Chapter XXXIII
Electronic Submission of New Drugs in Europe

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ABSTRACT

All over the world, drugs and drug applications have to be submitted to and approved by an admission office before they may be sold on the market. All procedures are extensive, time-consuming, and costly. To simplify the process, it could be organised electronically. In an economic perspective, there are many benefits by using the electronic form for the pharmaceutical industry: managing knowledge, cost advantages, and time savings. All, pharmaceutical industry and institutions have undertaken lots of efforts to enforce the electronic solutions. They focus on international standards in order to harmonise structures and processes. It would be necessary to reduce paper and copies, especially if the electronic solution takes place. This method will simplify the way to deal with data and documents and reduce process time and costs.

INTRODUCTION

The pharmaceutical industry is characterised by high expenditures on research and development. In 2003 in Germany, over 3.56 billion euros were spent for the development of new drugs and new drug applications (Bundesverband der Pharmazeutischen Industrie e.V., 2004a). In the year 2004, almost 9,000 drugs were listed in the *Rote Liste*, a compendium of all medication patients may get (Bundesverband der Pharmazeutischen Industrie e.V., 2004b). The developing process for a new product lasts on average between 8

and 11 years and costs about 800 million euros (Bundesverband der Pharmazeutischen Industrie e.V., 2004a). The duration of a patent for a new drug or new drug application lasts 20 years. Usually, in the product-development process, the application for a letters patent takes place early. Therefore, the patent time for the producer, the time in which they can promote the drug on the market and amortise the costs of research and development, is reduced to about 10 years (Bundesverband der Pharmazeutischen Industrie e.V., 2004a). Thus, time to market is a critical issue for firms in order to economically succeed in a long-term perspective. The duration for research and development of a drug usually is fixed. But the time for the submission of a new medicine, which takes about 2 years, may be reduced. If firms do so, they may gain profit.

Electronic solutions are more and more common in the healthcare sector (e.g., electronic prescription), and it may be useful to submit pharmaceutical products electronically. This article will give a closer look on the opportunities of electronic submission concerning processes, time, and costs.

SUBMISSION OF DRUGS

All over the world, drugs and drug applications have to be submitted to and approved by an admission office before they may be sold on the market (Jordan, 2002). Usually, for the submission, the producer has to get in contact with the local admission office (for example, in Germany, it is the Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM, 2004) and with the European Medicines Evaluation Agency (EMEA; Europäische Arzneimittel-Agentur, 2003). The firm has to send a submission dossier to the office. It contains information about the harmlessness, effectiveness, and quality of the drug. For some medicines, registration is sufficient for the firms: No clinical evaluations or pharmacological-toxicological tests have to be conducted by the producer. Within Europe, several regulations, directives, legal decisions, and guidelines have to be considered (Bundesverband der Arzneimittel-Hersteller, n.d.). They are especially concerned with technical aspects and harmonisation, form, and content. The detailed Common Technical Document (CTD) has existed since 2003. It is a guideline for the technical documentation of any drug in Europe, the United States, or Japan and was established in the International Conference on Harmonisation (ICH; BfArM, 2003). Formal aspects of the dossier are shown in the European standardised *Notice to Applicants* (NTA; Wagner, 2000). The content specifications are described in EU (European Union) guidelines or country-specific rules. In Germany, for instance, firms must fulfill diverse criteria set by the Arzneimittelgesetz (AMG), the AMG-Einreichungsverordnung, the Verwaltungsverfahrensgesetz, and the Arzneimittelzulassungsgesetz. Products released in just one country might be accredited just for this region. But drugs that are placed on the European market have to fulfill European standards. Depending on the requested licensing, the submission dossier for a new drug or drug application will be made up of about 1,000 folders and more than 500,000 pages (Mitteleuropäische Gesellschaft für Regulatory Affairs, n.d.).

As one can imagine, all procedures are extensive, time consuming, and costly. To simplify the process, it could be organised electronically. Doing so, in 1985, the United States founded the Computer Assistance in New Drug Applications (CANDA) project. In 1994, the SMART (Submission Management and Tracking System) project displaced the labor-intensive CANDA project. This system is based on