# Capsulas

## Our contributions to the Draft Law on Medicinal Products and Medical Devices

*Executive summary of Faus Moliner's contributions to the Draft of Law on medicinal products and medical devices*

In early April, the Ministry of Health welcomed contributions of interested parties on the Draft Law on medicinal products and medical devices.

The proposals made by Faus Moliner included the following:

### General features of medicinal products and the relevant economic operators

1. Reinstate the idea, in the definition of "generic medicinal product", that bioequivalence with the reference product must be demonstrated through "appropriate bioavailability studies".

2. Recover the need for generic medicinal products to include the acronym EFG (Generic Pharmaceutical Equivalent).

3. Amend the definition of "strategic medicinal product" to always include critical products listed in the Union List of Critical Medicines.

4. Define "therapeutic gap" to enhance legal certainty in cases where this concept may be relevant (e.g. sanctioning regime, discontinuation of marketing, etc.).

5. Clarify that those operating in the pharmaceutical market must respect the principle of continuity in the provision of service to the community "within the limits of their respective responsibilities".

6. Empower the Spanish Medicines Agency (AEMPS) to intervene ex officio to protect the regulatory period of marketing protection for medicinal products.

### Dispensing and home delivery

7. Enable health care centres that do not have their own pharmacy service to purchase (and invoice for) medicinal products, provided that a pharmacy located within their basic health area acts as guarantor for the proper storage of such products.

8. Define "dispensing" to distinguish patient counselling from the physical delivery of medicinal products, in order to provide legal clarity for innovative models for dispensing and delivery of medicinal products.

### Conflicts of interest

9. Allow that, in exceptional cases, professionals affected by a potential conflict of interest but possessing indispensable specialized knowledge may participate with voice but without vote in the various bodies or committees.

### Transparency

10. Limit the transparency guarantees provided for in the Law to safeguard intellectual and industrial property rights and business secrets.

11. Reinforce the confidentiality of the information provided by health technology developers, the ex-factory price (PVL), the reimbursement conditions and the unit price of medicinal



products (both in contracts subject to the Law on Public Sector Contracts [LCSP] and in others).

12. Remove the obligation to share information on cost structures and public funds received for the development and research of medicinal product.

## Non-industrially manufactured medicinal products

13. Clarify that magistral formulae and officinal preparations cannot be prepared by industrial processes, but on a case-by-case basis upon receipt of the corresponding prescription.

14. Specify that the preparation, prescription, dispensing, and use of magistral formulas or officinal preparations is not possible if the patient can be treated with an authorised industrially manufactured medicinal product that is effectively marketed within the European Union.

15. Expressly provide that the non-industrial preparation of advanced therapy medicinal products shall be limited to cases where there is no industrially manufactured medicinal product authorised for the same indication, and shall always comply with the specific conditions and general principles of quality and safety established in EU legislation.

16. Provide that authorisation for the use of non-industrially manufactured advanced therapy medicinal products shall cease to be valid when an industrially manufactured medicinal product is authorised for the same indication.

17. Increase penalties for infringements of requirements relating to the prescription or preparation of magistral formulae, officinal preparations, standardised preparations or autovaccines.

## Freedom of enterprise

18. Establish that the only obligation of the marketing authorisation holder when intending to temporarily suspend or permanently discontinue the marketing of a medicinal product is to notify the competent authority within a reasonable advance notice period.

19. Specify that the marketing of a medicinal product on Spanish territory will only require "having submitted" the offer to the National Health System, allowing the product to be sold in the private market before the pricing and reimbursement procedure is completed.

20. Recognise the right of companies to request and obtain the delisting (removal from reimbursement) of their products.

21. Remove the provision allowing AEMPS to require the effective marketing of medicinal products in certain cases.

22. Strengthen the freedom of companies to decide freely on their distribution strategies, while maintaining the voluntary use of wholesalers under the conditions each company deems appropriate.

23. Clarify that the obligation to keep the market supplied begins as of the launch date not from the date of granting its marketing authorization.

24. Extend the effects of the sunset clause to parallel import authorisations approved by AEMPS.

25. Refine the classification of infringements which have caused problems due to deficiencies and flaws in their drafting. For example, the classification of "cessation of supply of a medicinal product by the marketing authorization holder" as an infringement should not apply to any supply issue.

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## Discount

26. Clarify that discounts offered by marketing authorization holders or their local representatives to pharmacies are permitted, and that such discounts should not be limited solely to "early payment" or "volume-based" discounts.

27. Remove or clarify the condition that "the purchase of a product must not be incentivised over its competitors when giving a discount".

28. Eliminate the current legal obligation to notify discounts to the Ministry of Health through an electronically interconnected registry, as such interconnection has never been established.

## Health Technology Assessment

29. Provide for a homogeneous health technology assessment system across the national territory to avoid duplication and re-evaluations at regional levels.

30. Provide that for technologies with an available joint clinical assessment, the national evaluation will be limited to aspects not covered by the joint assessment at the national level.

31. Avoid evaluation reports that are binding for the Ministry of Health.

32. Explicitly state that evaluation reports constitute administrative acts that conclude autonomous administrative procedures; and clarify that these acts are separate and distinct from the price and reimbursement procedure and are neither mandatory nor binding in that procedure.

## Access and price and reimbursement

33. Establish that the price and reimbursement procedure for new medicinal products or new indications should be initiated at the request of a party, and not ex officio.

34. Eliminate the involvement of the Government Delegated Commission for Economic Affairs in multiple stages of the price and reimbursement procedure.

35. Specify that the public funding of new medicinal products does not always result in increased costs for the National Health System (NHS), as it may also generate savings.

36. Clarify that, when assessing the inclusion of an industrially manufactured medicinal product in the pharmaceutical provision and/or setting its price, comparisons with other therapeutic alternatives must be made only with authorised industrially manufactured products that are comparable in terms of efficacy and safety.

37. Add orphan, paediatric or strategic status as new criteria for the inclusion of medicinal products in the pharmaceutical provision of the NHS.

38. Restore the provision in the current law that the decision to reimburse new medicinal products shall consider the innovation component for indisputable therapeutic advances that may modify or improve the course of the disease, its prognosis or therapeutic outcome.

39. Provide for the possibility for price and reimbursement procedures to be concluded through an agreement rather than through an administrative ruling.

40. State that any special reserves that may be exceptionally established for one or several Autonomous Regions must be reviewed annually by the Interterritorial Council of the NHS or, at any time, at the request of the company marketing the product.

41. Set maximum deadlines for price and reimbursement procedures in line with those provided for in Directive 89/105/EEC.

42. Provide that once the additional information requested by the Ministry has been submitted, the maximum time limit for issuing a decision shall resume, rather than restart.

43. Provide that, when evaluation reports are delayed beyond the regulatory established timeframe for reasons noy attributable to the developer, the developer may request the continuation of the price and reimbursement procedure, and the absence of the evaluation and/or positioning reports shall not be used to the developer's detriment.

44. Provide that orphan, paediatric and those medicinal products selected under the EMA's PRIME scheme shall always be subject to the accelerated price and reimbursement procedure.

45. Eliminate the obligation to supply units intended for compassionate use free of charge.

46. Provide that the cost equalisation rule (obligation to compensate for the difference between the price charged for the supply of the medicinal product in special situations and the reimbursement price (PVL):

    (a) Shall apply only when the medicinal product obtains a favourable price and reimbursement decision and, in case of partial funding, only for the funded indications (provided that separation by indication is feasible); and

    (b) Shall be limited to units supplied during the six months prior to the price and reimbursement resolution.

47. Eliminate the notified price system and provide that non-reimbursed medicinal products, as well as reimbursed products intended for the private market, may be marketed at free price.

48. Enhance the stability of price and reimbursement decisions by reintroducing the rule that prevents any downward revision or modification of the price within one year from its initial setting or latest adjustment.

## Prescription, substitution, dispensing and homogeneous groupings

49. Define the limits applicable to the selection and substitution of medicinal products across all levels of care (pharmacy and hospital pharmacy).

50. Strengthen the right to freedom of prescription for healthcare professionals and the right of patients to receive the prescribed medicinal product.

51. Establish that prescription by brand name shall be permitted when the healthcare professional deems it necessary for medical reasons.

52. Specify that information systems designed to support prescribing shall not create differences in access conditions to publicly funded medicinal products, nor result in the unilateral establishment of specific prescribing, dispensing, or reimbursement restrictions. Such systems shall not be binding for prescribers.

53. Establish that, as a general rule, the pharmacist shall dispense the prescribed medicinal product.

54. Prohibit substitution of biological medicines, inhaled products for the respiratory system, and any other medicinal product designated by the AEMPS as "non-substitutable."

55. Remove the selected price system.

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## Homogeneous groupings and reference price system

56. Establish that homogeneous groups shall only include identical and substitutable presentations of medicinal products.

57. Provide that presentations of orphan medicinal products with protected indications may not be included in homogeneous groupings.

58. Provide that only medicinal product presentations that have obtained a price and reimbursement decision and are marketed may be included in reference groups.

59. Provide that different active substances may only be included in the same reference group if a generic or biosimilar exists for each of them.

60. State that the potential use of a paediatric medicinal product in the adult population shall not preclude the formation of separate reference groups.

61. Exclude from reference group formation the following:

    (a) Strategic medicinal products;

    (b) Products for which there only exists the original one, any licences and/or parallel imports;

    (c) Medicinal products marketed by the same company;

62. Broaden the circumstances under which measures may be adopted to exclude, freeze, or increase the price of medicinal products subject to the reference price system.

63. Establish mechanisms to prevent that medicinal products with marginal market shares or lacking the capacity to ensure continuous supply disrupt the dynamics of homogeneous groupings and/or the reference price system.

## Information and promotion of medicinal products

64. Reinstate the possibility of producing and distributing free samples of medicinal products.

65. State that the promotion of medicinal products is permissible once its marketing authorisation has been granted.

66. Prohibit the promotion of standardised preparations and non-industrially manufactured advanced therapy medicinal products.

67. Remove the requirement that any information on medicinal products must comply with the authorised technical and scientific information, since this obligation should only apply to the promotion of medicinal products.

68. Eliminate the obligation to include in promotional materials the information produced by the NHS regarding the health technology assessment and the price of product. The price may be replaced with the obligation to inform about the reimbursement status of the medicinal product or medical device.

69. Explicitly recognise the possibility of offering hospitality to healthcare professionals at both promotional and professional/scientific meetings.

70. Clarify the sanctioning regime applicable to advertising of medicinal products directed at the public and at healthcare professionals, especially eliminating the idea that advertising approved products before their launch is an infringement.

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71. Remove the obligation to include the price and estimated treatment cost in the Summary of Product Characteristics (SmPC).

## Public procurement of medicinal products

72. Exclude from the scope of application of the LCSP the acquisition of medicinal products protected by exclusive rights and whose PVL has been set by the Administration.

73. Provide that price may not have a weighting of more than 50% in the award criteria.

74. Provide that for the procurement of medicinal products subject to the LCSP, the tender price shall not be lower than the lowest reimbursement price among the presentations eligible to participate in the tender.

75. Provide for a revision of contract prices at the end of each year to adjust for percentage variations in the cost of energy, transportation, and raw materials during the preceding year.

## Contribution based on sales volume (DA 6)

76. Exclude orphan medicinal products, those "that may be acquired on" (instead of those "that are acquired on") a competitive and concurring basis, as well as those medicinal products whose price and reimbursement decision incorporates a risk-sharing agreement based on financial results.

77. Provide for a correction period in case the Ministry detects an error in the sales data provided.

78. Evaluate the incorporation of an alternative system of reductions to the one currently envisaged for those companies marketing orphan medicinal products that are not eligible for the Profarma Plan.

79. Clarify the entry into force of DA6 in order to avoid any retroactive effect.

## Other proposals

80. Provide that logistics service providers with which marketing authorisation holders enter into private agreements for the distribution of their medicinal products in Spain shall not be subject to the public service obligations applicable to full-range wholesalers.

81. Provide that it shall be the Ministry of Health, and not the Government, the one who may adopt measures related to the economic and fiscal regime of orphan and strategic medicinal products in cases of supply issues or shortages.

82. Promote the use of electronic leaflets.

83. Strengthen the requirements for parallel import of medicinal products into Spain in line with the latest European case law.

84. Facilitate collaboration agreements between industry and the NHS for the design, implementation and execution of projects that benefit the NHS and public health.

85. Eliminate or revise the deductions provided for in Royal Decree Law 8/2010.

86. Limit the additional requirements that the Autonomous Regions may impose for the conduct of certain observational studies.

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