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AIFA officially to apply the “reimbursement price linkage” provisions

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In an earlier post, I reported the news that a new piece of legislation (the so called “Balduzzi Decree”, Law No. 189/12 of 8 November 2012 confirming Law Decree 158/12 of 13 September 2012 – a consolidated version of the Decree is available here) introduced a rule which some have already labelled as *“reimbursement price linkage”*. In substance, according to Article 11 of the Balduzzi Decree, the Italian regulatory Authority will refrain from granting a reimbursable price to approved generic drugs when the reference product is still covered by a patent or SPC.

Last week, AIFA officially confirmed that it will apply such a rule, by issuing a communication to all pharmaceutical companies that is currently available via the AIFA website. In this communication, AIFA explained the guidelines it is going to follow to implement the overall new set of rules introduced by the Balduzzi Decree, including the *“reimbursement price linkage”* provisions.

The Balduzzi Decree provisions in fact reorganized the procedure of marketing approval and price negotiation quite a bit. Historically, the Italian rules aimed at the grant of a Marketing Authorisation and those aimed at the determination of a reimbursement price have always been merged together. In particular, a generic could start selling its product only once the Marketing Authorisation had been published in the Official Journal of the Italian Republic (OJIR) and no such publication was made before the determination of the reimbursement price as well. In fact, the document published in the OJIR used to contain both (i) the announcement that the permit to market had been granted and (ii) the relevant reimbursement price. The generic could start selling as of the day following such a publication in the OJIR. Based on the rules of the Balduzzi Decree, the stage of Marketing Authorisation and that of price determination have somehow been split. In particular, the price classification “C-nn” (i.e. “C – non negotiated”) has been added to the already existing price classifications (“A” for reimbursed products; “C” for non reimbursed products; “H” for hospital only reimbursed products). In the new framework, if the Marketing Authorisation procedure has been completed, the approval may be published in the OJIR even before the determination of the price, if no request of price negotiation has yet been filed by the relevant company, or else if the price negotiation procedure has not been completed when the time has come, according to the more stringent calendar now in place at AIFA, to publish the Marketing Authorization. In this case,

the product will be classified as "C-nn", which classification will be changed if and when a proper price negotiation procedure will be completed.

As regards the *"reimbursement price linkage"* provisions, in particular, the AIFA guidelines state what follows: *"Article 11, paragraph 1, last sentence, of the Decree does not prevent the filing of an application to obtain that the product be classified as reimbursed even before the expiry of the patent rights, nor the commencement of the possible procedure for the negotiation of the price. In case the procedure for the determination of the price is completed before the expiry of the patent rights, the order concerning the classification of the price of the medicinal product shall indicate that the product has been included in class "C(nn)" until the expiry of the patent, and shall also indicate the prospective classification of the product as reimbursed by the National Health Service and the relevant price, which classification will enter into force as of the date of expiry of the patent or the supplementary protection certificate as indicated by the Ministry of Economic Development".*

I have to admit, I still have to see one case in which these guidelines have in fact been applied, i.e. in which a class "C-nn" classification was granted due to existing patent / SPC rights. At the same time, there is no clear indication on whether these guidelines are already in force and whether they will apply to all cases or to newly filed Marketing Authorisation applications only. We'll see…

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