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Medicinal products in the European Union in 2020

With regard to the Resolution of the European Parliament, of 2 March 2017, and the Conclusions of the European Council of 17 June 2016

Background

The Resolution approved by the European Parliament on 2 March 2017 concerning the EU options to improve access to medicines is a politically-charged document, produced as a result of the Cabezón Report promoted by the Spanish Socialist Member of the European Parliament, Soledad Cabezón. Therefore, it is not surprising that many regard it as just another resolution that will be difficult to transpose into Community-wide legislation. However, having read the Resolution, if we go back and read the Council's conclusions approved in June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States, we can observe a number of parallels that should be taken into account when reflecting on how the legal, administrative and economic context of medicinal products may develop in Europe in the coming years.

The most likely development of the "Bolar" exemption

The European Parliament, through its resolution, calls on the Commission to "analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition".

The Council, in turn, had invited the Commission to produce, with the involvement of Member States, a summary of legislative instruments in force in the EU and other related incentives that seek to facilitate investment in the development of medicinal products and the marketing authorisation for medicinal products in the EU, in addition to an analysis of the effects of these instruments and incentives, highlighting the need to pay particular attention to the purpose of supplementary protection certificates, the use of the "Bolar" exemption, the data exclusivity for medicinal products and the market exclusivity of orphan medicinal products.

Reading the two documents together, it is possible to predict changes in the environment in which the manufacturers of active principles in Europe will operate in the short to medium term. The Parliament recalls that, in the context of a European Union affected by offshoring, the pharmaceutical industry is an important industrial pillar and a catalyst for job creation; furthermore, it calls for the supplementary protection certificate (SPC) required from manufacturers to be waived thus facilitating the production of generic and biosimilar medicinal products in Europe in order to export them to countries with no SPC. Eventually this would inevitably mean allowing stockpiling of generic medicinal products in order to facilitate their industrial production in the EU before the SPC expires.

Greater economic transparency and faster access

The European Parliament calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible for the purpose of standardising transparent criteria in order to assess the added therapeutic value of medicinal products compared to the best available alternative. It also calls on the Council to reinforce cooperation between Member States in terms of pricing procedures with a view to making it possible to exchange information and avoid unnecessary administrative requirements and delays.

The Council, in turn, invites Member States to examine the possibility of continuing to develop voluntary collaboration in the field of pricing and reimbursement of medicinal products, in addition to exploring potential areas in which said voluntary collaboration can contribute to greater affordability and access to medicinal products, even suggesting a "pro-active exchange of information between Member States" in addition to the countries that wish to join forces in this regard "exploring possible strategies on voluntary joint price negotiations". The Council also invites countries to further explore closer voluntary collaboration on health technology assessments.

In short, progress in this regard is also expected. In the European market, amounts paid by health systems, especially in the case of more expensive medicinal products, will be transparent sooner rather than later, which will lead to working on shared criteria to instruct prices.

Greater vigilance in terms of the protection of competition

Both the Council and the Parliament show determination in calling on the Commission to intensify the investigation and prosecution of possible anti-competitive behaviour on the part of pharmaceutical companies operating in the EU. The industry has been subject to pressure in this area for a number of years, which will not only not decrease, but rather increase, and the expectation is that the focus will be on the prosecution of those abusing their position of power, setting excessive prices for their products. The industry's capacity to negotiate with payers will be affected by the threat of applying measures to protect competition.

Access to medicinal products and the right to health

On the other hand, the right to health will continue to serve as a guiding principle that must steer the actions of public powers; however, it is difficult to imagine it being upgraded to the status of a fundamental right. States shall retain their sovereignty in terms of deciding which health protection measures require public coverage, and to what extent, at any given time. In this regard, the efforts of the European Parliament will probably be ignored; however, we are likely to see progress as regards the rights of patients in cross-border healthcare within the European Union and measures to ensure the reimbursement of cross-border healthcare costs, including the reimbursement of medicinal products.