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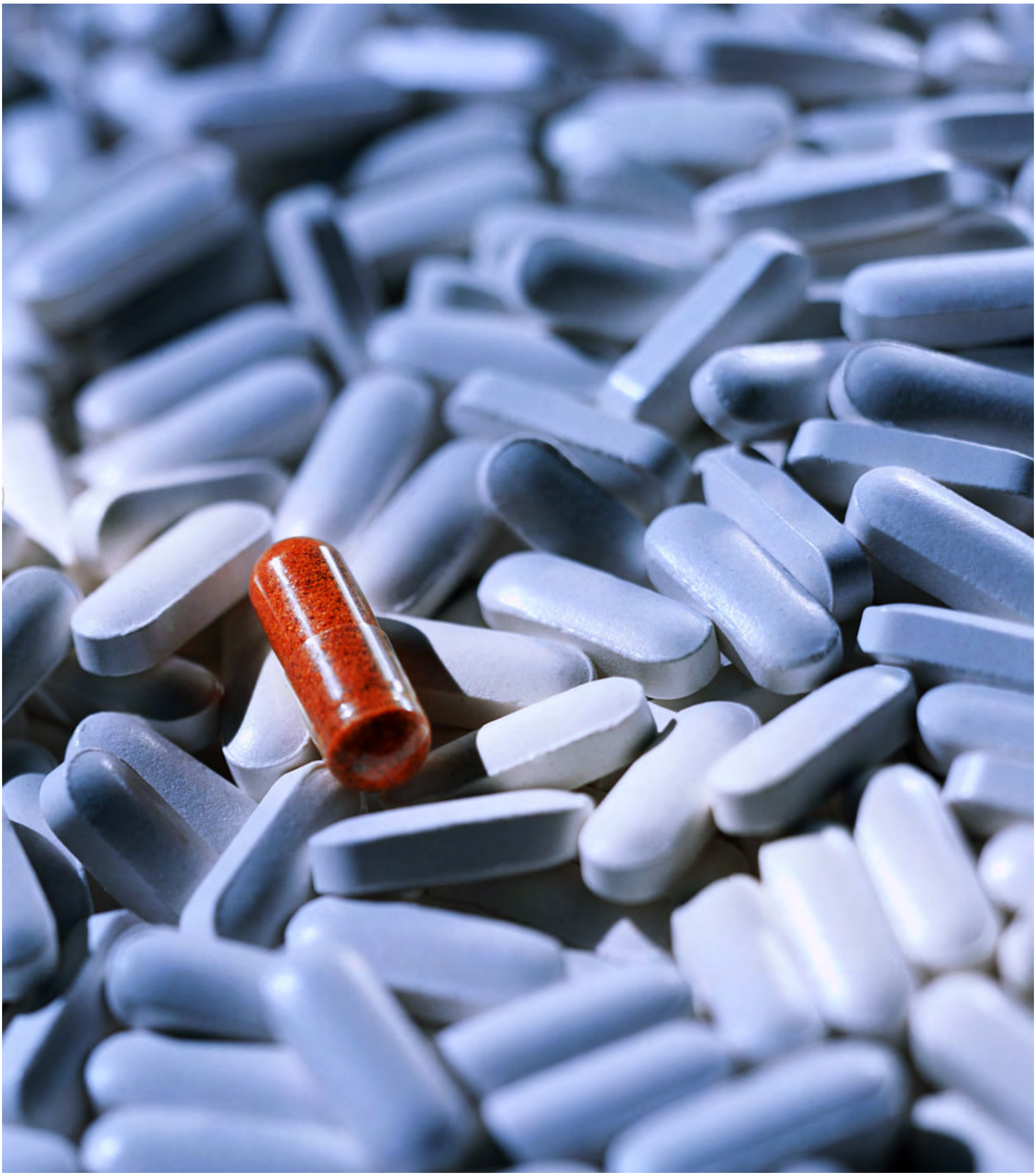

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Changes in Law: Licensing Procedures & Classification of Medicinal Products in Italy

By Linda Longo & Andrea Moretti

New rules relating to licensing procedures and classification of medicinal products have been introduced in Italy in September 2012 by the so called "Balduzzi Decree" (from the name of the Minister of Health in charge at the time of its enactment). Under the new legislation (articles 10 and 12 of Decree Law n. 158 of 13 September 2012 converted into Law 8 November 2012 n.189 as amended by Law Decree n.69/2013 converted in Law 9 August 2013 n.98) medicinal products approved by the regulatory authorities, but not yet evaluated for the purpose of reimbursement, are classified in a special new section "Class C non-negotiated (nn)". This allows companies to provide these drugs after the publication of the regulatory authorisation, without waiting the time of the negotiation of price with AIFA (the Italian Drug Agency). Before the implementation of these rules the newly authorized medicinal products could be marketed only after publication on the Official Gazette (OJIR) of a resolution containing both (i) the notice that the permit to market ("MA") had been granted and (ii) the relevant classification and reimbursement price. This caused significant delays for the patients to have access to new products.

In any case, before the beginning of the marketing of the product, the holder of the MA must communicate to AIFA the ex factory price and the price to the public of the "nn" product as well as the date of first marketing of the product.

Accelerated path for orphan drugs.

An accelerated path for orphan drugs, other drugs of exceptional therapeutic relevance and medicines dispensable only in hospital or similar health structures is provided under the new rules. For such medicinal products, pursuant to paragraph 3 of article 11 (as amended in June 2013) it is allowed to file the request of classification and reimbursability before the issuance of the marketing authorisation. In this way, the two authorisation processes (MA and reimbursability) can work in parallel, limiting delay to patient access.

Generic and bio-similar drugs.

For generic and bio similar drugs a special procedure is provided: when the holder of the MA proposes a price "clearly convenient" for the NHS (i.e. when the proposed price in comparison with that of the reference product, has a reduction at least equal to the one established by a decree adopted by the Minister of Health, upon proposal of AIFA, in relation to the volume of sales provide) the product is immediately classified in the reimbursable class at the time of the issuance of the MA.

Immediate availability of "innovative" medicinal products.

In order to guarantee in the entire Italian territory the essential levels of health care assistance, the Decree provides that innovative medicinal products must be made available in all the Regions and autonomous Provinces immediately after their approval by the central authority, regardless of their introduction in the Regional or Hospital formularies or similar lists. This rule applies only to products which have been recognised as "innovative" at the time of their authorisation, but it is a significant improvement to avoid unjustified delays caused by local procedures for the approval of Regional medicinal product list which were an unnecessary duplication of the evaluation process made at central level by AIFA.

Recent Case Law: Italian Regional Administrative Court on the controversial stem cell therapy

Another Balduzzi Law Decree was issued in 2013 (24 March 2013, No. 24) and its contents did not receive the favour of the scientific community as they related to the controversial therapy based on

stem cell treatment called "Stamina Method".

Originally the wording of the Decree contained a paragraph intended to consider the stem cell therapy equivalent to tissue transplant in order to deregulate the treatment from the strict rules to which the medicinal products are subject, including the GMP. After the position taken by the scientists and the European Medicines Agency on the 22 April 2013 stressing that *"the Cell therapies are defined as medicinal products when there is more than minimal manipulation of any cell type destined for clinical application or where the intended use of the cells is different to their normal function in the body. Any use of such cell-based medicines is subject to authorisation and controls,* including their manufacture." the Decree was partially amended and the controversial paragraph was cancelled.

However, urged by the pressure of the parents of children suffering severe diseases, of TV programs and protest on the streets of the general public, the Italian parliament converted into law the Decree (Law No 57/2013 23 May 2013) and the continuation of the controversial and secret therapy (previously banned by AIFA) was allowed (and funded!) for those who already started the first cycle of therapy. Section 2 bis of the Decree provided also the conduct of a clinical trial for a period of 18 months under the evaluation and control of AIFA (the Italian drug Agency) and ISS (Superior Institute of Health).

A Scientific Commission was appointed to advise on the clinical trial treatment in June 2013 by the Minister of Health and after few months the Commission unanimously resolved that the Stamina Method had no scientific basis and recommended to stop the "compassionate therapy".

The inventor of the Method, Prof Vannoni (a professor of Cognitive Science at the University of Udine i.e. not a medical doctor) appealed to the Lazio Administrative Court (TAR LAZIO) against the appointment and the opinion of the Scientific Commission claiming that its members were a priori contrary to the Method and therefore were not in a position to issue in an "independent way" a fair and proper evaluation. Quite surprisingly the Administrative Court on 4 December 2013 accepted the arguments of Prof. Vannoni and ordered the suspension of the Scientific Commission. The decision of the Administrative Court ruled that some of the scientists members of the Commission were not "ideologically independent" having already expressed an opinion contrary or doubtful in respect of the Stamina Method. It is, indeed, very strange to read in the decision that the requirement of independence (which normally refers to absence of economic interest) was interpreted in an ideological sense by the Court. Despite the defence of the Ministry of Health and AIFA, the Lazio Administrative Court disregarded the evaluation made by the most reputable, experienced and well known Italian scientists! The Italian scientific and medical community reacted very negatively to the ruling of the Administrative Court ("it will be very difficult to find in Italy or abroad a stem cell scientist who did not express criticism in respect to the Stamina Method"), but the Italian Minister of Health, Ms Lorenzin, decided to appoint an other Scientific Commission with the aim to protect the patients which should not be submitted to a risk of useless and/or potentially dangerous compassionate therapies. Despite the chaotic situation caused by the above decision, it does not seem that the stem cells therapy "Stamina Foundation" shall have a great future in Italy: criminal courts are investigating on the economic interests of the promoter of the treatment, Prof. Vannoni and evidence of violation of rules and lack of efficacy of the alleged therapy are emerging.

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Linda Longo is a name partner at Biolato Longo Ridola & Mori, Rome since 1992 and is in charge of the life science department of the firm. Linda is involved in general counselling to international and Italian companies with a special orientation to pharmaceutical, biotech, medical device and food industry. She is familiar with regulatory, contractual, competition, pricing, and compliance matters relating to pharmaceutical products and medical devices. She is also involved with merger and acquisitions relating to the industry and she acts as member of the Supervisory body pursuant to Legislative Decree 231/2001 and is involved in training in anti-corruption and data protection matters for pharmaceutical companies. Linda was mentioned as "Highly Recommended Lawyer" for Pharmaceuticals (regulatory matters) by Global Counsel Handbook, Life Sciences Industry Report 2005, Practical Law Company Ltd and the firm is regularly ranked as one of the leading Italian firm on life science matters.

Andrea Moretti is a partner at Biolato Longo Ridola & Mori.

He is involved with general civil and commercial practice, trademarks, intellectual property, pharmaceutical, medical device and food law and he has developed a significant expertise in the regulatory matters concerning in particular advertising of medicinal products and clinical research contracts.

Andrea is also specialised in competition law issues and he advises international and Italian clients with regard to out-of-court and litigation matters.

He is co-author of the Italian Chapter of the book "A practical guide to National Competition Across Europe" published by Kluwer Law International, 2007and of various publications on Life science matters.