Purchase of expensive drugs from outside the EU: did AIFA open the Pandora's box?

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By Ministerial Circular of 23 March 2017, AIFA clarified the conditions under which unauthorized medicinal products may be purchased abroad further to the procedure laid down by the Ministerial Decree of 11 February 1997.

1. Importation of medicinal products under exceptional circumstances and at expenses of the patients

The Ministerial Decree of 11 February 1997 provides for the procedure that must be followed for the importation of medicinal products that are regularly authorised abroad but not in Italy, shipped in Italy upon the request of the treating physician. The medicinal product, although requested by the physician, is paid by the patient. We will see how this circumstance matters in the case at hand. The Ministerial Decree of 11 February 1997 does not provide for an exception to the general rule that medicinal products can be put on the Italian market only upon authorisation. Indeed, according to Article 2 (1-bis) of the Ministerial Decree of 11 February 1997, the importation must be "justified on objective and exceptional grounds". The procedure is intended to monitor the importation, which is subject to the clearance from the competent health unit of Italian customs (USMAF). If the importation of a medicinal product appears to be "excessive" in respect of the trend observed in the past, the USMAF shall request additional clarifications as to the "medical and epidemiological rationale" that justifies the importation. Such regulation has been confirmed by Article 158 (6) of the Legislative Decree No 219 of 24 April 2006 (Italian Pharma Code) and may be regarded as Italian law. The objective and exceptional grounds boils down to the lack of a valid and approved therapeutic alternative in Italy and the certified indispensability of the medicinal product authorised abroad to treat a named patient.

2. The lack of therapeutic alternatives

While the Ministerial Circular of 23 March 2017 is intended to provide an interpretation of the law, things might indeed materially change. According to AIFA the lack of a valid therapeutic alternative "may be acknowledged also when:

a) Regardless that a similar regularly approved medicinal product is available on the market, the medicinal product the importation of which is sought presents a different dosage, route of administration, excipients or formulation of active ingredients.

b) The patient does not have access to the medicinal product available in Italy, as he/she does not meet the eligibility criteria for the supply of the medicinal product at expenses of the National Health System, or for it being overly expensive".

The first exception relies on the assumption that any difference in the dosage, route of administration, excipients or active compounds always amounts to a distinct clinical benefit, whilst this may be not always the case. Hence, whether an unmet clinical need may justify the importation, it should be evaluated on a case by case basis. The second exception may be actually of concern since it appears based on exclusive economic grounds. It may be worth noting that the National Health Service was established in 1978 to the purpose of providing the general public with full healthcare coverage, which is usually free of charge in case of serious and life threatening diseases. The lack of eligibility for the supply free of charge of a medicinal product should therefore be decided on exclusive clinical grounds (i.e. the medicinal product is not indispensable). To be sure, budgetary limits must be taken into account. However, it does not appear an answer, allowing the patients to buy at their expenses in low cost jurisdictions generic copies of innovative medicinal products.

3. Comment

While the exception should apply on a named-patient basis, we see the risk that expensive medicinal products may not be approved in Italy, the prices undergo to further deflationary pressure, the approval delayed, or the products may not be purchased by hospitals under budgetary constraints, relying on the assumption that patients may eventually buy them in low cost jurisdictions. Rumour has it that the provision has been introduced to the benefit of patients, who are not eligible for the treatment with the new and expensive anti-HCV medicinal products and would thus be allowed to purchase such products in low cost jurisdictions. We should be aware that this pattern may apply to several expensive medicinal products. While this may superficially appear to benefit the patients, actually it may open the door to large scale distribution of non-approved and low cost medicinal products in Italy. As we learned from the experience on counterfeited goods, single purchases may sum up and eventually lead to a parallel commercialisation of unauthorised medicinal products. In addition, when it comes to rare or relatively rare diseases, the single purchases matter.

We note that a similar regulation was introduced by amending the Law No 648 of 23 December 1998, laying down provisions on early access. In that case, the early access of was extended to the supply of unauthorised medicinal products (or their off-label use) also in the case there is an approved therapeutic alternative but the off-label use is justified on economic grounds. The Italian Supreme Administrative Court has submitted a request for preliminary ruling to the European Court of Justice, on the ground that such provision may be inconsistent with EU law.

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