Parallel Trade of Pharmaceuticals: A Review of Legal, Economic, and Political Aspects

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ABSTRACT

Objectives: An overview of the status quo of parallel trade of pharmaceuticals (pharmaceutical parallel trade [PPT]) was performed. The different economic, political, and legal viewpoints as well as the public health perspective are being taken into consideration. Analysis is being undertaken on a worldwide level, focusing on the situation of Switzerland in the context of current developments in the United States as well as in the European Union (EU).

Methods: Desktop analysis using publicly available information (e.g., scientific literature, congress reports, official statistical databases) was performed during the years 2006 through 2007. Such gathered information was compiled and systematically structured to allow a crude overview of the development of intellectual property law in the last 100 years (as a prerequisite under which PPT legally can exist) as well as a description of the health economic and political context in which PPT is set currently.

Results: It could be shown that PPT is an ubiquitous phenomenon, appearing in industrialized countries as well as in the developing world. Economically, it has gained a significant weight in substantial parts of the EU in the last decade. This has to be seen in the context of EU efforts of enhanced economic and political integration. The worldwide constant growth of health-care expenditures, with its strain on national health-care budgets, has led to increased discussions about the necessity and consequences including possible dangers of PPT, namely, in the United States and in Switzerland, where up to now PPT has been only of marginal importance.

Conclusions: The analysis of the value of PPT depends strongly on the importance that is given to different perspectives by the individual analyst. It is clear that an item-centered view of PPT is not able to analyze this phenomenon in an equitable way. Further attempts have to be made to standardize evaluation as well as to increase available information to empower science and decision-makers to perform objective analyses and informed decisions.

Keywords: comparative study, health economics, multi-country economic evaluation, pharmaceutical pricing, Switzerland.

Introduction

This article tries to give an overview of the current international situation of pharmaceutical parallel trade (PPT). Parallel trade is not limited to pharmaceutical products (see later in the article, but because of the special nature of pharmaceuticals, which differentiate them from “normal” consumer goods, there are not only economical facts to be given, but legal considerations and political implications to be remembered. This becomes clear among others when analyses of the same phenomenon come to completely different, sometimes even contradictory results, as it is the case with the recent economic studies on this subject, which will be shown next. Part of the reason for such different results could lie in some shortcomings in economic theory as well as in the limited availability of appropriate data.

By giving an economic, legal, and political outline, the reader of this article should be enabled to understand the international status quo of PPT as well as the different interests, policies, and aims of the individual market participants.

Definition of PPT

Parallel trade is a phenomenon well known internationally: A common definition is worded in the fundamental work of Arfwedson [1] as follows:

Re-importation (or parallel trade as it is known in Europe) occurs when products protected by patent, trademark or copyright are first placed into circulation on one market, then (re-) imported into a second market without the authorization of the original owner of the intellectual property rights (IPRs).

Arfwedson concludes his definition with the remark that “Myriad products are re-imported, including...
automobiles, clothing, perfume and other consumer goods.” This shows to us that parallel trade is an almost ubiquitous phenomenon (at the end of the last decade, it was estimated, for instance, that up to 20% of the market for Coca-Cola in the UK was served by parallel imports coming from wholesalers in other European countries [2]).

**Price Differentials As Driving Forces**

What are the reasons of this situation? Apparently, there must be a strong driver for the international, almost ubiquitous appearance of parallel trade: profit, or better said, price differences allowing firms to make profits in exploiting the possibility of arbitrage if transaction costs are low enough. Wherever there are sufficient price differentials to make movement of goods economically viable, and a regulatory framework, which permits it, parallel trade comes into action. In the case of pharmaceuticals, Maskus [3] obtained international ex-manufacturer’s prices and sales data for major molecules (20 brand-name drugs) in 14 countries, for which he calculated average per dosage prices (see Table 1). In the same study, he used data from the Swedish Medical Products Agency for a basket of 90 brand-name drugs (see Table 2) to make a European price comparison.

Maskus [3] identified the price differentials on the international as well as on the European level, with low-price countries like Greece and Spain, and high-price countries like the UK or Switzerland. Maskus found that prices in many drugs were relatively low in numerous developed countries, e.g., Canada, Italy, and Spain, whereas in other less developed countries, e.g., Mexico, Brazil, and South Africa, they were relatively high, which he explained mainly with the existence of significant price controls in countries with low prices.

Costs of marketing pharmaceutical parallel imports (PPIs) are high—it is a tightly regulated industry with rigorous standards and regulatory requirements, but there are still enough margins to make it worthwhile, and parallel trade in pharmaceuticals has grown consistently in Europe. The market size has been estimated at a value of EUR 4.2 billion in 2004 [4], a development of between EUR 2.6 billion in 2001 and EUR 5.8 billion in 2006 [5], respectively.

### Legal Background

**Exhaustion and Its Different Forms**

The definition of parallel import in Deardorff’s Glossary of International Economics [6] is as follows:

“Trade that is made possible when the owner of intellectual property causes the same product to be sold in different countries for different prices. If someone else imports the low-price good into the high-price country, that is a parallel import.

The legal basis of parallel import lies in the European principle of exhaustion and the American “first-sale doctrine,” which are explained in the following: Exhaustion was developed in Germany in the early 20th century by the pioneering work of Josef Kohler [7]. Its American equivalent, the “first-sale doctrine,” was established at roughly the same time by a decision of the US Supreme Court in 1908 [8].

Exhaustion is one of the basic principles of intellectual property (IP) law worldwide. The concept of exhaustion can be explained in the following: Once trademarked goods are put on the market by the trade-mark owner or with his consent, the trademark owner is no longer allowed further to control the distribution of those goods. He has “exhausted” his distribution right by the first sale of the goods. There are basically three different forms and concepts of exhaustion:

1. National exhaustion means that the trademark right (or patent or copyright) is exhausted only

### Table 1 International comparison of average per dosage ex-manufacturer’s prices, common drugs, 1998 (US$)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of drugs</th>
<th>Average price (US$)</th>
<th>Average price relative to the USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>19</td>
<td>2.72</td>
<td>1</td>
</tr>
<tr>
<td>Brazil</td>
<td>19</td>
<td>2.03</td>
<td>0.81</td>
</tr>
<tr>
<td>Mexico</td>
<td>18</td>
<td>2.02</td>
<td>0.76</td>
</tr>
<tr>
<td>Japan</td>
<td>8</td>
<td>1.33</td>
<td>0.74</td>
</tr>
<tr>
<td>Sweden</td>
<td>16</td>
<td>1.79</td>
<td>0.73</td>
</tr>
<tr>
<td>UK</td>
<td>20</td>
<td>1.85</td>
<td>0.7</td>
</tr>
<tr>
<td>Canada</td>
<td>19</td>
<td>1.63</td>
<td>0.63</td>
</tr>
<tr>
<td>South Africa</td>
<td>19</td>
<td>1.37</td>
<td>0.58</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>17</td>
<td>1.18</td>
<td>0.56</td>
</tr>
<tr>
<td>Italy</td>
<td>20</td>
<td>1.39</td>
<td>0.55</td>
</tr>
<tr>
<td>Korea</td>
<td>18</td>
<td>1.35</td>
<td>0.54</td>
</tr>
<tr>
<td>Spain</td>
<td>17</td>
<td>1.35</td>
<td>0.52</td>
</tr>
<tr>
<td>Thailand</td>
<td>17</td>
<td>1.12</td>
<td>0.41</td>
</tr>
<tr>
<td>India</td>
<td>7</td>
<td>0.14</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Source: IMS data, in Maskus [3].

### Table 2 Average percent deviation from European mean prices in pharmaceutical products, 1998

<table>
<thead>
<tr>
<th>Country</th>
<th>All 90 products</th>
<th>Products in all 15 countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece</td>
<td>−28</td>
<td>−16</td>
</tr>
<tr>
<td>Spain</td>
<td>−20</td>
<td>−12</td>
</tr>
<tr>
<td>Portugal</td>
<td>−13</td>
<td>−4</td>
</tr>
<tr>
<td>Italy</td>
<td>−13</td>
<td>−4</td>
</tr>
<tr>
<td>France</td>
<td>−10</td>
<td>−1</td>
</tr>
<tr>
<td>Finland</td>
<td>−2</td>
<td>−2</td>
</tr>
<tr>
<td>Austria</td>
<td>−2</td>
<td>+0</td>
</tr>
<tr>
<td>Norway</td>
<td>−1</td>
<td>−5</td>
</tr>
<tr>
<td>Sweden</td>
<td>−1</td>
<td>−1</td>
</tr>
<tr>
<td>Belgium</td>
<td>−1</td>
<td>+0</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>+2</td>
<td>+3</td>
</tr>
<tr>
<td>Denmark</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Germany</td>
<td>+11</td>
<td>+8</td>
</tr>
<tr>
<td>UK</td>
<td>+19</td>
<td>+12</td>
</tr>
<tr>
<td>Switzerland</td>
<td>+25</td>
<td>+17</td>
</tr>
</tbody>
</table>

Source: Calculations by Mattias Ganslandt with data from Swedish Medical Products Authority, in Maskus [3].
with respect to the countries on the market of which the goods were put. If the applicable law follows only national exhaustion, a parallel importer would infringe the relevant trademark right in the country of importation. National exhaustion (regarding patents) is being practiced, e.g., in the United States and Switzerland. The United States recognizes national exhaustion of pharmaceutical patents, and gives the patent holder the explicit right of importation [9]. In Switzerland, the concept of national exhaustion is also being followed: The Swiss high court underlined this in a decision in 1999, the so-called "Kodak Trial" [10]. (Pharmaceutical products beyond patent protection are allowed for parallel trade in Switzerland though, a fact that will be discussed at a later stage. It should be also mentioned at this point that there is a different legal situation regarding trade mark rights: Whereas in patents national exhaustion is being practiced, in trade mark rights, international exhaustion is the current modus operandi in Switzerland.)

2. Regional exhaustion means that the exhaustion relates only to a market that is broader than the purely national market but is nevertheless limited to specific countries. The European Union (EU) follows the concept of regional (EU-wide) exhaustion whereby a company marketing a product in one member state cannot object on the grounds of trademark infringement to subsequent sales of that product in any other member state [11]. The concept of EU-wide exhaustion is tied to the free movement of goods, founded in the Treaty of Rome (Articles 30 and 36), which authorizes the free movement of goods and confers the right to control the import of goods by national governments, provided the products are not harmful or pose a threat to the public. It was extended, under an EU agreement, with certain European Free Trade Association (EFTA) countries (Iceland, Norway, Liechtenstein, forming the European Economic Area [EEA]). Regional exhaustion is increasingly being discussed in North America: Among others, a policy to admit parallel imports has been proposed by US policymakers. Both the US House of Representatives and the Senate approved an amendment in 2007 that would permit pharmacists and wholesalers to import cheaper drugs from other countries [12].

3. International (global) exhaustion means that the trademark right (or patent or copyright) is exhausted by putting the goods on any market anywhere in the world. If a jurisdiction adopts this rule on exhaustion, owners of rights in the jurisdiction cannot stop parallel imports into the jurisdiction by reliance on IP rights alone. At present, India, Indonesia, Malaysia, Taiwan, South Africa, Hong Kong, Israel, Singapore, Argentina, Thailand, and New Zealand recognize international exhaustion, allowing parallel importation of patented pharmaceuticals [13]. The principle of international exhaustion in the context of parallel trade came under worldwide attention when, in 1997, South Africa made an amendment to its Medicines Act, permitting the Health Ministry to suspend patent rights in special cases of urgency (namely, the AIDS epidemic), as such legalizing parallel imports of (copied) patented medicines like certain high-priced AIDS treatments [14]. Following this, 39 pharmaceutical companies brought in 2001 an action against the South African government concerning the constitutional status of the Medicines and Related Substances Control Amendment Act [15]. Nevertheless, yielding to substantial pressure from public opinion [16], the research-based companies dropped their claim in April 2001.

### Exhaustion and Its Political Implications

Opinions on exhaustion are very diverse internationally. The choice on which concept to adopt depends strongly on the presence of a local or regional research-driven pharmaceutical industry. It is interesting to note in this context that the World Trade Organization (WTO) did not only touch the issue of exhaustion in the treaty on Trade-Related Aspects of Intellectual Property Rights, but explicitly excluded it: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights" [17].

### Importance of Parallel Trade

#### Key Economic Data

As said above, parallel trade in pharmaceuticals is a multibillion euro business in the EU alone. To give an example: The value of PPIs in Germany, the third largest market for pharmaceuticals worldwide, reached EUR 1.25 billion in 2005, according to the German Association of Research-Based Pharmaceutical Companies [18]. Kanavos et al. [19] came to similar results in their study. The detailed results and conclusions of this study will be discussed later in this article. In Figure 1 below, the volume of parallel trade of six EU countries, calculated by the authors of the above-mentioned study, are depicted. The differential between Greece, the only net (parallel) exporter and prime source for parallel imports for the other countries, gives an idea on the price differentials realized through this arbitrage.

The estimations of market share of parallel imports differ also, but it is clear that in markets like, e.g., Denmark and the UK, parallel trade has reached a significant share of pharmacy market sales, reaching 15.7% and 14.5%, respectively, in these two countries.
Health Care As a Macroeconomic Cost Factor

The phenomenon of parallel trade of pharmaceuticals has to be seen in the context of mounting health-care budgets in the developed world: Almost everywhere, a substantial part of national income is spent for health, reaching 11.6% and 15.3% of gross domestic product (GDP), respectively, in Switzerland and the United States (Fig. 3).

It is clear that there are different reasons for the mounting health-care costs, among them general progress in the medical sciences, and an aging population in the industrialized countries. Nevertheless, drugs are most often in the center of the discussion, as they and with them the pharmaceutical industry are easy identifiable targets in campaigns to curb national health-care expenses. The actual rates to which drugs contribute to those expenses range between 10.4% of total health expenditures in Switzerland and 22.9% in Spain (Fig. 4).

Political Context

As said, mounting health-care expenditures, together with significant international pricing variations, are a situation which stimulates policymakers: They endorse parallel trade with the long-term aim of a reduction of drug prices. This is, e.g., reflected in the 1998 EU commissions original Communication on the Single Market in Pharmaceuticals [22] stating: “Wholesale intermediaries buy products in lower priced parts of the European Union and sell them in higher-priced parts of the Union. In an effectively integrated market, the prices of tradable goods tend to converge towards a situation where arbitrage is no longer an issue; in this sector, since maximum prices are fixed in many Member States, the price convergence pressure on products already in the market will be towards lower prices.”

![Market value of pharmaceutical parallel trade in selected EU countries](image1)

**Figure 1** Market value of pharmaceutical parallel trade in six European Union (EU) countries. Data source: Kanavos et al. [19]. Conversion of noneuro currencies (DKK, SEK, GBP) into euro based on exchange rates as per August 12, 2006.

![Market share of pharmaceutical parallel trade in selected EU countries](image2)

**Figure 2** Market share of pharmaceutical parallel trade in six European Union (EU) countries. Source: Kanavos et al. [19].
prices, at least for out-of-patent products. Unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient. Nevertheless, parallel trade must equally be seen as an important driving force for market integration and, consequently, for achieving the Single Market.”

It is interesting to read in the above communication that the European Commission speaks rather clearly of a political and economic trade-off. The possibility that most of the benefit will go to the parallel trader (which is the main argument against parallel trade given by Kanavos et al. [19] in their London School of Economics and Political Science (LSE) study) is spoken out. The European Commission also does stipulate clearly and precisely that with the endorsement of parallel trade, not only a tendency for lower prices for pharmaceuticals throughout the EU is favored, but also one of the great goals of the EU, the Single Market, is supported through the driving force of parallel trade.

Possible Negative Effects of Parallel Trade of Pharmaceuticals

Among others, two major risks of parallel trade can be identified:

First, the authorization of parallel imports may open the door to falsified products. The problem of counterfeit drugs does not only concern developing countries [23], but industrialized countries as well, as a recent example shows: The British Medicines and Healthcare Products Regulatory Authority published a drug alert in May 2007 [24], informing the public that counterfeit products appearing as French parallel imports were introduced into the legal UK supply chain.

Second, it is often argued that parallel trade is undermining the ability of the research-based pharmaceutical industry to develop new drugs and is staying competitive through the fact that it does strip those companies from profits needed to perform further research and development (R & D). Arfwedson remarks in 2004, that empirical data show a certain coincidence with the rise of parallel imports (plus dirigiste price controls) and
the relative downfall of the European pharmaceutical industry: The European share of the world pharmaceutical market has declined from 32% to 22% over the past decade; the United States share has increased from 31% to 43%. Additionally, many EU pharmaceutical companies have moved their research centers to the United States [25]. To attribute this relative downfall only to the rise of parallel imports is most probably too one-sided. In general, there are a lot of factors that play a role in this development: The general social, economic, and health-care environments as well as basic financial and regulatory conditions certainly play an additional role here.

Assessments of Parallel Trade

Economic Research in the EU

The recent international research trying to find objective data on benefits of parallel trade in pharmaceuticals is very controversial: Results differ vastly in judgment of the welfare effects of the concerned countries or regions. The main ambiguity lies in the evaluation of potential gains consumers (or better “payers,” as costs for drugs are reimbursed in different degrees in most European countries by health insurances) of pharmaceutical products in high-price countries versus potential of reduction of incentives to innovation in research-driven pharmaceutical industries in the concerned countries and areas.

West and Mahon come in the York study [26] in 2003 to the conclusions of significant savings throughout five European countries (UK, Germany, Sweden, The Netherlands, Denmark) totaling EUR 631 million, with evidence of indirect competitive effects through forced reduction of prices, thus helping to contain mounting public health-care expenditures in several European countries. This is supported by the findings of Ganslandt and Maskus [27]. They showed in their 2004 empirical analysis of the Swedish pharmaceutical market between 1995 and 1998 that “prices of goods subject to import competition, including parallel-traded products themselves, fell approximately four percent in the import market relative to the prices of products not subject to parallel trade.” Moreover, their econometric investigation suggests that original producers cut prices by up to 19%, relative to other drug prices, concluding that parallel imports represent a significant form of competition in markets such as Sweden.

Maskus’ and Chen’s (theoretical) analysis of 2004 [28] suggests that in the presence of low trade costs, allowing parallel imports is likely to increase welfare, particularly within a region like the EU or North American Free Trade Agreement (NAFTA). Szymanski [29] argues differently in 2004 through his calculation of a negative effect on the UK pharmaceutical industry of more than GBP 770 million (EUR 1140 million) per year. With a gain of up to GBP 480 million for the UK economy from parallel trade, the total net (negative) effect on the UK economy (including the benefit to consumers of lower pharmaceutical prices) is calculated at more than GBP 290 million (EUR 430 million / exchange rate as per August 12, 2006).

An important argument against parallel trade, recently used by the above-mentioned authors Kanavos et al. [19] in their so-called “LSE study,” is the fact that the party mostly benefiting from parallel trade is the parallel importer himself. Kanavos speaks of modest benefits for payers between 0.3% and 2.2% of the total market, being substantially exceeded by profits for parallel importers, mounting to more than EUR 700 million in 2002, with some EUR 500 million of this total realized by British parallel importers. The results of Kanavos et al. [19] have been challenged by parallel importers, saying that with a different mode of calculation, the results would have been similarly positive as those of the York study [30]. In their theoretical work, Bordoy and Jelovac [31] find a decreased total welfare in countries with similar health insurance systems and an increased welfare in the case of a different drug valuation. Enemark et al. [32] come in their very recent work (“Odense Study,” 2006) to results similar to those of the York study and very different to those of the LSE study: In their analysis of four European countries (Denmark, Sweden, Germany, UK) they estimate savings totaling EUR 441.5 million. The savings calculated by Enemark et al. have decreased, compared to the 2001 estimates of the York study. It is speculated that regulatory changes as well as pan-European price convergence or parallel importers stock-out, generated by increased manufacturer restriction of deliveries have contributed to this situation.

The results of the three major studies discussed above are summarized and compared in Table 3.

Economic Research in Switzerland

Vaterlaus [33] calculates in 2005 the effect of a change in exhaustion on drug prices in Switzerland: adoption of regional exhaustion would lower wholesale prices of drugs between 9% and 20%, adoption of international exhaustion between 14% and 32%, thus leading to nationwide savings on drug expenditures between CHF 130 and 420 million (EUR 203–655 million). These savings would be relatively higher than those calculated in the aforementioned York study, because of the higher price level in Switzerland, compared with the countries analyzed in the latter (Germany, Sweden, Denmark, UK, The Netherlands). The findings of Vaterlaus [33] regarding a system change in patent exhaustion on pharmaceuticals in Switzerland are collected in Table 4.
In a recent (2006) publication [34], the two authors Weder and Barsuglia conclude that Swiss consumers should profit from an approval of PPIs in Switzerland (assuming no negative impact on international R & D through the relative small size of the Swiss pharmaceutical market). They argue further that incomes of Swiss pharmaceutical producers could fall if the worldwide price level on patented drugs would decrease (because of the reference price system) through parallel trade into Switzerland. Although a switch toward a system of regional exhaustion would seem conceivable on first sight, legal problems through different WTO regulations and possibly difficult negotiations with the EU make this step difficult to realize. Their opinion is that in the present situation, regulatory measures, further limiting maximum prices, would be a preferable way to reach the goal of lowering the prices for patented drugs.

**Economic and Regulatory Environment in Switzerland**

The situation of Switzerland regarding its pharmaceutical industry distinguishes it from that of other countries.

First, for a small country of seven and a half million inhabitants, it has a pharmaceutical industry of remarkable size, with two Swiss companies (Novartis and Roche) in a total of five European companies (two British, two Swiss, one French) ranking in the international top 10 (see Fig. 5).

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**Conclusions**

In general, parallel trade of pharmaceuticals remains a frequently discussed topic. Results and conclusions of research in this field are very different, sometimes even contradictory. This could be due to the fact of sponsoring of studies by different stakeholders. To name the three most important recent studies on parallel imports: while the York and Odense studies have been sponsored by the European Association of Euro-
Pharmaceutical Companies, the parallel importers’ European representative, the LSE study, was sponsored by Johnson & Johnson, a pharmaceutical company.

Parallel trade of pharmaceuticals takes place in a playground with different stakeholders having different and contradictory interests: the multinational pharmaceutical industry with their interest of maximizing profit; national governments with the interest of keeping a research-based industry offering high number of qualified jobs on the one hand, and on the other hand keeping costs for health care low, or at least, reduce their growth; health insurers (and their clients!) heading for low monthly fees; and last but not least, parallel importers to make use of the existing legal possibilities to realize profits out of price differentials.

Parallel imports depend on the legal environment of an economic area. This is even more the case with pharmaceuticals, because of the highly regulated distribution of drugs. Drug prices remain a target of politicians worldwide, because of their visibility and to the relative ease with which this sector of the health-care industry can be manipulated. On the other hand, the economic power of the pharmaceutical industry, especially of the big globally acting companies, is of influence, especially in countries where pharmaceutical industries are big taxpayers and providers of qualified workplaces. Because of this, parallel trade remains an issue in the EU and will become a greater issue in the United States and in Switzerland, two countries with high drug price levels and a very strong pharmaceutical industry.

Further research is needed to investigate this field in the most objective manner possible. To do this, it is of prime importance to standardize evaluation methods, as well as to increase quality and quantity of available objective information to empower science to perform sound analysis and to enable decision-makers to implement informed and well-balanced decisions.

Source of financial support: None.

Figure 5 Top ten pharmaceutical companies in the world (2006 global pharmaceutical sales, US$ billion). Data source: Interpharma [35].

Figure 6 Investments in pharmaceutical research and development (R & D) relative to national market value in Europe. Data source: EFPIA [37].
References


15. High Court of South Africa, Case no. 4183/98.


39 Swiss Law on therapeutic products, Art. 14, Par. 2 (HMG; SR 812.21).

40 Verordnung des Schweizerischen Heilmittelinstituts für die vereinfachte Zulassung und die Meldepflicht von Arzneimitteln, Art. 16 Par. 2 der (VAZV; SR 812.212.23).