Our proposals in relation to the amendment of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices

Executive summary of the intervention of Faus Moliner in the Public Consultation procedure organized by the Ministry of Health.

At the end of July, the Ministry of Health invited all interested parties to make their proposals regarding the preparation of the draft bill amending the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. The proposals made by Faus Moliner included the following:

General considerations and industry obligations

1. To amend the name of the Law to "Law on Medicinal Products and Medical Devices".

2. To clearly express that the obligation to respect the principle of continuity in the provision of services to the community by those operating in the pharma market must be “within the scope of their responsibilities”.

3. To revise the wording of the Law in order to distinguish between the obligations of the marketing authorization holder and those of manufacturers, so as to avoid vague references to "pharmaceutical laboratories".

4. To clarify the scope of the third-party intervention justifying the inclusion of the so-called "third parties for the distribution of medicinal products" in the relevant authorization either as a laboratory or distribution entity; and to address the situation of marketing authorization holders that use third parties for the distribution of their products in Spain.

Marketing authorizations and industrial manufacturing products

5. To specify that unapproved products that are prescribed to meet individual patients’ special needs under the responsibility of the prescriber cannot be industrially manufactured. This idea should also apply to the individualized preparation of vaccines and allergens for a single patient, which should not be manufactured at industrial level.

6. To clarify that magistral formulas cannot be prepared through industrial processes, but rather on an individual basis after receiving the corresponding prescription; and to specify that it is forbidden to produce magistral formulas to treat pathologies for which there is an authorized medicinal product.

7. To include that the Spanish Medicines Agency shall register *ex officio* the expiration of authorizations affected by sunset clauses so that public information available in the medicine registry corresponds both to reality and to the applicable legal provisions.

Dispensing, home delivery and substitution

8. To set out the requirements for a given medicinal product to be collected by a person acting on behalf of the patient for who the product has been prescribed.

9. To define the term "dispensing" and to cover shipping/home delivery and reception by third parties, considering Judgment no. 4101/2021 of the Supreme Court.

10. To include a set of principles to regulate home delivery of medicinal products, including also prescription only products, with the necessary intervention of pharmacies or pharmacy services.

11. As regards direct sales, to health professionals and/or health centers, of medicinal products that are necessary to exercise their activity, to include that this may be conducted if a pharmacy located in the same basic health area acts as guarantor of the conservation of such products.

12. To clarify the terms "selection" and "substitution" of biological products and to provide that substitution at pharmacies (whether hospital or retail pharmacies) requires the consent of both the prescriber and the patient.

Therapeutic Positioning Reports (IPTs)

13. To identify the legal nature of IPTs in a concise manner and to clearly determine the relationship between the IPT and Pricing & Reimbursement Procedures.

14. To reinforce/establish participation, hearing and appeal rights of all interested parties.

15. To expressly state that the economic assessment of a product should not contradict the results of the efficacy and safety assessment conducted by the competent regulatory agency.

16. To consider the need to review and update the content of the IPT whenever information altering the initial positioning becomes available.

Pricing, public financing and equity

17. To expressly provide that pricing and reimbursement procedures may be concluded through an agreement between the parties rather than just through a unilateral administrative act adopted by the pricing authority.

18. To specify that the maximum time limits to conclude pricing and reimbursement procedures are 180 calendar days if a joint decision is made regarding the reimbursement of the product and its maximum ex-factory price (PVL); and 90 calendar days in all other cases.

19. To update the reimbursement criteria so that orphan and pediatric medicinal products are always reimbursed and to expressly indicate that "innovation" also includes incremental innovation through which new indications, routes of administration or formulas can be added to existing products.

20. To define the competences of the Interministerial Commission on the Pricing of Medicinal Products and Medical Devices in a more concise manner as regards pricing and reimbursement procedures.

21. To include a provision clarifying that, when assessing the reimbursement of an industrially manufactured medicinal product and/or setting its PVL, products use as comparators may only be industrially manufactured ones.

22. To grant greater stability to reimbursement decisions by reintroducing the prohibition to revise or alter prices before one year has elapsed since it was last granted/modified.

23. To mention that information systems supporting prescription should not lead to differences in access conditions to reimbursed products or to the unilateral creation of limits to the prescription, dispensing or reimbursement of medicinal products.

24. In accordance with current article 17(6) of Royal Decree 1718/2010 on medical prescriptions, to expressly consider that products that are not reimbursed can be acquired and used by public hospitals if the prior approval of the committee responsible for therapeutic protocols or equivalent collegiate body of the Autonomous Community is obtained.

25. To specify the cases in which the "notified price" applies and clarify that it does not apply to products that are not reimbursed.

26. To regulate the basic aspects of early access to authorized products that are pending a price and reimbursement resolution:

    a) To recognize the patients' right to receive the treatment prescribed by a physician.

    b) To differentiate the regime applicable to authorized but not commercialized products from the regime applicable to unauthorized products.

    c) To eliminate the need of an individualized authorization provided for in Royal Decree 1015/2009.

Reference prices

27. As regards the Reference Price System, we propose that the new Law allows the Ministry of Health to, exclude medicinal products or groups of medicinal products from the reference price system at any time in order to ensure supply or to protect public health, this being possible *ex officio* or at the request of an interested party.

28. To exclude orphan drugs from the Reference Price System in all cases.

29. To revise the criteria to create reference groups, particularly in the case of pediatric presentations, and to acknowledge the value of incremental innovation.

30. To provide for the establishment of specific Defined Daily Doses (DDD) for presentations of products that are not equipotent with the rest of the presentations included in a given group.

Discounts

31. To avoid limiting discounts to early payment and volume discounts.

32. To clarify that discounts may be offered by marketing authorization holders or their local representatives.

33. To eliminate or otherwise clarify the condition that "the purchase of a given product over that of its competitors is not incentivized".

34. To eliminate the obligation, as included in the current version of the Law, to notify discounts to the Ministry of Health by means of a digitally connected registry system with the Ministry, as this system has never been put into place.

Transparency

35. To indicate that transparency guarantees provided for in the Law are subject to industrial property rights, as well as to the limits set out in Law 19/2013 on transparency, access to public information and good governance.

36. To expressly state that the PVL, price rulings and the reimbursement conditions applicable to a given product are confidential.

37. To include a specific regime for access to public information related to medicines, specifying who may request information and/or the contents and limits of the information that may be provided.

Public procurement of medicinal products

38. To state that the Public Sector Contracts Law should not apply to the acquisition of products which PVL has been set by the Ministry of Health, with the only exception of products included in the reference price system.

39. To set out the rules to divide tenders in lots when such tenders refer to medicinal products with different indications, if some are protected by orphan exclusivity and others not.

40. To clarify what information contained in any resolution awarding a supply contract for a medicinal product must be published.

Advertisement and Information

41. As regards advertisement of medicinal products, to clarify that informative and promotional actions may be conducted as from the date on which the marketing authorizations is granted.

42. To review the graduation of penalties for promotion with a view to differentiate conducts that are clearly and willfully non-compliant and/or endanger public health from those that merely infringe other provisions on advertising of medicines.

43. To clarify the set of competences as regards sanctions, namely to specify whether the authority competent to act against a company is the one where the company has its main place of business in Spain or the one where the advertising activity has been carried out. The law should also consider how to act when the company who advertises the product is not established in Spain, and when the promotional activity is conducted by telematic means at a national level.

44. To remove the obligation to attach "updated information on the price of the product and, when possible, the estimated cost of the treatment" to the SmPC, thus making it clear that the SmPC is a health-related document that should not deal with economic issues.

Penalty Regime

45. To fine-tune the classification of some violations that have generated problems due to inadequate wording. By way of example, the classification of the violation consisting of "ceasing to supply a given medicinal product" should not apply to mere supply problems.

46. To define the contents of the sanctioning procedure.

47. To eliminate the sanctioning regime for cosmetic and personal care products, as the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices does not set any regulatory requirements for this type of products.

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