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New policy for the Italian drugs agency on the disclosure of information on Gx applications

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In a recent post of mine I have reported that by decision of 29 July 2010, the Italian Supreme Administrative Court (Consiglio di Stato) had tackled the issue of whether the Italian drugs regulatory authority (Agenzia Italiana del Farmaco – AIFA) should or should not consider the existence of a patent when adopting decisions relating to the marketing authorisations of generics. The conclusion was that it should not. Well, AIFA has subsequently released a circular letter to inform how it will proceed in case Originators raise that generic copies of drugs which they consider to still be protected by patent rights should not be authorised or included in the substitution list, or even in case originators file a request with AIFA for the disclosure of certain information relating to the MA procedures of generics copies of their branded products. The circular letter was released on 16 September 2010 and, in summary, it states that starting from October 2010, AIFA will issue a monthly publication of the active substances for which an administrative procedure leading to MA grant has been commenced. Said list will refer to applications filed pursuant to Articles 10 (1) and 10 (3) of Directive 2001/83/EC via national, centralized, decentralized or mutual recognition procedures. According to AIFA, the issue of said list would allow AIFA to comply with the requirement of communication of commencement of the administrative procedure to the interested parties pursuant to Articles 7 and 8 of Law No. 241/90, i.e. the Italian Freedom of Information Act. Should a motivated request for additional information come forward – continues AIFA – this will be provided only after the completion of the authorization procedure, i.e. after the generics in question have already been authorized and the relevant price (in case of reimbursable drugs) negotiated. No further requests can be forwarded to AIFA. In particular, AIFA expressly states in the circular letter that it will not refrain from, stay or delay the registration procedures and/or the inclusion of authorized generics in the substitution list should Originators raise the existence of patent rights as, according to AIFA, these are issue for the ordinary courts only.

In practice, what currently happens is that, on a monthly basis, AIFA publishes on its website a list of active substances for which abridged procedures are pending. The list is “anonymous”, i.e. the names of the companies holding the relevant MA applications are not included. Furthermore, comparing the two lists that were published to date (the October 2010 and the November 2010 lists), it seems that these lists only contain “new” applications, i.e. each month the list refers to the MA applications that have been filed in the preceding month. “Older” – but still pending – applications are not covered. Furthermore, recent practice has shown that AIFA is rather reluctant in providing any relevant additional information in case of motivated requests submitted by Originators, even when the registration procedures have been completed already. One may

therefore certainly argue that, in this way, AIFA is not meeting the requirements of the Italian Freedom of Information Act. I would find it very interesting to hear how the national regulatory authorities of other countries are behaving in this respect and what policies they have adopted in terms of disclosure of information on pending or granted MA applications for generics.

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