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A specialised service provider can also undertake regulatory manufacture of drugs and medical products independently of their production or distribution

FASTER TO MARKET

Production, fabrication – or manufacturing? The manufacture of drugs and medical products is more than just a technical process, but instead a regulatory one: recognition of this fact can reduce costs.

For the consumer the case is clear cut: The manufacturer is the company whose brand name appears on the product. In actual fact, that company is frequently not the manufacturer. As distributing company it farms manufacturing out to a contract manufacturer. So far, so good. However, according to drug and medical product legislation, the manufacturer is that company which releases the product for the market or places it on the market. And it can make perfectly good sense if that company is neither the distribution company nor the contract producer.

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A Question oft Delimination

Companies in the food, pharmaceutical, and cosmetics industries are constantly on the lookout for new products to add to and round off their portfolio. If, in the course of an in-depth search in the growth area of healthcare, they come across OTC drugs or medical products, for example, then a phase of disenchantment often sets in. The regulatory demands and quality standards that have to be satisfied in an area that does not belong to their core competence soon create the impression that such products are unprofitable. In such situations, however, everything is a question of delimitation – in this case between distribution, manufacturing, and production.

The demands on a licence to place medical products or drugs on the market are clearly stipulated in EU directives and national legislation. Thus since July 2006 manufacturers of medical devices of higher classes have to fulfil the quality standard DIN EN ISO 13485:2003. A cosmetics company which wishes to extend its product portfolio by a single medical product, such as a tooth whitener, suddenly faces a considerable certification effort. In addition, the time-to-market of the new product is significantly lengthened by the necessary reorganisation of the existing quality management systems.

A similar situation occurs, for example, with manufacturers of medical products who, for strategic reasons, wish to add a drug or a combination product to their portfolio: As manufacturer they are required by the 14th amendment of the Federal German Drugs Act of October 2005 to have each individual product batch released by their qualified person – as a rule a pharmacist with appropriate professional experience.

In addition, the food, pharmaceutical, medical product, and cosmetics sectors each have their own set of regulatory demands. Only few companies are likely to have an interest in adding further regulatory demands to their existing organisational structures for the sake of just a single additional product.

In some cases, contract manufacturers can take on these tasks and also the necessary regulatory activities for placement on the market. Outsourcing of manufacturing, packaging, and control activities can help to save expensive production equipment on the part of the distribution company and to ensure best possible utilisation of such equipment by the contract manufacturer. Rationalisation effects can thus be optimally exploited by both parties.

Contract Manufacturer ist Legally Liable

The distribution company/contract manufacturer construction is frequently non-optimal from a regulatory stand-

For Outsourcing Companies

- The manufacturer is the person who releases the product for the market or places it on the market.
- The food, pharmaceutical, medical product, and cosmetics industries each have their own set of regulatory demands.
- An alternative to the conventional approach is to engage a specialised service provider who takes care of the regulatory manufacture of drugs and medical products independently of their production and sales.
- This external contractor contributes its completely certified organisational structure with a corresponding quality management system, relieving the distribution company of these tasks.
- As the manufacturer, the external service provider coordinates initial certification and subsequently assures the marketability of the medical products by monitoring the maintenance of conformity.
- In the drugs sector, specific activities or, if desired, the entire pharmaceutical responsibility for manufacturing, control, packaging, and product release can be delegated to the service provider.

point. For example, the contract manufacturer also has to take on additional legal responsibilities relating to liability. Moreover, although the distribution company does not have to demonstrate the availability of certified quality management systems the production company does. This has an influence on the production costs.

If the product turns out to be a blockbuster, allocation of the increasing production volume to several product-releasing contract manufacturers cannot be solved satisfactorily: Each one of them has to be named on the packaging as manufacturer of the batches they have released onto the market. The distribution company pays the price of an inflexible tie-up with its suppliers in order to relieve its own organisational and financial burden; rationalisation effects go unexploited. An alternative to this model is to engage a specialised service provider who takes care of the regulatory manufacture of drugs and medical products independently of their production and distribution.

In the case of medical products this option is based on Section 3 Article 15 of the German Medical Products Act. The act contains the following definition: "The manufacturer is the natural or legal person, who (...) is responsible with regard to first placement on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party." The manufacturer takes responsibility that the medical product fulfils its intended purpose and the safety of the patient and user is assured. Compliance with basic demands is indicated by affixing the CE mark.

Focussing on Core Competence Generates Rationalisation Effects

In the German Drugs Act, Section 13, Paragraph 1 states the conditions for manufacture: "Whoever wishes to manufacture drugs (...) for the purpose of supplying them to others, requires permission from the responsible government agency."

Hälsa Pharma, a company belonging to the Diapharm Group, certified according to DIN EN ISO 13485:2003, DIN EN ISO 9001:2000, and Good Manufacturing Practice (GMP) and in possession of a corresponding "manufacturing licence for the release of drugs" is the first company in Germany to specialise in these tasks. In this model, the external contractor contributes its completely certified organisational structure with a corresponding quality management system, relieving the distribution company of these tasks. In this way the distribution company and the contract manufacturer can focus entirely on their respective core competence – development, marketing, distribution, and manufacturing – and exploit the resulting rationalisation effects. The same applies for the outside contractor who places its specialised organisational structure at the disposal of several different companies.

Depending upon the terms of the contract, in the area of medical products the outside contractor can act as manufacturer, as safety officer, and/or as medical products consultant. If desired, the outside contractor can also take on further regulatory tasks the for the distribution company, and take complete responsibility for performing conformity assessment procedures (Class I to III), produce the product dossier, and undertake clinical assessment and DIN-based risk assessment.

As the manufacturer, the external service provider coordinates initial certification and subsequently assures the marketability of the medical products by monitoring the maintenance of conformity. This is accomplished by the contractor's quality management system. In addition, as manufacturer, the contracting company handles negotiations with the notified bodies and government agencies. In the drugs sector, specific activities or, if desired, the entire pharmaceutical responsibility for manufacturing according to Section 4 Paragraph 14 of the German Drugs Act, for control, packaging, and product release can be delegated to the service provider, who will provide the quality management and a qualified person. The contractor performs GMP active ingredient audits according to the Pharmaceutical Company Ordinance, certifies the active ingredient manufacturer, and accompanies the distribution company in all regulatory and quality-relevant steps.

Qualified Person Must Audit and Accept QA System

Being responsible for batch release, the qualified person has to audit and accept the quality assurance system of the upstream production and testing steps. The name of the manufacturer, which appears on the packaging, can stay the same even if prior production steps are performed by different contractors. It can thus serve as a kind of quality seal such as is encountered in the food industry.

In such an arrangement, the intellectual property of the pharmaceutical company must, of course, be contractually protected: As a rule, the company will be the exclusive taker of the products marked with its own name and will determine the marketing strategy and the distribution channels used. The details are set out in a liability limitation agreement.

Since the distribution company is free to choose the extent to which it delegates tasks to the contact manufacturer and the external contractor, it will possess maximum design freedom for its product. In addition to relieving the regulatory pressure on the company, whose main job it is to produce food, pharmaceutical, medical product, or cosmetics manufacturer, for a side line belonging to another market segment, the time factor also plays a role. Thus the drugs manufacturer GlaxoSmithKline Consumer Healthcare was able to commercialise a physically active tablet for relief of flatulence within just five months: Hälsa Pharma GmbH of Lübeck took on responsibility for implementation of the business project and for manufacturing the product and has since been using its own quality and risk management for the medical product. Other distributing companies have meanwhile committed to cooperation in the manner described and are creating enormous synergistic potential through this rational outsourcing. ■