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NO REIMBURSABLE PRICE FOR GENERICS LAUNCHING AT RISK IN ITALY

Daniela Ampollini (Trevisan & Cuonzo) · Friday, November 30th, 2012

Recently approved "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) seems to have changed quite a lot in terms of the protection of pharmaceutical patents in Italy, making it totally Inconvenient for generics to launch at risk.

The relevant provision is Article 11.1. It is in fact quite a complex provision, which literally states that by June 2013, the so called *"Prontuario Farmaceutico Nazionale"* (in substance, the catalogue listing all medicinal products approved for sale in Italy and reimbursed by the National Health Service) will be subject to an extraordinary revision in order to eliminate so said *"obsolete medicines"*. Furthermore, when this revision will occur and, thereafter, on the occasion of the ordinary revisions of the catalogue, all products having a reimbursable price (i.e. having a so called *"A price classification"*) that are equivalent to products for which patent protection has not expired yet, will lose their reimbursable price (i.e. their so called *"A price classification"* will be transformed into a so called *"C price classification"*). Although this is not expressly stated by the provision, it should go without saying that, if already approved *"A price classification"* generics shall soon lose their reimbursable price, no new generics should from now on be approved with an *"A price classification"* if patent rights are still in place. It remains unclear from which source the Italian Regulatory Authority (AIFA) should derive the information of the existence of patent rights. For the time being, no specific notification system is in place, so it seems feasible to assume that AIFA will have to base on the mere knowledge of the existence of the patent rights, regardless of the source.

As many will recall, Italy has recently been accused of patent linkage by the European Commission and, therefore, to be in breach of EU law (see my earlier post here). This eventually lead the Italian government to repeal old Article 68 (1bis) of the Italian IP Code, according to which abridged MA applications for generics could not be submitted to the Italian Regulatory Authority earlier than 1 year in advance of the expiry of the patent protection on the active substance. But is this Article 11 of the Balduzzi Decree truly a new patent linkage, as some (in the generic industry, of course) already said? My first comment is that, in fact, the existence of the patent does not preclude the grant of the MA and, as far as I know (comments would be

extremely welcome on this point) EU law does not directly interfere with the reimbursement regimes of the Member States. At least, the Commission would find it harder than in the past to readily accuse Italy of having breached EU law on this point. In any event, I find the paragraph of the Government's explanatory note of the Balduzzi Decree on Article 11.1 worth reading: *"The provision is intended at ensuring the respect by the National Health Service of the effective duration of the patent protection of innovative drugs, also in case generics are launched before the expiry of the patent"* . As too often in Italian law, the language is too ambiguous. One may read this paragraph as meaning that the Italian Government is preoccupied of not being found liable of infringing the patent for the fact of reimbursing the price of an infringing product. Interesting point…

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