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Access to new medicinal products: analysis and proposals

Executive summary of Lluis Alcover's presentation at the Pharmaceutical Law Course organized by Fundación CEFI.

The Pharmaceutical Law Course organized by Fundación CEFI was held in Madrid on September 27th and 28th. Among the ideas that were discussed, I would like to highlight the following:

First, access to innovation in Spain must certainly improve. In many cases, innovation does not reach patients, or does so under restricted conditions, late or unequally across regions. This situation has a tremendous negative impact on the constitutionally protected rights of patients, on the competitiveness of the pharmaceutical industry and, in general, on all relevant stakeholders in the sector.

Second, there is an urgent need for action and the time is ripe for it. Profound reforms of the current legal framework are underway, which offers an undeniable opportunity to lay the foundations for a new model of access to information. In Europe, pharmaceutical regulations are undergoing a general revision. Changes to the orphan and pediatric incentive system are to be expected shortly. The EU Regulation on health technology assessment came into force in January and the structure necessary for its implementation is being constructed. In Spain, the reform of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices is underway. Other reforms have been pending for some time, such as that of the Royal Decree on Reference Prices or the Royal Decree on Access to Special Situations.

Third, it would be advisable to review the access regime for authorized and non-marketed medicinal products, in order to distinguish it from the access regime applicable to unauthorized medicinal products. These first type of medicinal products have one key difference: the safety, efficacy, quality and benefit/risk ratio have been endorsed by a regulatory agency; which is not the case of the second. Both cases are currently regulated by Royal Decree 1015/2009 and require authorization from the Spanish Agency for Medicinal Products and Medical Devices. In the case of authorized, non-marketed medicinal products, the authorization regime could be replaced by a responsible declaration by the holder. This system would be more well-aligned with the precautionary principle and the principle of proportionality, which should always orientate the action of the Public Administration. It would be also more protective of patients' rights.

Fourth, the regulation of therapeutic positioning reports (TPRs) should be improved. The new regime could clarify the nature of TPRs, their position in the context of price and funding procedures, and the deadlines for completion. In addition, the new regime should regulate the right of access to their complete dossier, especially the contributions of experts and autonomous communities. Another interesting issue for revision is the relationship between the therapeutic and the economic evaluation included in the TPRs. While economic assessment is important and constitutes a useful tool to promote sustainability and prioritizing cost-effective products, its conclusions should be clearly differentiated from therapeutic-related observations. If a medicinal product has great therapeutic value, but is unaffordable for the payer, this should be

clearly stated, as the economic analysis should not undermine the information regarding the therapeutic value of the relevant product. Only by clearly differentiating both aspects will we be able to fine-tune the search for appropriate solutions that grant patients the access to innovation, while respecting the aspirations of system sustainability.

Fifth, time is key when it comes to access to information. It should be stressed that it is crucial that the Public Administration respects the deadlines set out in Directive 89/105/EEC. Other formulas should be considered to make better use of the period that elapses between the positive opinion of the CHMP and the formal initiation of the price and refund procedure. Pre-submission activities conducted in the context of the EMA are a good example to follow.

Sixth, an express resolution regarding non-inclusion in the pharmaceutical provision of the NHS cannot be the end of the road. Regional health services and hospitals should be able to acquire non-financed medicinal products upon agreement of the commission responsible for therapeutic protocols or the equivalent collegiate body in each autonomous community. The Report "of those that are expressly not included" signed by the General Director on 11 April 2019 should not apply. From a legal perspective, the conclusion drawn from this Report is clear: it is merely informative and does not affect or bind regional administrations or healthcare organizations. Moreover, its conclusions are contrary to the provisions of Royal Decree 1718/2020 on medical prescription as well as to patients' constitutional rights.

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