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CHANCE

NEWSLETTER
HEALTHCARE, LIFE SCIENCES
& CHEMICAL INDUSTRY

RISK MANAGEMENT IN HEALTHCARE, LIFE SCIENCES & CHEMICALS SECTORS

"Companies are exposed to an increasingly complex range of risks, as well as subject to local, regional and international regulations.

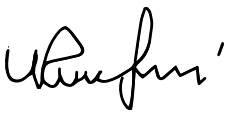
A full understanding of an organisation's current and future risk profile is essential. It is only when decision makers understand the key risks that management can make proper commercial decisions; otherwise organisations are left vulnerable to events that may have adverse repercussions on reputation and corporate strategy. Businesses that meet the new and evolving challenges of risk management stand to gain – by enhancing, and protecting their reputations, and differentiating themselves from competitor organisations that have not reacted as effectively.

The Healthcare, Life Sciences & Chemicals (HLS&C) sectors comprise several industries, each characterized by an above-average number of regulations and commercial challenges.

In such context, risk management is more important than in most other industries. While corporates in all industries develop and implement risk management strategies to prevent and to mitigate financial losses, in the HLS&C sectors, these strategies must go hand in hand with safety and ethical concerns and companies must research industry trends to ensure that it is ahead, and not behind, the standard.

Our expertise means that we can help our clients find a balance between growth and risk.

This issue of our Healthcare, Life Sciences & Chemical newsletter focuses on certain risks that may arise in these sectors, for which we propose strategies to be considered in the context of risk management."



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M&A INSURANCE POLICIES IN PHARMACEUTICAL SECTOR

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Companies active in the HLS&C sectors are traditionally very active in the M&A arena, both in terms of numbers of deals and volumes.

M&A can be a quick way to increase products portfolio, enlarge geographic footprint and boost revenues and size. However, without adequate protections, M&A could also unfortunately result in the “inheritance” of risks.

In implementing M&A transactions, buyers and sellers have different ideas on how the allocation of the known and unknown risks should be addressed: on one side buyers want security and protection and, on the other side, sellers want a clean exit.

Warranty and indemnity insurance policies are becoming increasingly important in order to reduce the risks associated with M&A transactions and to resolve impasses between sellers and buyers when negotiating sets of warranties in sale and purchase agreements.

Pharmaceutical, chemicals, medical device and healthcare are highly regulated sectors which may create further uncertainty and an increase of the unknown risks arising in the context of business.

The above means that the typical risk management techniques employed in other M&A transactions are not fully effective. Furthermore, due diligence in this sector can be very expensive and time consuming, targets are often reluctant to give the buyer’s experts and scientists access to sensitive and highly competitive information regarding technology. The regulatory and intellectual property due diligence that should be done is extensive, if a buyer wants to ensure that it fully understands the assets of the target and the related risks.

The advantages of the M&A Insurance Policy in order to cover the unknown risks arisen from the performance of the target’s business appear then to be much more relevant in the healthcare sector.

In particular, such insurance products protect a party from financial losses resulting from breach of the representations and warranties and can be structured to protect either sellers or buyers in relation to the liabilities deriving from breaches of representations and warranties given in the context of a M&A transaction. A seller-side M&A insurance policy protects the seller in case of misrepresentations or failure to adequately disclose against the warranties. In such a case, the buyer makes its claim against the seller according to the SPA and the insurer pays directly the buyer on behalf of the seller. While in a buyer-side M&A insurance policy, the buyer makes its claim for indemnification directly against the insurance company without need for recourse to the seller and the insurer indemnifies the buyer for losses caused by breaches of warranties by the seller under an SPA.

Moreover several companies active in pharmaceutical, chemicals, medical device and healthcare sectors in Italy are owned by important families or private equity funds which are not willing to accept liability for warranties for a long period and aim to exit from their investment without retaining liabilities: (i) the private equity funds regulation usually provides that no liabilities shall be kept after closing of the relevant transaction, unless the approval of the fund's investors is obtained; (ii) family based sellers are hesitant to put their separate financial resources at risk in the event of possible indemnification obligations under an SPA following the sale of the target.

Against this backdrop, the M&A Insurance Policy may be an efficient way to facilitate M&A transactions in the healthcare industry due to the fact that these policies may actually be used to obtain coverage under the warranties in the SPA for a longer duration than the seller is willing to accept.

Furthermore M&A transactions in HLS&C sectors are often implemented through an auction process. In this context too, the M&A Insurance Policy represents a valid instrument in order to submit a competitive bid. Indeed, bidders in an auction sale may propose such insurance policy as part of their bid to reduce seller's retained liability and thus enhance the value of their bid.

BIOSIMILARS AND BIOLOGICAL DRUGS: POSSIBLE DETECTION OF ONE SINGLE RELEVANT MARKET

2

The evolution in pharmaceutical drugs is continuously under the scrutiny of antitrust authorities in order to detect all the possible implications of new products for competitive dynamics. In particular, the analysis of scientific developments in pharmaceutical sector is important mainly for updating the definition of relevant markets from antitrust perspective; and such a definition, as well known, represents the first important step to be taken for carrying on any competitive assessment (and mainly for assessing merger and acquisition as well possible abuses of dominant position or the effects of unlawful agreements among competitors).

There is an open debate within the international antitrust community about how anticompetitive concerns can arise from separating the market of originator biological from the market of biosimilar products, especially with regards to allotment procedures under public tenders.

From a competitive standpoint, indeed, the possibility to consider biosimilar drugs and biological originators as part of the same market represents the first step to assume they can be included in the same single lot of a public tender as interchangeable products. And it is very important, taking into account that biosimilars competition on biological allows member states national health services to reduce their expenditure and, given member states financial problems in providing their citizens such services, it is reasonable to assume that purchasing institutions will tend to deem biosimilars and originators substitutable when possible.

On this point, the Italian Competition Authority ("**ICA**") adopted a very peculiar position, showing a different approach from that of Italian Medicines Agency ("**IMA**") and European Commission as well.

In particular, in two Opinions addressed to Italian Government and Regions, the ICA clearly pointed out that biosimilar products belong to the same relevant market of the originator biological drugs, and added that such a situation should be "subject to subsequent revisions in view of the development of a broader competitive relationship between biological and biosimilar drugs."

Up to now, the Italian Legislator has not seemed open to follow the ICA position. Finally, the Law on provisional budget for 2017, contrary to the ICA's suggestions (which once again expressed concerns about the detection of two separate markets for biological and biosimilars drugs) clearly stated that "*the existence of a relationship of biosimilarity between a biosimilar drug and its reference biological drug occurs only if certified by the European Medicine Agency and IMA in accordance with their respective competences"* and that *"in public tender procedures aimed to purchase biosimilar medicines, it is forbidden to put in the same lot different active substances even in the event they have the same therapeutic indication*".

On the basis of the consideration set out above, we note that it is quite unclear whether it is possible to identify one single market for both biological and biosimilar drugs. However, it is expected that the level of substitutability between biological and biosimilar drugs will increase over time. In the near future the existence of one single market for the two kinds of drugs will be more evident, and, therefore, we cannot exclude that also the Legislator will share the ICA's position and support the possibility to put into one single lot of a tender biosimilar and biological drugs having the same therapeutical indications.

THE RECENT DECISION OF THE REGIONAL COURT ON THE "PRECAUTIONARY PRINCIPLE" APPLICABLE TO MEDICINAL PRODUCTS

3

The Regional Administrative Court of Lazio (Rome) recently stated the relevance of the "precautionary principle" with regard to the medicinal products, including anti-obesity medication with certain specific active substances.

In particular, with decision no. 2225 of 9 February 2017, the Regional Court rejected the claim brought by the SITAP (i.e. *Società Italiana dei Farmacisti Preparatori*) and the ASFI (i.e. *Associazione Scientifica Farmacisti Italiani*) against the Ministry of Public Health and AIFA (i.e. *Agenzia Italiana del Farmaco*) for the annulment of the Ministry of Public Health Decree (dated 4 August 2015) prohibiting any doctor to prescribe and any pharmacist to perform pharmaceutical preparations as anti-obesity medication with specific active substances (e.g., clorazepate, fluoxetine, furosemide, metformin, bupropion and topiramate).

According to the Regional Administrative Court, the economic freedom principle does not receive an unconditional protection, but must be coordinated necessarily with other collective interests as the public health. For this purpose, with regard to medicinal products prepared by a pharmacist, Article 6 of Law no. 833/1978 grants the State (and AIFA) control functions. Indeed, Article 126 of Law no. 1265/1934 introduced a ban on the use of dangerous medicinal products.

The possibility to ban the production and distribution of medicinal products has been confirmed by Article 25, para. 8, of Legislative Decree No. 178/1992 with specific reference to preparations carried out by a pharmacy and, relating to clinical trials, with Legislative Decree no. 219/2006. In particular, Article 154, paragraph 2, of Legislative Decree no. 219/2006 states: "*the Minister of Health may prohibit the use of medicines, which are prepared in-pharmacy, regarded as dangerous to public healthy*".

As stated by the European Court of Justice, in accordance with the precautionary principle, as interpreted by the Court's case-law "*where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent"* and *"(…) where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures*" (10 April 2014, C-269/13, Acino AG).

The Regional Administrative Court, based on the precautionary principle affirmed by the European Court of Justice decisions, rejected the judicial-review and confirmed the lawfulness of the Ministry of Public Health Decree providing a ban for anti-obesity medication prepared by pharmacists.

THE PERFORMANCE OF PHARMACEUTICAL REPRESENTATIVES (*informatore medico del farmaco*) CANNOT BE MEASURED BY SALES ACHIEVED

4

The Court of La Spezia, with a recent decision dated 17 January 2017, qualified as unlawful the conduct of a pharmaceutical company that, by evaluating its pharmaceutical representatives' performance on the basis of sales achieved, in case of declining sales, put the pharmaceutical representatives under continuous pressure. These pressures were such as to imply the right of the pharmaceutical representative to obtain compensation for biological damages, and for damages to his professional image and dignity.

A pharmaceutical representative brought a claim before the Court of La Spezia seeking compensation for damages arising from the unfair conduct of the area manager, who in several instances had put pressure on the representative, even applying "informal" disciplinary sanctions such as requiring the employee to attend "remedial training courses", when sales in the representative's territory decreased.

The representative maintained that, in breach of the law, he had been measured on the basis of sales volume, more precisely on the basis of subsequent sales products he had proposed during his visits to them. This is inconsistent with the tenor and literal wording of the national collective bargaining agreement (NCBA) for chemical and pharmaceutical companies, which defines a pharmaceutical representative as an employee whose main activity is to inform physicians and other health care professionals by explaining the characteristics of pharmaceutical products, to ensure their proper use.

Leaving aside the quantification of actual damages as a result of the area manager's conduct, this decision is particularly interesting because it creates a distinction between the activities that a pharmaceutical representative may be required to perform depending on the type of relationship with the employer, whether of autonomous employment (i.e., pursuant to an agency contract) or of subordinated employment.

The Court of La Spezia pointed out a material difference between the activity of an autonomous agent and the activity to be performed by a subordinated-employee representative, finding that autonomous agents are required to promote sale contracts, and their compensation is directly related to the number of contracts so stipulated, while the activity of subordinated – employee representatives consist in persuading potential clients to purchase products and informing them about the relevant characteristics; however, for subordinated – employee representatives the promotion of contracts may be only an ancillary part of their activities.

THE ITALIAN COMPETITION AUTHORITY HAS ISSUED FINES FOR ABUSE OF A DOMINANT POSITION BY ASPEN PHARMA GROUP

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In its decision no. 26185 of 29 September 2016 (the "**Decision**"), the Italian Competition Authority (the "**Authority**" or the "**ICA**") in case A480 – Increase of Aspen pharmaceuticals price (the "**case**"), found that Aspen Pharma Trading Ltd., Aspen Italia s.r.l., Aspen Pharma Ireland Ltd. and Aspen Pharmacare Holdings Ltd (jointly "**Aspen**" or the "**Company**") abused a dominant position in breach of art. 102(a) of the Treaty on the Function of the European Union ("**TFEU**") consisting of the imposition of unfair prices for the sale in Italy of life saving and irreplaceable pharmaceuticals for oncohematological patients.

The Authority set out the legal and regulatory context and clarified that the pharmaceuticals for human use are classified on the basis of their regime of reimbursability which distinguishes between the persons which bear the cost i.e. the Italian National Health System ("**SSN**") or the patient which gives rise to a distinction between pharmaceuticals: class A – essential and for chronic illnesses and thus paid for in their entirety by the Italian NHS (direct distribution), class H – for hospital use and also to be paid for by the SSN and class C – to be paid for in their entirety by the patient. Within the last class, moreover, a distinction is made between pharmaceuticals requiring a medical prescription and those not requiring a prescription and, as regards the latter, between pharmaceuticals for slight pathologies which may be advertised and are available over the counter (OTC – so-called class C-*bis*) and those for which no advertising is allowed (SOP).

With specific regard to the reimbursability regime, the pharmaceuticals of classes A and H are reimbursed in full by the SSN when they are covered by a patent or in any case where there is no generic pharmaceutical or equivalent on the market. In particular, for these pharmaceuticals (class A and H are reimbursed by the SSN) the prices are defined through a process of negotiation between the undertaking and the Italian Pharmaceutical Agency ("**AIFA**").

Class A pharmaceuticals whose patents have expired, however, the SSN repays the so-called reference price or the lowest price of the equivalent pharmaceuticals present on the market. The prices of the pharmaceuticals of class C are freely determined by the producers and are paid for in full by the patient whilst AIFA only monitors those requiring a medical prescription whose prices can be increased every two years only and can only be increased by an amount not exceeding forecast inflation.

Having clarified the regulatory and legal framework the ICA found that Aspen had a dominant position as regards the so-called Cosmos pharmaceuticals, in other words the medicinal speciality called Leukeran (clorambucil), Alkeran – by injection or in tablet form – (melfalan), Purinethol (mercaptopurina) and Tioguanina (tioguanina), which were classified in class A and H and, accordingly, the determination of their prices was subject to the obligation of negotiation with AIFA.

The Authority, therefore, found unlawful behaviour by Aspen in particularly aggressive negotiating strategy in respect of AIFA consisting of:

I. reiteration of its request to move the pharmaceuticals to class C, paid for in full by the patient, albeit in the full knowledge of the inadmissibility of the regime for oncological pharmaceuticals declared not to be replaceable by the hematological experts contacted by AIFA;

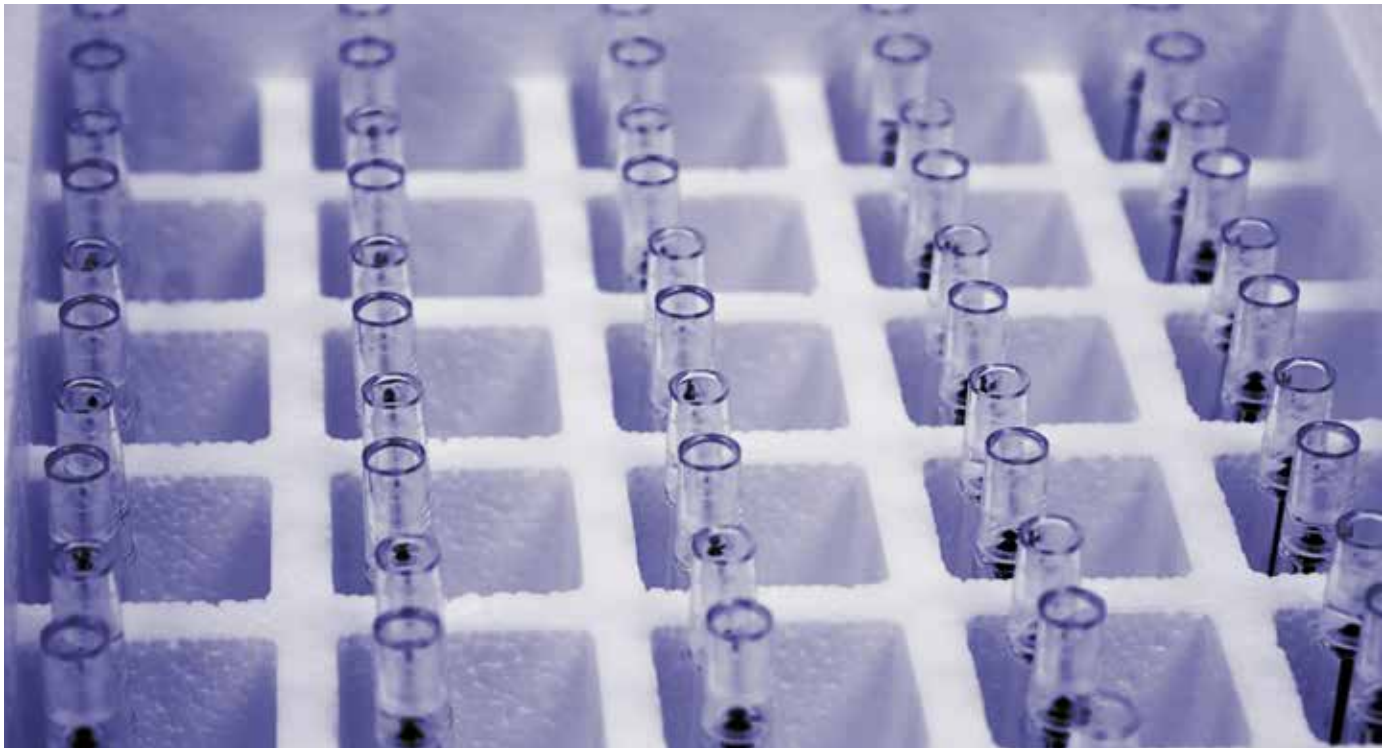
II. a credible and repeated threat to withdraw the pharmaceutical from the market in the absence of acceptance by AIFA of the proposals put forward;

III. use of the inaccessibility of the product on the Italian market.

This strategy, according to the reconstruction by the ICA, allowed Aspen to obtain very high price increases, ranging from 300% to 1500% on the initial prices, leading to an increase in the public and private cost of the pharmaceutical for the purchase of such life saving specialities corresponding to a more than proportionate increase in the company's profit, in view of the huge disproportion in respect of the costs incurred without any economic justification.

The price increases, furthermore, were even more unjustified as they did not correspond to the investment in research and development incurred by the group given that the Cosmos pharmaceuticals were developed by another company and the related patent has now expired.

The ICA took the view that Aspen's behaviour constituted an abuse of a dominant position by imposing unfair prices for Cosmos pharmaceuticals through the negotiating phase with AIFA, with an adverse effect on both the SSN and consumers and issued fines of more than Euro 5 million.



OUR CORE TEAM

As part of the firm's global matrix, members of the global Healthcare, Life Sciences & Chemicals sector team specialise both in specific subsectors and the relevant practice areas, to pool our collective resources and experience to benefit our clients.

Having cultivated an expertise in the healthcare and life sciences industry over two decades and having worked with many of the world's leading and emerging pharmaceutical, chemicals, medical device and health care services companies, we know the importance of anticipating regulatory and contractual issues in the context of corporate investment, finance, competition, strategy and operations.

Established in the early 1990s, the Global Healthcare and Life Sciences sector team consists of more than 140 dedicated lawyers in 30 centres including Belgium, China, France, Germany, Italy, the Netherlands, Poland, Russia, Spain, United Arab Emirates, the United Kingdom and the United States.

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