

# Consolidation in the pharmaceutical sector – practical aspects to be remembered when merging/acquiring a company – part I

M&A transactions play a significant role in increasing the level of growth in the worldwide pharmaceutical sector. But about 70% of all such deals fail to provide the anticipated benefits. Both tax and legal aspects must be taken into consideration if you like to avoid being among the failed business marriages.

People say there is an easy rule in business – you grow or you die. Companies that are on the growth path take away market share from competitors, increase profits and provide respectable returns for shareholders. In recent years, the pharmaceutical industry all over the world has experienced accelerating growth coinciding with the occurrence of a large number of M&A transactions. The realisation of cost synergies is the main approach to further realise high margins, as many patent-related “super-margins” will erode during the next years. When “blockbusters” with their billion-dollar sales disappear, generic companies will expand their market power. However, practice so far and detailed research clearly show that the issue of value creation might not be straightforward, namely – not all the expected benefits are realised following the formation of M&As. Accordingly, apart from a careful target-setting and target-selection process, post merger integration remains a key issue. Careful integration helps to ensure a “happy ever after marriage, once the excitement of the wedding party has worn off”.

In this article we are not elaborating on all issues/exposures related to M&A transactions. Based on our experience in our advisory practice and observation during a series of M&A transactions, in particular in the

pharmaceutical industry, we could notice outstandingly planned and thoroughly considered transactions from the business perspective. At first glance everything was signed, sealed and delivered. At first glance. People say the devil is in the details and unfortunately this simple principle triggered (indirectly, of course) substantial tax and legal exposures in some cases. On the other hand, the same principle meant that some executives had to say “good bye” to the savings they could generate.

The article delivers a brief review of a few “details driven by the devil” concerning practical aspects worth remembering during M&A transactions in the pharmaceutical industry in Poland.

## Legal aspects

One of the most prominent features of the pharmaceutical market having a substantial influence on M&A transactions on this market is the high level of regulation, which results mainly from health protection considerations. Production and marketing of medicinal products is regulated both at national and Community level. The mentioned specifics of the pharmaceutical market entail that apart from the traditional legal aspects

which need to be taken into account within each M&A transaction, such as adherence to regulations on trade in financial instruments (in the case of listed companies) or to consumer protection and concentration laws, there is a necessity to cover the regulatory issues typical for this sector. These issues are of vital importance both at the pre-transactional stage, where a due diligence of the target is carried out and the transaction is structured, and at the post-transactional stage that starts as of the moment when the purchase agreement becomes effective.

## Compliance with applicable administrative rules

Within almost each professionally structured M&A transaction, the first step to be undertaken by the investor consists of the process of carrying out a legal due diligence of the target whose shares or assets are to be purchased. Such a process is carried out with an aim to identify potential legal risks associated with a given investment. The high level of market regulation and the severe sanctions that are imposed in the event of violation of the provisions on production and marketing of medicinal products further increase the importance of the examination of the target's compliance with the applicable administrative rules.

When examining regulatory issues, particular emphasis shall be put on the identification of the status of the products marketed by the target, especially in relation to borderline products. The real character of the products is essential from the perspective of the determination of the applicable legal regime. For obvious reasons, medicinal products, food products and cosmetics are treated differently from the legal perspective. Therefore first of all it is necessary to determine if the target has classified the products in conformity with the applicable law provisions and consequently if the products are marketed legally. It needs to be remembered that any violation of the norms in this respect may ultimately result in substantial financial consequences for the investor. After determining the legal status of the mentioned products, the validity of the marketing authorisations held by the

target needs to be examined. Further, where the transaction is structured as an asset-deal, confirmation of the validity of the permit for the production of medicinal products is of vital importance. Additionally due to legal limitations on the advertising of medicinal products, compliance with the applicable law provisions in this respect shall be examined.

### Compliance with intellectual property rights

Apart from regulatory issues it is important to investigate thoroughly issues related to intellectual property rights. This is particularly essential in the event the target is an innovative firm that is marketing new medical products. The issues that need to be addressed within this area include in particular:

- the level of patent protection concerning the inventions relating to the medicinal products produced by the target
- identification of potential violations of third parties' intellectual property rights by the target
- examination of license agreements entered into by the target as the licensee (especially from the perspective of „change-of-control” provisions that may be structured in a way that enables the licensor to terminate the license or increase the amount of the license fees in the event of control over the target being taken over by a third party).

### Structure of the transaction

If after performing the due diligence process the investor decides to close the transaction, it shall in the next step decide how to structure the transaction. Particularly it shall decide whether the transaction shall be formed as a share or as an asset deal. This decision is especially essential from the regulatory law point of view. It shall be stressed that in case the transaction is to be carried out as a share-deal it is not necessary (at least so long as a formal merger in accordance with commercial law provisions is not implemented) to amend the existing marketing authorisations relating to the medicinal products held by the target (such marketing authorisations remain valid). On the other hand, where the deal is structured as an asset deal, due to the fact that there will be a change of the responsible entity it will be necessary to amend the marketing authorisations. Such an amendment will be effected as a transfer under art. 32 of the Polish Pharmaceutical Law (in relation to national marketing authorisations) or under the provisions of Commission Regulation No 2141/96 (in relation to Community marketing authorisations).

### Appropriate wording of the purchase agreement

Irrespective of the investor's decision as to how the transaction is to be structured, it is

very important for him to ensure that the provisions of the purchase agreement are worded in the right way, especially in the part relating to representations and warranties and concerning the extent of the seller's liability. This is of course important in each M&A transaction; however, it is worth noting that in relation to M&A deals on the pharmaceutical market, particular emphasis shall be placed on areas that are connected with the highest risk taking into account the specifics of the sector. Thus it is of particular importance to negotiate with due care the provisions on product liability or the “reps and warranties” relating to compliance with intellectual property rights and regulatory issues relating to production, classification and marketing of medicinal products.

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