

THE LEGISLATION ON PUBLIC PHARMACEUTICAL EXPENDITURE AND THE COMPETITION

THE ITALIAN EXAMPLE

At the end of a broad investigation on the pharmaceutical industry carried on in 1997 [\[1\]](#), the Italian Antitrust Authority pointed out that some legal hurdles, lacking a justification based on needs of a general interest, prevented a free development of the competition in the pharmaceutical market.

Those hurdles were:

a) the rule of the “national one—price system” [\[2\]](#) applied to not reimbursed drugs and the consequent prevention for the pharmacists to practice discounts on the price affixed on the label by the manufacturer [\[3\]](#): this would avoid the transfer to consumers of the benefits, if any, originated by the competition at distribution level; pharmacists –who have the monopoly of the sale of drugs, included OTC- are not encouraged seek better purchase conditions and to select more efficient distributors, and, when they succeed in finding better prices, for instance purchasing directly from manufacturers, consumers are not permitted to share the margin;

b) the obligation for the wholesalers to keep in stock at least 90% of the drugs on the market [\[4\]](#); this interpretation of the EEC directive, providing only for a stock sufficient to respond to the needs of the territory served by the wholesalers, goes beyond the principles of the health protection which inspired the European rule [\[5\]](#); wholesalers are bound to purchase practically all the drugs on the market without triggering any competition mechanism;

c) the reimbursement system in force at that time, based on the principle that among drugs containing the same active ingredient and having the same dosage form, only those having the lowest price are reimbursed [\[6\]](#); this, according to the Authority, discriminates unnecessarily the drugs with a higher price, while a reference price system would encourage competition at all levels of price;

d) a little development of the generic market, due to (i) the impossibility for the pharmacist to substitute generics to equivalent branded drugs, (ii) the duration of SCP, (iii) the impossibility to file an application for registration pending the patent or SCP protection [\[7\]](#).

Six years later it may be of interest to see whether the legislation has addressed or not such issues and if the development of the rules has been in the direction of fostering competition or, on

the contrary, the policy of the legislator has increased its bureaucratic and planned economy approach.

a) Nothing has changed with respect to the public price of not reimbursed drugs, including OTC products. In the budget laws for 2000 and 2001 there is a generic indications of «competitive mechanisms» to be introduced for OTC products [\[8\]](#), but they remained without a follow up; the law, dating back to 1934 [\[9\]](#), establishing, for all kinds of drugs that the pharmacist is not allowed to change the public price showed by the label is still there; moreover, the price of all not reimbursed drugs, notwithstanding they are free, are subject to a sort of surveillance, as the variation of them must be notified, before their entering into force to the CIPE (Interministerial Committee for Economical Planning).

The private pharmaceutical expenditure is about 33,5% of the total pharmaceutical expenditure [\[10\]](#).

b) The obligation of minimum stock for wholesalers has not changed; the system of fixed margins for reimbursed drugs is still in force [\[11\]](#). On the other hand, the distribution system has changed as the public healthcare local units are now authorised to purchase drugs directly from manufacturers not only for internal consumption in the hospitals but also for territorial distribution to patients [\[12\]](#). The units de facto avail themselves of the 50% discount originally established by a law of 1974 for the hospitals [\[13\]](#); it has to be added that public healthcare units purchase through public tenders and the system of public procurement has broadly changed insofar the regions and a recently constituted public central agency are authorised to organise public tenders on a regional or national basis (and every single hospital is forbidden to tender or purchase autonomously unless an economic advantage is proven) [\[14\]](#).

c) The reimbursement system is now based again on a positive list including drugs at a price established on the so called defined daily dose basis; the reference price system, clearly introduced in 2001 with a limited substitution system is still in force, but in practice it is overcome by the criteria of inclusion in the positive list; regions have a broad power to establish its own rules in terms of co-payment, distribution systems an even price, provided they ensure the so called essential levels of healthcare, established on a national basis.

d) The patent protection of pharmaceutical products was introduced in Italy in 1978 by a judgement of the Constitutional Court [\[15\]](#), which declared unconstitutional the prohibition established by the patent law since 1855.

Not later than 13 years after, the Parliament passed one of the widest complementary patent protection laws [\[16\]](#), as it permits to recover all the gap between the patent application and the first marketing authorisation, extending the effective duration of the patent for up to 18 years.

The Italian system applies to all the supplementary certificates issued before 3rd January 1993, date of entering into force of the EEC Regulation n. 1768/1992.

With the aim to encourage the generic market, art. 3 of the law n. 63/2002 provides that, effective from January 1st 2004, the duration of the Italian SCP shall be reduced by six months every year up to equal the European discipline.

The Italian Patent Office has notified to the patent holders said reduction and many companies have challenged this notification before the administrative tribunal asking for the referral to the Constitutional Court. The decision is expected in next weeks.

The law also provides the possibility to file an application for marketing authorisation during the year preceding the expiration of SCP.

The law poses some problem of interpretation.

The reduction of the SCP duration is established until the complete adjustment to the European discipline.

The Italian and the European disciplines differ in many aspects.

The duration of the Italian SCP is equal to the entire time passed between the date of the patent application and the date of the first marketing authorisation (i.e. in Italy) with a maximum of 18 years from the original date of expiry of the patent; the duration of the European SCP is equal to the time passed between the date of the patent application and the date of the first authorisation in EEC country less five years with a maximum of five years from the original date of expiry of the patent. Then, the equalisation leads only to the reduction to five years of the extension as previously calculated or does it imply a recalculation according to the European regulation?

In my opinion this second interpretation is more correct as the reference is to the “discipline” as a whole, but it may be presumed that the some controversies will arise.

The same law establishes that third parties wishing to manufacture in Italy active ingredients covered by Italian SCP for the purpose of export in countries where the patent protection (including SCP) has expired, and in compliance with the laws of said countries, may start with the SCP holders, under the direction of the Ministry for industrial activities, a procedure for the grant of voluntary royalty based licenses.

The procedure has been approved by a decree of October 2002 [\[17\]](#). First of all this decree extends the scope of the law (and this is, according to the principles of the Italian administrative law, questionable), as it provides that the export may be referred also to the countries where the patent protection “does not exist” (the law provides only for the “expiry” of a patent protection) and, what is more important, where the export of the active ingredient does not constitute an infringement of the of the patent according to the law of the destination country; this last provision in practice permits to start the procedure also in cases where a patent protection still

exists also in the country of destination and open the way to discussions about the area of protection of such still existing patent.

According to the procedure in a first phase the Ministry offices are only a sort of mediator between the parties. If they reach an agreement within 90 days of the starting of the procedure on a basis of a fairly limited royalty, then the agreement enters into force, unless the Ministry notifies objections within thirty days. If they do not reach an agreement, a special conciliation commission (which in fact has not yet been appointed) calls the parties to a meeting and proposes a draft of an agreement balancing the interests of the parties, in view of ensure to the licensor a fairly limited consideration, established according to criteria which take into account the need of international competition of the manufacturers of active ingredients. If the conciliation does not succeed, the Ministry may refer to the Antitrust Authority (which sounds a sort of threat, particularly in view of the doctrine of abuse of patent rights, which is appearing now also in Europe [\[18\]](#)).

With respect to the patent issue, it has to be noted that a judgement of the Administrative Tribunal of Rome (the tribunal competent for the judicial review of the administrative decisions) has established that the Health Authorities are not bound to check the patent situation of the drug in granting the marketing authorisation (in other words, a marketing authorisation of a drug infringing a patent is valid, without prejudice of the patent owner to sue the infringer before the ordinary courts) [\[19\]](#).

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Notes

[1] Autorità garante della concorrenza e del mercato (AGCM), Decision 6th November, 1997, in AGCM Bull. n. 9/1998.

[2] Art. 1.2 law-decree n. 390/1995 passed into law n. 490/1995; art. 36.12 law n. 449/1997; art. 85.24 law n. 388/2000.

[3] Art. 125 royal decree n. 1265/1934.

[4] Art. 7 legislative decree n. 538/1992.

[5] Directive 92/25/EEC.

[6] At the time of AGCM's decision, art. 3.129 law n. 549/1995.

[7] At the time of AGCM's decision generics were disciplined only by art. 1.130 of law n. 549/1995 as amended by art. 1.3 of law-decree n. 323/1996 passed into law n. 425/1995; the impossibility to file an application for marketing authorisation pending a patent protection is not expressly provided by the statutory law, but affirmed in the case-law.

[8] Art. 85.24 law n. 388/2000 and art. 3.39 law n. 448/2001.

[9] See endnote 3.

[10] Source: Farindustria.

[11] Art. 1.40 law n. 662/1996.

[12] Art. 8 law-decree n. 347/2001 passed into law n. 405/2001.

[13] Art. 9 law-decree n. 264/1974 passed into law n. 386/1974.

[14] Art. 24 law n. 289/2002, as amended.

[15] Const. Court 20th February 1978.

[16] Law n. 349/1991.

[17] Ministerial decree 17th October 2002.

[18] See Statement of objection notified to Astrazeneca on 31st July 2003 (Press release IP/03/1136)

[19] Decision date 27th February, 2003 (Astrazeneca).

 [top](#)