Regulatory Aspects of Due Diligence in German Pharmaceutical Mergers & Acquisitions

a report by

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Due diligence is a detailed investigation into the affairs of a business. The aim of due diligence is to identify problems within the business, particularly any issues that may give rise to unexpected liabilities in the future. Due diligence involves a number of different areas of investigation. For example, the company’s financial status will be assessed by accountants and its pension arrangements will be the subject of an actuarial review. As intellectual property (IP) rights are the key assets of any biotech company, the business’s IP portfolio will inevitably be the subject of close scrutiny.

Before any legal transaction between pharmaceutical companies takes place, when at least one company is based in Germany, a review of certain legal and regulatory material must be provided by the seller in the form of a high-level due diligence review. The purpose of this review is to offer the potential purchaser a chance to assess the legal and regulatory material provided by the seller. Information about the seller’s activities, marketing and sales, and certain regulatory and research and development (R&D) activities will be assembled in a ‘data room’ to which the purchaser and its advisors will have access.

Contents of Due Diligence Relating to Regulatory Aspects

Any due diligence report should give general information about the valid legal preconditions that must be fulfilled to ensure that the marketing of pharmaceutical products can be continued.

In a recent example, a selling pharmaceutical entrepreneur failed to notice the necessity of applying for a wholesale dealer’s licence as stipulated in the 12th Amendment to German Drug Law (Paragraph 52a AMG) to guarantee straightforward marketing of the products. The application should have been submitted to the local authorities within the transition period before 1 December 2004 to continue marketing the products. If the application is submitted later than this date, the marketing of the products must be stopped until wholesale dealer’s licence is granted.

The facts of this case have concluded that the spin-off should have been carried out in such a way to guarantee that the buyer will be in a position to use the wholesale dealer’s licence for its own business. This licence was applied for in the name of seller or had already been granted to the seller, and the buyer is now the legal successor of the seller.

As for the spin-off, a change of company name will be carried out for that part being holder of the market authorisations; there will only be a variation necessary to Germany’s Federal Institute for Drugs & Medical Devices (BfArM), who will correct the name of the company being pharmaceutical entrepreneur afterwards. Therefore, in the same variation the seller should be named as manufacturer.

The main emphasis of a due diligence report, in order to allow a reliable risk assessment, is to investigate the history of each single product, its date of marketing authorisation, the necessity of application for prolongation or fulfilment of conditions imposed by the BfArM, or the danger of revocation of its marketing authorisation.

An inspection of the official data base from the drug information system (AMIS-Datenbank) is carried out to verify whether the seller is registered as the pharmaceutical entrepreneur for each of the products to be listed in the disclosed documents.

If the seller is registered as pharmaceutical entrepreneur for all the medicines, it is sufficient to relate the research to the seller’s medicines only. If there is no accordance with the seller for some product names, a second phase search shall be conducted (data ‘AMIS Suchschritte’). Where none of the products can be found, a third stage search, looking for identical product names in the seller portfolio (‘Suchschritt 3’; data ‘AMIS ex seller’) will be conducted.
It is particularly important to check the history of the products, especially whether the seller made a complete application for every single product and for each necessary prolongation of the marketing authorisations granted. As Paragraph 31, Section 1, No. 3 German Drug Law (AMG) states:

“The marketing authorisation shall expire after the completion of a period of five years from the date of its granting, unless an application for prolongation is filed three to six months at the latest prior to expiry of the period.”

Another important issue is to check the fulfilment by the seller of conditions imposed to market authorisations. Paragraph 28, Section 2, No. 2 German Drug Law (AMG) states that the BfArM may revoke the marketing authorisation if one of the reasons for refusing marketing authorisation as defined in Paragraph 25, Subparagraph 2, No. 2, 6a, 6b or 6c has subsequently developed, or if one of the conditions imposed relating to Paragraph 28 has not been met and the deficiency has not been rectified within the period of time specified by the BfArM.

For products involved in re-registration procedures, there was the issue to scrutinise the legitimacy and the following fulfilment of deficiency reports. Paragraph 105, Section 5, German Drug Law (AMG) determines that the applicant shall be given the opportunity to correct faults within an appropriate period of time, but not longer than 12 months. Should these faults not be corrected, then marketing authorisation shall be refused.

For all pending re-registration procedures, if, from a scientific point of view, it shall be clarified that the products do not meet one of the conditions, then as stated in Paragraph 5, Section 4f, in connection with Paragraph 25, Section 2 of the AMG, marketing authorisation shall also be refused. In particular, if:

- the drug has not been sufficiently tested to a high enough standard;
- the drug does not show adequate quality pursuant to the acknowledged pharmaceutical principles; and
- the drug is lacking therapeutic efficacy at the time of application, or is insufficiently substantiated by the prevailing standard of scientific knowledge.

If a due diligence considers the above-mentioned aspects, a reliable risk assessment of the portfolio of marketing authorisations to be part of the transaction shall be possible in order to protect from unpleasant surprises relating to the marketability of pharmaceutical products.
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