violation of the principle of rational use and public expenditure constraint.

It is generally recommended that in the future the following shall be taken into consideration: i) **measures distinct from price interventions, such as those based on demand**[28] that offer a pronounced pro-competitive component with proven efficiency in order to reduce public spending on pharmaceuticals; ii) if price intervention is maintained, that **it should be done with less intensity**[29] and less broadly

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

[27] Exhaustive coverage of all this literature and empirical evidence can be found in "Current policies on medicines' prices in Europe" F. LOBO 2015.

[28] Pharmaceutical policy measures can be classified in two sections: supply-side policy and demand. Within supply-side policies, price regulation -and all its adjustments- cost control measures -discounts, returns and others-, regulation of the industry and rebate or financing schemes are found. On the demand side, all those measures directed at prescribers (**doctors), dispensers (pharmacists) and patients (final consumers) may be found**. Articulation of the principle of rational use of medicines (and their placement under regulation on the pharmacists' obligation to substitute the prescription for an active principle, development of prescription guides and distribution campaigns and information) is an example of the demand measures, although there are other examples.

[29] The intensity and width refer to the fact that price regulation of each link in the production chain are covered and include their fixing. For example the actual configuration of the reference prices system in its current configuration.

, and intervention mechanisms should be carefully designed with particular consideration for the basics of micro-economics within the remit of pharmacoeconomics; (iii) lack of regulation development on the evaluation of pharmacoeconomics in deciding on pricing; (iv) lack of transparency since decisions based on pricing are not published.

III.2.1.3 Analysis and evaluation of the different pricing regimes: reported prices, newly marketed funded medicines, reference prices and homogeneous groups and selected prices schemes.

Firstly, the reported **prices scheme.** Even though Art. 95(1) TR establishes that[30]: "For the purposes foreseen in this Act, it is understood that non-funded medicines are covered by the free price scheme", the system operated is undoubtedly one of reported prices, where even a mere communication may be opposed by the Administration.

This scenario includes all non-funded medicines, whether they are a) excluded from the pharmaceutical provision[31]; b) medicines and sanitary products where no doctor's prescription is needed[32]- and so are not funded[33]-; c) non-funded prescribed medicines[34]. Holders of authorisations/responsible for distribution

[30] Introduced by RD Act 16/2012.

[31] Art. 94(3) and (4) TR: "Those ***responsible for products excluded from funding shall communicate to the competent body the prices to be marketed*** for said medicinal products. *The same obligation extends to* ***variations*** *in prices. In the month following entry into the Register of the* ***competent body for communications referred to in the previous section, said body shall make a decision regarding its conformity or lack thereof for the proposed price****s. In the event of non-agreement, said body shall raise the discrepancy with the Inter-Ministerial Commission for Medicine Prices, who shall resolve said issue. Said decision shall be notified via resolution of the competent body to the interested party. "*

[32] Art. 93(3) and 4 TR **"***The Government may regulate the pricing mechanism for non-prescription medicines and sanitary products dispensed within the Spanish territory,* ***following a general objective and transparent scheme****. In all cases, holders of marketing authorisation for the same may market the medicines dispensed within Spanish territory under a price notification scheme, under the understanding that the price be communicated to the Ministry of Health, Social Services and Equality,* ***so that the department may object to the same for reasons of public interest****".*

[33] As covered by Art. 93(2) TR in its first paragraph: "In any case, non-prescribed medicines shall not be included in the pharmaceutical provision".

[34] *Art. 95(5) in fine: "Corresponding to the Inter-ministerial Commission for Prices of Medicines, ascribed to the Ministry of Health, Social Services and Equality to fix, in a reasoned manner and in accordance with objective criteria, funding prices for the National Health System for medicines and sanitary products that may be needed for medical prescriptions and that are dispensed within the Spanish territory. When these same products are not funded, if they are dispensed within the Spanish territory, the provisions set forth in section 3 shall apply."*

of medicines (laboratories) should notify their price to the MSSSI which, in all cases, may either accept it or oppose it.

Submission to this notified prices scheme with possible opposition merits the following assessment:

- it may only be justified in cases (a) relating to medicines excluded from public funding for reasons, when relevant, of equitable access to protection of health.
- weaker justification in cases (b) of non-funded prescribed medicines , for the aforementioned reasons of asymmetry of information and delegated decision to purchase the medicines;
- seemingly scarce or zero justification (c) for non-funded and non-prescribed medicines and sanitary products that are also governed by government "objective and transparent" criteria.

It would be wise, in addition to being subject to more clarification, to provide adequate justification for the choice of this scheme and its rationale or properly rethink it.

Secondly, **pricing of newly distributed and funded medicines** (Art. 95 TR). These are fixed by the Inter-Ministerial Commission for Medicines Prices (ICMP) with barely any weighted criteria (they must merely take into consideration the cost-effectiveness analysis, the budgeting impact and the reports compiled by the Advisory Committee for Pharmaceutical provision to the NHS, Art. 95(1) TR in fine and 95(8) TR)[35]. As a shielding clause it adds that the price funded by the NHS shall be lower than the industrial one when dispensed by the NHS (Art. 95(7)).

[35] Art. 95(5) TR**:** The Inter-Ministerial Commission for Medicine Prices, ascribed to the Ministry of Health, Social Services and Equality shall set, in a reasoned manner and in accordance with objective criteria, the funded prices for the National Health System for medicines and sanitary products that may be needed for medical prescriptions and that are dispensed within the Spanish territory. 8. For decision-making purposes, the Inter-Ministerial Commission for Medicine Prices shall take into consideration the reports compiled by the Advisory Committee for Pharmaceutical Provision to the National Health System.

This regulation is worthy of critique as:

i. it is too vague -it barely takes any criteria into consideration-[36];

ii. it does not have an adequate development regulation. Eight years have passed since the approval of the Guarantees Act of 2006, and the Royal Decree 271/1990 of 23 February, on the reorganisation of price intervention of specialist pharmaceuticals for human use is still apparently in force. This RD establishes a mechanism for determining prices based on addition of costs[37] - which is opposite to the spirit of this TR and the original regulation itself from the Guarantees Act- on the basis of information provided by the manufacturer and checked by the Administration in order to definitively set the price (sum of costs intervention method or "cost-plus"[38]).

iii. The mechanism is neither transparent nor predictable. The exact criteria are unknown. There is a lack of information regarding the ICMP arrangements in the last 3 years for newly marketed medicines. No reasoned resolution reports are published on funding or pricing. In this regard, there seems to be room to introduce more transparency on the base of objective and transparent criteria[39].

[36] The original regulation from the Guarantees act established that the ICRP should take into account i) reports on therapeutic use that AEMPS should compile; and ii) criteria for inclusion in funding of medicines (former article 89.1 of the Guarantees Act: [...] a) Seriousness, duration and consequences of the different pathologies for those indicated. b) Specific needs of certain collectives. c) Therapeutic and social use of the medicine. d) Rationalisation of the public expenditure destined for pharmaceutical provision. e) Existence of medicines or other alternatives for the same medical conditions. f) The level of innovation of the medicine.)

[37] This RD establishes a mechanism to determine LSP prices based on the addition of costs, using the information provided by the manufacturer as a basis and verified by the Administration for final pricing. That is, the Laboratory selling price (LSP) = cost price + R&D expenses + company profit. The wholesale dealer's and dispensing pharmacy's margins should be added to this LSP in order to reach the RP, to which indirect taxes are then applied.

[38] The method has gradually been eliminated in the majority of countries in our setting due to its many limitations such as: it reduces incentives for efficient production; it is difficult to verify and has high transaction costs; the asymmetry of information regarding real costs between laboratories and administration, meaning higher costs are assigned than the real ones; and the difficulty in charging for R&D expenses etc.) F. LOBO (2015)

[39] Financial assessment of medicines as a sustainability factor in public healthcare — *Blog: Nada es gratis*

iv. It can be seen through certain empirical evidence[40] that the regulation together with the non-existence of price review mechanisms constitutes a deficient framework that enables the strategy of setting prices excessively high, independently of the incremental efficiency of the drug. The regulation could be more precise on the criteria for price reviews by the Administration, especially with respect to its frequency.

v. Structural changes in the price intervention must be taken into consideration[41], centred around mechanisms that particularly take into account cost-effectiveness considerations, as well as therapeutic contributions and any innovation of the medicine[42].

Regulation of this intervention mechanism (legal and procedural) - when relevant- for newly distributed medicines is urgent in each case where the criteria are vague and manifestly insufficient. It is therefore crucial for the development of innovation and market access for operators as well as for the rationalisation of public expenditure and budgetary stability.

Thirdly, **reference prices.** These are used in cases dealing with a medicine that has been on the market for more than 10 years or where there are generic alternative versions. The reference price system, regulated by Art. 99 TR[43], is the maximum amount that "presentations of medicines included in determined sets" are funded.

They are calculated according to the lowest cost of treatment and day rate for grouped medicines ("presentations of medicinal products included in each of the determined sets"), taking into consideration a set of EU countries. In theory it is not a direct pricing system but an indirect one as it determines the maximum funding and the amounts are revised periodically.

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[40] *"Launch prices for new pharmaceuticals in the heavily regulated and subsidized Spanish market 1995-2007"* J. PUIG-JUNOY, B. GONZÁLEZ LÓPEZ-VALCARCEL 2014.

[41] An example of good international practice is found in the United Kingdom and its exhaustive study on price systems for medicinal products (it also analyses the systems of other countries such as Spain).

[42] There are similar experiences in the United Kingdom (NICE) and Sweden.

[43] And developed by the RD 177/2014, of 21 March, regulating the reference price system and of grouped homogenous medicines in the NHS and certain and certain information systems relating to funding and prices of medicines and healthcare products and Order SSI/1225/2014 of 10 July, updating the reference price system for medicines within the National Health System.

That is to say, it works like a maximum pricing system if we also take into account i) the obligation for prescription on the active ingredient (Art. 88(2) TR); ii) the obligation for the pharmacist to dispense at the lowest price[44] ("substitution by the pharmacist" Art. 90(2) and 90(5) TR) and the consequent lack of possibility of the final customer choosing to pay the difference for a more expensive medicine; and iii) the incentives that introduce an overall decrease in laboratory prices, but only to the full price for funding.

However, regarding price competition between laboratories, only pharmacies have benefited via discounts (estimated at an average of 40%[45]) due to not having passed them to the consumer (among other reasons because the NHS reimburses pharmacies the LSP plus the fixed margin) and due to the non-existence of mechanisms for the NHS to reimburse pharmacies for the amount they have actually paid (considering the discount).

In general, under the designed system i) there has been no competition at the RP or at end customer level and thus no benefit has been passed on to them; ii) the regulation may imply a particular risk of express or tacit collusion (due to the lower price dispensation rule)[46]. Therefore, an option could be to rethink the reference price system together with the regulations on discounts, reductions and the possible increase of consumers' margin of choice and other mechanisms to promote competition at the end customer level.

Lastly, **selected prices** systems. Regulated under Art. 100 of the TR, and possibly applicable to medicines included in the reference prices' system. The MSSSI provides a maximum selling price for funding, communicates it to the suppliers for them to advise their intentions and in accordance with the communications received, proposes a selling price to the Inter-Ministerial Commission for Medicines Pricing for its approval. In principle, this is a pro-competitive mechanism where there is no price intervention and market mechanisms are used, which is deemed to be a positive provision.

[44] Obligation for substitution and waiver in the two scenarios: i) when it is prescribed within a framework and has a lower price, the pharmacists must substitute it for the lower price in the homogenisation groups; and ii) for reasons of replenishment or urgent necessity.

[45] *"Impact of price regulation on medicines on competition in the generic products market: evaluation of the effects and need for reform"* J. PUIG-JUNOY. 2009. Be aware that the original text of the Act on Guarantees (Art. 3()) allowed discounts for prompt payment and volume of purchase without any limit. (Currently as covered in the TR, the limit is 10%).

[46] As shown in file S/0437/12 ESPECIALIDADES FARMACÉUTICAS GENÉRICAS (although it was dismissed due to unfound infringement indications)

Even though it is not yet in practice, its use should be particularly cautious so as not to introduce possible entry barriers to bidding.

III.2.1.4 Limiting discounts and price reviews.

The DRLD is restrictive regarding discounts in several concepts: i) possibility of discounts for prompt payment or volume of purchase, awarded by distributors to pharmacies but limited to a maximum of 10% for funded medicines charged to the National Health System and provided that they do not encourage the purchase of one product over its competitors and are reflected in the corresponding invoice. (Art. 4(6)); ii) no possible amendment or allowance on the LSP for medicinal products dispensed by pharmacies via official doctors' prescription, unless it is a percentage or linear discount; and iii) transfer via regulation, of the maximum discount available for medicinal products subject to publicity - any non-prescribed medicines or non-funded by the NHS- (8th Additional Provision).

It may be wise to reconsider the justification, rationale and proportionality of i) such intense limitation on discounts. It is true that in practice, pharmacies have not passed their savings (on average 40% according to various studies) on to the end customers, but there are mechanisms for this to happen[47]; ii) as to why only linear or percentage discounts are allowed; and iii) reconsideration of the limitation on discounts of non-prescribed and non-funded medicines (those that allow publicity).

On the other hand there is a minimum threshold of 10% under which a lower price review could be used under article 97(6) TR. In general, pricing or minimum thresholds cause inefficiencies in the adjustment mechanisms between supply and demand, translating into static inefficient prices and worse conditions in terms of quality and product variety. In this specific example, in a market where medicine prices are regulated, fixing minimum thresholds will affect the incentives for operators to distribute medicines and/or particular launches. The need to rethink this measure was already pointed out on the occasion of IPN 105/13 on the RD regulating the reference prices system and of grouped homogeneous medicines in the NHS.

Finally, and with respect to the possible overall price review by the government, and without a more specific reference, it would be recommendable to limit and specify the assumptions and criteria under which it would take place given its excessive ambiguity (Art. 97(3))[48]. This would reduce excessive discretion by the Administration and would increase the legal certainty of the operators.

[47] Among other mechanisms, there are discount recovery systems such as the so-called clawback system in the United Kingdom.[48] The Council of Ministers, after prior agreement of the Government Executive Committee for Financial Matters, may make a comprehensive review or may set the conditions for the periodic review of industrial pricing and, where appropriate, sales prices to the public, for all or part of the medicines and healthcare products included in the National Health System's pharmaceutical provision.

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III.2.1.5 Other alternative policies to price intervention that promote competition

In general, as indicated in the overall price intervention assessment, the intensity and design of price regulation should be reconsidered. It would be very interesting to consider other competition advocacy policies, largely on the demand side: a large penetration of generics, despite recent advances (which leads them now to have a market share of 40%) and the intensification of the competition on consumer final-level prices, would add on benefits being transferred to the final consumers.

The deepening of measures for the rational use of medicines, also considering the establishment of incentives (more than mandates) to prescribers and dispensers, could also help the prior cause.

One market mechanism that, in accordance with international experience, would provide significant savings to the public sector (NHS) would be auctions and centralised public purchasing, as it could include price competition - and consequent reductions and budgetary savings-, increased transparency and improvements in administrative efficiency[49]. However, the main guarantors for effective competition should be considered in its design,, including: i) facilitate entry access to bidding, ii) avoid discrimination among operators, iii) reduce risks of concentration among operators and iv) counteract the risk of collusive behaviour.

III.2.2 Distribution restrictions via non-traditional channels

The sale of medicines through different channels (mail order and by internet) other than traditional ones (pharmacies), is restricted under Article 3(5). Specifically, the regime is as follows:

i) absolute prohibition for prescribed medicines and healthcare products;
ii) regulatory development[50] to touch upon the procedural regulations and requirements of non-prescribed medicines but, guaranteeing in any case that, "*they be dispensed by a pharmacist, after prior personal advice, under Articles 19(4) and 87(1)*"; and
iii) prohibition of door-to-door sales and any type of indirect sale of medicines to the public and the possible restriction or ban of healthcare products;

[49] SEPI report on shopping centres and their use as a possible centralised purchasing platforms for medicines and healthcare products for the NHS (2012).

[50] Royal Decree 870/2013 of 8 November, regulating distance selling to the public via websites, of non-prescription medicinal products for human use

A certain **liberalisation of regulations on non-prescribed medicines** may be reconsidered, as the number and variety of operators is extraordinarily restricted, shutting off access for new operators who could introduce high levels of dynamism and competition into the market. Reserving the activity to pharmacy owners (who must also be licensed and be a member of a Professional College of Pharmacists)) seems disproportionate and could be re-evaluated.

On the other hand, the TR contains intense restrictions on **promotion and publicity**, in accordance with European Union regulations. Sometimes, the strict bans and regulations may be justified (Art. 5(2) for unauthorised medicines and Art. 80 on medicines funded by public funds that require the intervention of a doctor to make a diagnosis, prescription and treatment follow-up).

However, the intensity of the possible prohibition regulated in Art. 80(4) of the APL could be reconsidered, applicable to medicines that in principle, could be subject to publicity. The General Public Interest reasons alleged in this case (public health and people's security) are excessively vague and introduce legal uncertainty among operators. It is therefore advisable to rethink them or at least describe them with greater precision.

III.2.3 Excessive regulation of pharmacies and other establishments

Notwithstanding the conclusions that may be drawn from the CNMC study on the retail market for distribution of medicines in Spain- currently under way- the **excessive regulation affecting pharmacies** in Spain must be highlighted (Art 87 TR, although it is more extensively regulated under other development regulations), as it constitutes an obstacle to the freedom of establishment and free competition.

On one hand, Article 4(2) of the TR establishes a restriction on the exercise of the pharmacists' activities, as it determines the incompatibility of the professional exercise of the pharmacist in their pharmacy, in retail business establishments, in pharmaceutical groups, in a hospital pharmacy service or other welfare structure with any level of direct financial interest in pharmaceutical laboratories and/or wholesale storage.

Notwithstanding the justification for this restriction (guaranteeing the independence of the pharmacist when dispensing medicines and providing pharmaceutical service of financial interest to laboratories and wholesale distributors), said restriction impedes the potential benefits derived from the vertical integration of activities from the medicine chain being passed to the consumer or patient. It is therefore recommended that this be re-evaluated, taking into account the principles of necessity and proportionality, bearing in mind the margin allowed by the EU regulation.

On the other hand, in relation to the set of entities which participate in the chain relating to the sector (laboratories, distribution entities, warehouses when relevant, and pharmacies) it is worth defending with respect to the personnel and technical demands, a regime that rigorously maintains the aforementioned principles, in line with previously defended reports[51].

In this line, Art. 70 establishes that: *"All distribution entities authorised in accordance with article 68 shall have a Pharmacy Technician Director [...]."* The observations compiled in the aforementioned reports remain valid in the sense that, under the principles of efficient economic regulation, the need to maintain this legal reserve of activity for the case of distribution needs to be re-evaluated, above all bearing in mind the differences with regards to laboratories.

III.2.4 Behaviour classed as subject to disciplinary proceedings, arising from non-compliance with the replenishment guarantee

The singularity of the general legal interest protected, people's health, may justify certain obligations being imposed[52] (such as guarantees of replenishment or dispensing) to operators and extraordinary powers of intervention by the Administration are provided for.

There is an additional guarantee that consists of the classification, as a very serious legal infringement, for the distribution-authorisation holder, whether of medicines or sanitary products, of "*the obligation to have sufficient supply within the market, in an adequate and continuous manner" and "guarantee the replenishment of pharmacies ad pharmacy services regarding medicinal products included in homogeneous groups, with low and very low prices*" (Art. 112(2)(c) 25th and 113(2)(c) 14th) and 22nd). Furthermore, and to secure such a guarantee, it is anticipated that "*the Government, in order to secure replenishment of medicines, will be able to adopt special measures for their manufacture, import, distribution and dispensation.* (Art 3(2))

[51] IPN 81/12 DRAFT ACT AMENDING THE ACT ON GUARANTEES AND RATIONAL USE OF MEDICINES, IPN 18/09 OMNIBUS ROYAL DECREES. HEALTHCARE SERVICES AND PHARMACISTS and IPN 85/12 DRAFT ROYAL DECREE ON DISTRIBUTION OF MEDICINES FOR HUMAN USE.

[52] As an example, the replenishing and dispensing guarantee predicts all the operators who function in each link of the medicines' production and distribution chain: those responsible for production (laboratories), distribution (laboratories or distribution entities), sale and dispensing (pharmacies) medicines and sanitary products. Among other articles, they are included in Articles 3, 64, 67, 69, 99 of the DRLD.

The competition authority has been insisting on an alternative version that is more limited and more adapted to Directive 2001/83[53] from which this concept is derived. It advises assessing the due proportionality and reasonableness of both aspects and an improved precision, in order to avoid i) excessive administrative discretion, which could create legal uncertainty among operators; ii) that operators bear excessive and disproportionate burdens.

[53]In the current regulation of the Guarantees Act, it is established (and classified as an infraction) that "the act of distribution should guarantee a quality service, being the main priority and essential function, to replenish pharmacies and legally authorised pharmacy services. [...] "One solution in this line would be to incorporate the concept of replenishing under Article 1(18) of Directive 2001/83, which details wholesalers' public service obligation ""to guarantee permanently an adequate range of medicines to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question". This would allow, on the other hand, extensive interpretations of the violation of such an obligation, which exceed the scope anticipated by the Directive and allow or have the effect of influencing decisions relating to distributors' commercial policy, under the restriction of their business freedom and also generating legal uncertainty.

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