A road map to life sciences M&A in Italy

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U.S.-based life sciences companies considering transactions in Europe may easily become overwhelmed with the complexity of Europe's various jurisdictions. In this series, members of our European Life Sciences Transactions Team provide country-specific perspective and guidance to help you navigate the jurisdictional challenges and differences that you may run into when acquiring a European life sciences company.

In this edition, Francesco Stella will discuss life sciences transactions in Italy.

M&A in the Italian life science sector: lots of opportunities and a few legal pitfalls

M&A in the Italian life science sector is lively with a wide range of transactions spanning from large pharmaceutical companies that buy mature product portfolios to venture capitalists that invest into early stage biotech projects. International players have a substantial share of this market and they do not face particular legal obstacles.

There is however a number of peculiarities in doing M&A in Italy in the life science sector that a foreign investor is to be aware of.

On the one side, a foreign investor entering the Italian market may find that, while generally well aligned with international standards, Italian practice is sometimes not yet fully receptive of certain M&A trends:

- this is the case in particular of insurance policies to secure seller's indemnification obligations. While increasingly used in the US and English markets, they have not penetrated Italian market yet, unless to a certain extent for PE deals. So, bank guarantees and escrows continue to be more commonly adopted;
- VC transactions offer another good example. In the US model legal documents such as those made available by NVCA set the standard and their use substantially reduces negotiation time and effort. In Italy, each transaction is a whole other story and negotiation may prove longer than expected.

On the other side, there are Italian law provisions that may make an M&A life science transaction somehow different from what a foreign investor could expect.

This is the case in particular of those transactions that are structured as a sale of going concern. These are certain aspects to highlight for an international player looking at an investment into an Italian healthcare business:

- Corporate. The purchaser is liable for debts pertaining to the going concern remaining with the seller and arisen before the transfer, provided that these debts are recorded in the mandatory accounting books of the seller. The purchaser may therefore obtain full protection for undisclosed liabilities pertaining to the going concern, under the relevant transfer agreement, but not for debts recorded in the accounting books of the seller, it being understood that the seller shall hold the purchaser harmless and indemnified against any payment of debts not included in the going concern transferred made by the purchaser in compliance with the rule above.
- Labour. All the contracts with employees pertaining to the going concern will be automatically transferred to the purchaser by operation of law (no employees' consent is needed) on the same terms and conditions. This means that the transferred employees will maintain all accrued contractual rights, including their service seniority.

  Should the seller employ more than 15 employees (in a whole, not only with respect to the going concern to be transferred), a preliminary consultation procedure with works councils/Trade Unions shall be commenced at least twenty-five days before any binding agreement between the seller and the purchaser is reached. Works councils/Trade Unions have no veto power. Therefore even if the consultation procedure ends up with no agreement, the parties will be free to implement the transfer of the going concern and all employees dedicated to the going concern will be transferred to the purchaser.

  Finally, employees transferred can challenge their transfer to the purchaser within 60 days from the date on which the transfer of going concern was executed if they deem that their working activity is not relevant to the going concern transferred. Also, employees of the seller may claim their entitlement to be included in the branch of business transferred to purchaser if they deem that their working activity pertains mainly to the going concern transferred. Such right becomes time-barred after five years from the transfer.
- Regulatory. Transfer of the marketing authorizations needs to be approved by the Italian Medicines Agency (AIFA). The relevant process may last in the region of a couple of months. At the end, AIFA's approval is published on the Italian Official Journal and the transfer becomes effective. This is generally construed as a post-closing action. Accordingly, there two different ways that are developed under Italian practice to deal with inventory in the period between closing and transfer of marketing authorizations:
  - Either inventory is transferred at closing. In this case, during the transitional period, the purchaser may be appointed as distributor of the seller (so-called "*concessionario di vendita*") so as to be in the position to sell the products at stock under the marketing authorisation of the seller. The appointment of a *concessionario di vendita* needs to be communicated to AIFA. No changes to the packaging or labelling are required;
  - Or inventory is transferred only at a later stage upon transfer of the marketing authorizations. In this case, distribution on the market is continued by the seller until

completion of the marketing authorisations' transfer (so call Sales Order to Cash or SOTC). Profits however are returned to the purchaser which enjoys the full economic benefits as from closing as if the products were sold by it as the marketing authorisation holder, less a fee for the service rendered by the seller.

- Tax. the seller and purchaser are jointly and severally liable towards the tax authority for the following tax liabilities, whether known or unknown, pertaining to the going concern: (i) taxes and penalties due for tax infringements committed by the seller in the tax year in which the transfer occurs and in the two preceding tax years (even if not assessed in those periods); and (ii) taxes and penalties assessed during those same periods, even if the tax violations were committed in an earlier tax year. However, in terms of purchaser's liability in respect of tax liabilities referred to the above:
    - the Italian tax authorities must first seek payment of the amounts due from the seller;
    - it is limited to the value of the business transferred;
    - it is limited to the tax liabilities on the tax authorities' files on the completion date.

In order to limit its liability, the purchaser can request the seller to obtain from the Italian tax authorities a certificate on existing tax liabilities, if any. The purchaser will be jointly liable with the transferor only for the amount of the tax liabilities (if any) as set out in the tax certificate. If the tax certificate does not report the existence of tax liabilities (or if it is not released within 40 days of its request), the purchaser will not be jointly liable with the seller for any tax liabilities. It is therefore material to regulate such aspect in the going concern transfer agreement.

Francesco Stella is a partner in our Milan office. He has accompanied an impressive number of large international corporate and financial institutions in their M&A moves into the Italian market, and top Italian clients in their growth abroad through acquisitions and joint ventures. A passion for complex deals brought him to focus on regulated assets ranging from financial institutions to life science companies and energy businesses.

Our European Life Sciences Transactions Team

When the stakes are high, you want a partner who has the knowledge honed by decades of legal and industry experience on your side. A partner whose strategic advice is informed by a thorough examination of your business and your transaction. A partner who understands the challenges and opportunities you face and delivers solutions that achieve the best possible outcome. When faced with a difficult deal or a tough transaction, our European Life Sciences Transactions Team has you covered.

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