30 YEARS OF PARALLEL TRADE IN PHARMACEUTICALS
Analysis - Facts - Background
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Dear Readers,

Medical care must be affordable. In view of continuing demographic change, it is vital that politics is aware of and supports a healthcare system which, whilst guaranteeing a high level of patient care, does not impose undue burden on the public.

Drugs play a key role in this process: as a significant cost factor for statutory health-insurance funds, the potential for savings through using cheaper drugs is enormous.

Parallel trade recognized this potential over 30 years ago and uses it to serve the interests of the general public. In this process, medicines are bought cheaply in an EU country and imported to Germany, where domestic products are significantly more expensive. The presupposition of this process is of course, that the imported medicines comply with high German regulatory standards. The difference in price is passed on to the consumer both directly and indirectly and in so doing, parallel trade currently affords the statutory healthcare sector savings of over 200 million Euros per year.

One of the key tasks which we at the German Association of Pharmaceutical Parallel Distributors (VAD) have set ourselves is to support and strengthen the existence of economical medicines provision in Germany. Our combined membership produces 70 percent of total turnover in parallel and re-imported pharmaceutical products in Germany.

Openness and transparency are important to us. This brochure is thus intended to make a contribution to the understanding of the opportunities and challenges that parallel trade is faced with in an objective and factually relevant manner.

We hope that reading this brochure is both enjoyable and informative.

Edwin Kohl
President of the German Association of Pharmaceutical Parallel Distributors (VAD)
(Vorstandsvorsitzender des Verbands der Arzneimittel-Importeure Deutschlands e.V., VAD)
Dear Readers,

The government reforms of the health service in previous years has created the necessary conditions under which access to the fruits of medical progress can be secured for all. However, despite positive developments, the need to ensure the financial viability of healthcare in Germany will remain a continuous task. Of course, every member of the general public has the right to receive the best possible health provision. Still, we have to take advantage of every possible potential for savings without impeding quality and service.

Considerable savings can be made in the provision of medicines by using generic medicinal products or parallelly imported drugs. Reducing the price of trademarked medical products is not the only reason why our healthcare system needs imported pharmaceutical products. Germany is one of the few countries without state-regulation of prices and we trust that the pharmaceutical companies will make responsible use of this freedom. Imported drugs help to keep price levels comparable with those of our European neighbours. We expect these importers to pass on the cost advantage of purchasing in other EU countries to both consumers and the paying authorities for the benefit of healthcare provision in general. Under such circumstances, importers have a secure future in the German healthcare system.

Over the years, the German Association of Pharmaceutical Parallel Distributers (VAD) has made an important contribution to the public debate surrounding this topic. It also makes an important contribution to discussion of the question as to how patients can be guaranteed equal access to affordable medicines.

Best wishes,

Ulla Schmidt
German Minister of Health
(Bundesministerin für Gesundheit)
Dear Readers,

Healthcare is a fundamental human need and a basic human right. For this reason, it is very important that medicines are affordable. Over the last thirty years, parallel import has made an effective contribution to the provision of affordable yet high-quality medicines to German citizens.

Nevertheless, general diffidence and scepticism towards this valuable practice can still be found. Fears that medicines originating from parallel import are of reduced quality often outweigh perceptions of the benefits of this import economy. It is thus vital to educate the general public as to the benefits and opportunities provided by this practice, and in so doing, help reduce prejudice and fear. We need to make clear that drugs originating from parallel import are original products, produced by licensed multinational pharmaceutical firms, and imported to Germany outside official distribution networks of producers and licensed traders within the EU member-states. The importers make use of the price differences within the EU market, and so are able to sell their products in Germany at a reduced price. Licensing of these products for the German market follows intensive quality controls satisfying all consumer protection standards.

Pharmaceutical parallel imports make a contribution to the diversity of the commercial pharmaceutical product range and thus represent a clear benefit for the patient, providing him with the freedom to choose a more affordable medicine of identical quality and therefore save costs.

In 2007, the turnover from the sale of drugs to end customers in public pharmacies amounted to 36.1 billion Euros. The parallel import of pharmaceutical products makes a contribution to the reduction of drug costs by providing the patient with a cheaper alternative especially in over-the-counter medicines. This increases competition and brings the patient effective savings whilst maintaining identical quality standards. Access to a successful and high-quality medical service must not be allowed to become a privilege of the rich; parallel imports make a contribution to equitable pricing within the healthcare system.

With best wishes,

Peter Müller
Minister-President of Saarland
(Ministerpräsident des Saarlandes)
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The European legal foundation for parallel trading

Together with a number of landmark decisions, the single European market for pharmaceuticals, established in the 1960s provides the legal framework for parallel trading. In the 30 years of its existence, parallel trading has become an important instrument in reducing costs in the pharmaceutical provision system.

Dr. Wolfgang A. Rehmann
Taylor Wessing
Harmonization of the legal provisions regulating the licensing and marketing of pharmaceuticals by the European legislator began in the 1960s. The aim was to lay the foundations for a single European market in pharmaceuticals. The commission communiqué for 1998 summarized the common aim:

“The purpose of finalizing the single market for pharmaceuticals is not only to create an environment favourable to pharmaceutical innovation and commercial development, but also to improve the quality, safety and effectiveness of drugs at affordable prices.”

These harmonized provisions provide the legal foundation for parallel trading. They ensure a unitary safety standard for pharmaceuticals within the European Union and thus satisfy the requirements for European cross-border trading in medicines.

This foundation also contains the key principle of community law regulating trademark and patent law: the doctrine of exhaustion.

Trade with parallelly imported pharmaceuticals established itself on the foundation of these harmonized legal provisions at the end of the 1970s. It contributes to reducing costs in a number of EU high-price member-states. The economic basis of parallel trade is provided by the varying price levels for pharmaceuticals in the individual EU member-states.

“Parallel trade established itself in Europe on the basis of harmonized legal provisions established since the end of the 1970s.”

The establishment of inter-brand competition resulting from parallel imports in individual member-state markets had to overcome considerable resistance. It was first necessary to establish the legal framework within which parallelly imported pharmaceutical goods could be licensed within the individual member-states and the conditions under which parallelly imported pharmaceuticals could be repackaged without breaching trademark legislation or other commercial property rights. Finally, it was necessary to address the question as to whether to grant parallel imports access to established distribution channels via pharmaceutical wholesalers. Three landmark decisions opened the way for parallel imports and established its current success.
The European legal foundation for parallel trading

This pertains to the simplified authorisation of parallel imports. In its judgment from 25 May 1976 (Rs 104/75 – de Peijper; Court of Justice Reports. 1976, 613) the European Court of Justice (ECJ) established that the requirement from national licensing bodies, obliging parallel importers to produce the documents from a drug licensing procedure as a precondition for licensing the drug, was inconsistent with the principle of the free movement of goods, if the licensing authorities are already in possession of these documents as the result of the existence of a licence for the reference product. Furthermore, the requirement of administrative assistance now obliges the licensing authority to obtain supplementary information from the licensing body of the member-states from which the product is to be imported. In the so-called simplified authorisation procedure derived from this European community legislation, the licensing body in the country of importation must restrict itself simply to verifying whether the drug to be imported varies in its therapeutically relevant effects from those drugs already licensed in the country of importation. This principle has been repeatedly confirmed by the ECJ.

“Three landmark decisions have assisted parallel trading to its current success.”

A second landmark decision relates to the criteria for the repackaging of trademarked drugs. The area of intellectual property rights is regulated by the doctrine of exhaustion and is restricted under the terms of Art. 30 EC to the extent that it should maintain its essential function as a trademark for quality and the drug’s origin.

In its landmark decision from 11 July 1996 regarding the repackaging of proprietary medical products (associated circulars C-427/93, C-429/93 and C-436/93, Boehringer/Bristol-Myer-Squibb and others – GRUR Int. 1996, 1144) the ECJ established the following conditions, thus setting a further milestone on the way to opening markets:

1. “It is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and also carried out in such conditions that the original condition of the product cannot be affected by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States.”
2. “It is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer.”

3. “The new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorization of the trade mark owner.”

4. “The presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy.”

5. “The importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.”

“Parallel trade has the potential to realise savings in the healthcare service amounting to hundreds of millions of Euros.”
The basic principles were subsequently refined by various legal rulings on both the national level and by the ECJ (including the ECJ ruling from 26 April 2007 WRP 2007, 627 Swingward II) and now represent one of the foundations of parallelly imported pharmaceuticals.

The major antitrust disputes included the question as to whether pharmaceutical wholesalers are allowed to deny parallel importers entry to the distribution channels which they dominate. In a further landmark decision on 21 February 1995 (Az. KVR 10 / 94), the German Federal Court of Justice cleared the way for parallel importers, obliging pharmaceutical wholesalers to accept parallelly imported drugs in their product line. As a result, parallel importers were now in a position to be able to compete with the providers of domestic reference products, thereby gaining a considerable market share. The amendment to the prescriptions of the Sozialgesetzbuch V – SGB V (Social Code V) by the establishment of an obligation to dispense imported pharmaceuticals answered any remaining questions.

Having secured an opening in the market, parallel trade in pharmaceuticals was soon established, increasing its initially low market share (in places under two percent) to over ten percent in some member-states. In doing so, it enables healthcare provision systems to make annual savings adding up to hundreds of millions of Euros.

“The success of parallel trade provoked the resistance of the pharmaceutical industry.”

This success provoked further resistance, especially from the much-affected pharmaceutical industry, whose margins are under pressure. In the closing petition from 14 April 2008 (associated circulars C-468 / 06 – C-478 / 06) Advocate-General Dámaso Ruiz-Jarabo Colomer took up the case of the free movement of goods within Europe and thus parallel trade. He stated:
Furthermore, it does this whilst guaranteeing a high level of health safety. In their capacity as pharmaceutical enterprises, parallel importers are subject to exactly the same stringent EU regulations covering the production and labelling of pharmaceutical goods, the monitoring of drugs and corresponding liability legislation.

“The positive contribution of parallel trade to cost containment is incontrovertible.”

Parallel trade with pharmaceuticals will continue as long as sustained cost differences for pharmaceutical products remain in the European market. The consumer benefits from this form of inexpensive high-quality pharmaceuticals. The positive contribution made to cost containment in the healthcare service by parallel trade with pharmaceuticals is incontrovertible.

“Parallel trade makes an important contribution to establishing competition.”

Over the last 30 years, the parallel import of pharmaceuticals has often been denied the right to exist and its impending demise was an oft-heard prophesy. Nevertheless, in exactly the same time span, it has made a considerable contribution to establishing real competition and cost reduction in healthcare provision.

“Although the prohibition contained in Article 28 EC cannot be invoked against undertakings, the obligation not to impede the objectives of the treaty, and in particular freedom of trade between member-states, applies to them in the form of Articles 81 EC and 82 EC, which states that conduct which causes the artificial partitioning of national markets and impairs competition is incompatible with the treaty. It is therefore appropriate to mention the case-law of the Court of Justice on the free movement of goods, at least inasmuch as it concerns the partitioning of national markets.”
The free movement of goods within the European healthcare system

*The European healthcare market could draw much greater profit from the advantages of the free movement of goods. Parallel trade already uses corresponding opportunities, allowing for a greater competition within pharmaceutical supply.*

Dr. Jorgo Chatzimarkakis
Member of the European Parliament
The implementation of the European idea rests on the realization of the four freedoms that protect the ability of goods, capital, services and people to move freely within the internal market of the European Union. Based on this idea the longest period of peace and prosperity known on the European continent became feasible. Nevertheless, the EU member-states have not equally implemented the four freedoms. Whilst the free movement of people and capital experienced considerable progress during the last years, the service sector still lags considerably behind.

“The European health-care market uses only insufficiently the advantages provided by the free movement of goods.”

In particular, the European health-care does not yet use the four freedoms sufficiently. Although the healthcare market is unique in its specific requirements in terms of optimal and high-quality patient care, in the long-term there is a lot of potential to make much greater profit from the opportunities provided by competition and choice both in terms of quality of care and cost reduction.

“The pharmaceutical market would profit from greater choice.”

One example is trading with pharmaceuticals. Parallel trade already takes advantage of the price differences within national pharmaceutical markets in the EU in order to achieve cost reduction on the domestic market. This kind of trade provides an interesting alternative of establishing competition despite high level regulations. Both end consumer and patients are profiting from a considerable economic advantage that has in turn a significant impact on social well-being.

The strict regulation of distribution channels for pharmaceuticals in Europe outlines that parallel trade is also subject to strict sanctions. This becomes clear in the necessity of repackaging – medicines labelled and packed according to the requirements of one EU member-state cannot be distributed in another EU member-state without having their labelling and packaging being adapted to domestic requirements. Often, repackaging is a reasonable solution to meet the requirements set by a member-state. For example, one such requirement is to provide name and product description in the language of the importer state.
The free movement of goods within the European healthcare system

“A ban on repackaging would threaten the existence of parallel trade.”

As a result, the ECJ approved the right of pharmaceutical importers to repackage original products for distribution in another member-state. In case the right is rescinded – discussion on this issue comes up time and again – the existence of parallel trade would be threatened and the positive effect for free movement of goods and competition would fade away. According to European Law a comprehensive repackaging ban would constitute a measure equivalent to iSd Art. 28 EC and would thus demonstrate a breach of EU Law. Article 28 EC protects the free movement of goods and prohibits any restriction concerning the method of packaging, including any information on the package.

“End consumer and patients profit greatly from parallel trade.”

As a matter of principle, legislative measures must be proportional and should not restrict competition excessively and unnecessarily. In the case of repackaging, there are far more lenient instruments for ensuring patient protection effectively. Such methods include an overall monitoring of the packaging process or the requirement to obtain the manufacturer’s authorization for repackaging.

In the EU we work together to make healthcare more competitive. This includes the cross-border use of healthcare provisions that has so far been claimed by less than one percent of European patients.

“In the EU we work together to make healthcare more competitive.”

A further measure on EU level to achieve this aim was taken by the pharmaceutical forum in which I was also member of. This forum was set up by the European Commission in 2005 and finished its workings at the end of 2008. Within the scope of its three year project, the forum drew up a series of recommendations regarding patient information, pricing policy in the healthcare sector as well as cost-benefit considerations of using drugs against other treatment options.
“In the future, we need to make use of the advantages of free competition in the healthcare sector.”

In upcoming years we must firmly continue down the road we have already taken. In order to serve the common good we must fully use the advantages arising from the free competition in the healthcare sector.
Parallel importers are required to be licensed in Germany as pharmaceutical companies and to fulfil all the applicable regulations. In addition, the so-called simplified authorisation procedure guarantees that the medicinal products placed on the market by such companies comply with strict EU-legislation and German national legislation.
Parallel imports also need to satisfy all the qualifications of a pharmaceutical company.

EU law regulating the authorisation procedures for pharmaceutical products in Europe ensures that all drugs produced in a member-state are licensed according to the same regulations and that a Marketing Authorisation issued in a member-state has EU-wide accreditation. Hence, an authorised medicinal product originating from parallel import has been authorised based on the requirements for the proof of quality, safety and efficacy identical to the German reference product.

The fundamental requirements for parallel import are a valid Marketing Authorisation in the EU export country and its similarity with an authorised medicinal product in Germany to which the licensing dossier can make a direct and corresponding reference (reference product). The parallel importer is required to submit all documents to which he has access.

When submitting an application, the parallel importer is obliged to document its status as a pharmaceutical company. Notification in accordance with §67 para 1 AMG must be made at the responsible district authority before the start of trading.
The primary task of the simplified authorisation procedure is to establish that the parallel imported product is essentially similar with the German reference product. Only when the imported product and the reference product are demonstrated to be essentially similar in terms of the active ingredient, the pharmaceutical form as well as the route of administration is it possible to assume therapeutical conformity.

In order to reach a decision, the authorities work in close liaison with the licensing authorities of the export country to ascertain the validity of the Marketing Authorisation in the exporting country and data regarding the qualitative and quantitative composition of the product, shelf life, storage conditions and further characteristics.

When processing the authorisation procedure of parallel imports, the BfArM remains in close contact with the licensing authorities of other member-states. If the import product exhibits even minimal deviation in the composition of the excipients (according to ECJ rulings, this does not prevent parallel import of such a drug) it is necessary to rule out the possibility of further therapeutically-relevant differences.

In order to ensure that the drugs are monitored in accordance with all the requirements of pharmaceutical law, the parallel importer is required to name a qualified person to supervise the pharmacovigilance as specified by § 63a AMG and a qualified person for scientific advice (§ 74a AMG) respectively.

Furthermore, the importer needs a valid manufacturing license in accordance with § 13 AMG for every activity of the manufacturing process performed in accordance with the repackaging requirements for the German market. The importer also has to furnish the authorities with pictures of the product and drafts labels and texts.

“The simplified authorisation procedure ascertains product identity between the imported and German reference products.”
“The importer must notify all changes made to the imported drugs to the BfArM.”

The positive outcome of the evaluation results in granting a Marketing Authorisation for parallel import. This comes with the requirement to ensure continuing adaptation to the German reference product. Due to this close linking, the continuous accordance of the regulatory requirements and user safety are guaranteed. In his capacity as a pharmaceutical company, the parallel importer is subject to the duty of disclosure relating to any variation of its pharmaceutical products. It is also obliged to inform the BfArM of any variations of the imported medicinal product, any new export countries and other minor changes.

The parallel importer is bound to comply with the same regulatory framework as any other pharmaceutical company and Marketing Authorisation Holder in terms of the application for and administration and marketing of a Marketing Authorisation for a parallel import medicinal product. He is bound to uphold all applicable AMG regulations and valid legal provisions and ordinances applying to pharmaceutical companies. The manufacturer’s license, operating rooms and distribution of drugs are subject to monitoring by the responsible district authorities.

“It is essential to demonstrate due care and responsibility in the repackaging of parallel imported medicines.”

If evaluation of the licensing criteria returns a positive decision, the proposed repackaging of the import product is subject to critical assessment. In order to market the product in Germany the product must usually be repackaged in conformity with the German Medicines Act and labelled in German language. This requires the repackaging of the product (outer package and container) and production of a German language version of the package leaflet. The difference of pharmaceutical forms requires different packaging variations. The greatest care and responsibility are required not only from the perspective of pharmaceutical quality, but also in connection with promoting patient compliance.
Pharmaceutical supervision of parallel imports

As with all medicines, parallelly imported drugs are subject to strict safety requirements. Compliance with the requirements is ensured within the framework of a licensing procedure through supervision by the responsible state authorities and subsequent controls by the responsible state healthcare authorities.

Prof. Dr. Gerhard Vigener
Minister of Justice, Employment, Health and Social Issues of the state of Saarland (Minister für Justiz, Arbeit, Gesundheit und Soziales des Bundeslandes Saarland)
As with all pharmaceutical companies, parallel traders are subject to monitoring by the responsible health authority."

Such critics should bear in mind that parallel importers are subject to the same treatment as other pharmaceutical companies and manufacturers and are also subject to monitoring by the responsible state healthcare authorities. In monitoring the parallel importers, the state authorities make a contribution toward maintaining patient safety in the pharmaceutical industry including parallel importers.

Parallel importers are obliged to notify the responsible authorities before commencing any pharmaceutical-related activities.

In storing, labelling and re-packaging drugs with the aim of altering the exterior appearance of a product, parallel importers engage in pharmaceutical related manufacturing practices in the sense of § 4 para 14 Arzneimittelgesetz (AMG) (German Medicines Act) and thus require a manufacturing licence in accordance with §13 AMG.

The proportion of drugs reaching the pharmaceutical market via parallel import has risen from less than two percent to almost nine percent between 1998–2007. In 2007, the importers produced a turnover of over 2 billion Euros and in doing so, number amongst the winners on the German pharmaceutical market.

Indeed, the trend is rising and parallel and re-imports are assuming an ever-increasing importance in the pharmaceutical sector. This development brings large savings for the statutory health insurance system. § 129 para 1 Sozialgesetzbuch SGB V (Social Code V) obliges pharmacists to dispense drugs from parallel import, thus bringing considerable savings in pharmaceutical costs for the social security system.

In the rule, patients profit from parallel imports as they help to reduce co-payments. On the other hand, parallel imports have become an object of criticism and are often viewed as providing a gateway for counterfeit pharmaceuticals, bootleg drugs and products of lesser quality.
Pharmaceutical supervision of parallel imports

Before granting this license, the responsible healthcare authorities ascertain whether the importer observes and complies with the specifications included in the EU-GMP guidelines, the provisions relating to the state of science and technology, the licensing specifications and provisions of the AMG and the German Wirkstoffherstellungsverordnung (Pharmaceuticals and Active Agent Manufacturing Ordinance).

“Inspection by the healthcare authorities ensures compliance with all the relevant specifications.”

Within this context, parallel importers, just as all other pharmaceutical companies, are required to designate a named person to supervise the graduated plan as specified by § 63a AMG and a qualified person for scientific advice (§ 74a AMG). These individuals are required to provide proof of their expertise to the supervising authority. Within their company they are charged with the collection of new information regarding the risks associated with pharmaceutical products and with ensuring their evaluation and co-ordination. They are responsible for ensuring that the information on the containers of the drugs and the contents of the package inserts and specialist information conform with the notification of licensing.

These aspects are subject to scrutiny within the framework of a simplified authorisation procedure for every application made by a parallel importer. Thus before parallelly imported drugs can be brought into circulation, they must first be authorized for sale in Germany.

To this end, the German licensing authority, the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices) consults the licensing authority of the respective EU export state to obtain confirmation that the information contained in the licensing application conforms to existing information available for the import product forming the object of the licensing procedure.

“All the requirements made of the import company are subject to regular controls.”

Many of the licensed imported drugs are manufactured by the same pharmaceutical company in both the state of export and in Germany. As a result, the composition of the imported drugs is identical with that of the German reference product. In these cases, it is necessary to ensure that the nature and quantity of the active ingredient, the pharmaceutical form and the method of application are really identical.
“Checks in recent years have proven that parallel imports are not any more prone to adulteration or falsification than other drugs.”

Recent investigation results representative for the Saarland-based parallel importer registered that only 2/64 samples (2006), 4/69 (2007) and 3/49 (2008) were declared to be dissatisfactory (stand 24 October 2008). None of the faults identified involved any evidence of a false identity or an incorrect agent dosage. The tests did not identify any counterfeit pharmaceutical products.

These figures do not provide any evidence for the oft-heard phrase “parallel imports are a gateway for counterfeit drugs”. Rather, they demonstrate that parallel imports are no more prone to counterfeiting than other pharmaceuticals.

These comprehensive national and international requirements applying to parallel imports together with continual monitoring measures by the responsible authorities (which according to § 64 para 3 AMG are to be carried out at least every two years) and which take the form of so-called GMP inspections, ensure the safety of parallelly imported drugs.

The sampling and investigation specified by § 65 AMG play an important role in this process. For example, every year, a Saarland-based parallel importer submits 75 pharmaceutical samples for investigation and expert appraisal at the pharmaceutical survey institute specified by the state government, the AMI Nord GmbH (Official Medicines Control Laboratories OMCL) in Bremen.

The experts verify the samples against reference substances, test regulations, clearance and life-span specifications. It is vital to determine whether parallelly imported drugs contain the correct pharmaceutical substances in the right dosage and to ensure that they do not contain any impurities.
The economic framework conditions for imported pharmaceuticals

Parallel imports are one of the few instruments available in Germany that stimulate price competition and thus combat industrial price setting. The government has rightly decided to promote imported products.
“Improving the efficiency of the pharmaceutical provision in the statutory health-insurance system is a long-term task.”

Prescribing generics is one of the most important measures in optimizing the efficiency of pharmaceutical provision. As soon as a drug patent has expired, doctors should switch to a generic. Price competition resulting from generics usually produces a fall in price of the formerly more expensive primary product.

In other areas, where new products enjoy an unchallenged monopoly position without competition from me-too drugs (so-called “soloists”), price-reduction mechanisms (e.g. negotiations or a cost-benefit analysis) with a long history of use in other countries still have yet to be introduced in Germany.

The GKV-Wettbewerbsstärkungsgesetz (SHI Competition Re-enforcement Law) from 1 April 2007 introduced such a cost-benefit analysis but the German Institut für Qualität und Wirtschaftlichkeit (Institute for Quality and Efficiency in Health Care) will not be able to present its preliminary findings until towards the end of 2009.

Optimizing efficiency in the provision of pharmaceuticals by the statutory health-insurance system is a long-term task. Expenditure increases yearly – for example, spending of SHI funds increased by 27.8 billion Euros in 2007, representing a 6.7 percent increase against the previous year. The largest spending fields in hospital budgets (drugs and doctors’ fees) show the highest rates of increase.

It is noticeable that price increases for new pharmaceutical products in Germany – which themselves present only partial advantages over established drugs – are the direct result of the manufacturers’ decision-making process. Compared with other large European pharmaceutical markets, companies operating in Germany are in the privileged position of being able to market drugs at a price of their own choosing. The absence of negotiations or of official interventions in price formation for newly licensed drugs means that benefit analyses are crucial, as more affordable drugs such as far cheaper generics or the so-called “me-too drugs”, are of equivalent therapeutic value.
There are many reasons for the considerable price gap between European countries. On the one hand, the prices for drugs prescribed and paid for within state or legally regulated healthcare systems are set in many EU countries by negotiation. Price differences are also caused by differing living costs and rates of V.A.T. Some states subject drugs to reduced levels of sales tax, whilst others exempt prescription drugs from it altogether. Tourists to Southern European countries are often delighted when buying pharmaceuticals, which they know from Germany, at greatly reduced prices. This very situation has motivated the government to take action.

In order to ensure that pharmaceutical imports produce both savings and an increase in efficiency on a significant level, the GKV-Modernisierungsgesetz (SHI Modernization Act) from 2004 introduced a price gap clause in § 129 para 2 of the 5th Sozialgesetzbuch (Social Code V). Imported products also encompasses parallel and re-imports. Re-imports are drugs manufactured in Germany, sold abroad and then re-imported to Germany. Parallelly imported pharmaceuticals on the other hand are drugs manufactured in a third country and then imported to Germany. Parallelly imported pharmaceuticals are also required to contain identical agents in the same preparation.

All parallel and re-imports are licensed by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Federal Institute for Drugs and Medical Devices) according to the provisions of the Arzneimittelgesetz (AMG) (German Medicines Act) including evaluation of effectiveness, absence of risk, and quality in a simplified authorisation procedure. The drug is then repackaged and

"In the past there were almost no instruments through which to keep prices in Germany low."
Imported pharmaceuticals thus represent an excellent instrument for improving efficiency without loss in quality, especially in those areas dominated by “soloists”, as the high prices demanded by manufacturers for such products can be undercut by imported drugs. It is only understandable that the SHI set a quota for imported drugs.

Within this context, the German Association of Research-based Pharmaceutical Companies (VFA) criticizes “targeted state support (…) with guaranteed increases in turnover” for the re-importers. Such an opinion is understandable from the viewpoint of the pharmacy companies. Nevertheless, the SHI system does not exist in order to pay unnecessarily high prices for pharmaceutical products if they can be provided with the same quality at far more affordable prices. In this sense, imported drugs help to improve efficiency, quality and savings within the SHI system. In addition to the prescription of generics, import drugs are a further instrument with which to improve the efficiency of drug provision within the statutory health-insurance system.

An investigation revealed that the share of the 385 million Euros spent by one health-insurance fund on imported drugs in 2005 amounted to 22 million Euros, generating a saving of 2.3 million Euros. The list of imported drugs is headed by the agents Enoxaparin, Repaglinide and fusidic acid. Data from the same fund for 2007 shows that the total expenditure of 421 million Euros on drugs generated savings of 27 million Euros. 4 million Euros were saved by the improved use of imported drugs (GEK Pharmaceuticals Report 2008).
Commitment to safety in pharmaceutical distribution

Parallel imports have established themselves as an essential component in reducing costs and stimulating healthy competition on the healthcare market. Pharmaceutical wholesalers accept responsibility by cooperating only with reliable partners who are able to guarantee the necessary safety and quality.

Dr. Thomas Trümper
President and CEO of Andreae-Noris Zahn AG
(Vorstandsvorsitzender der Andreae-Noris Zahn AG)
Pharmaceutical imports are politically desired, and make a contribution to reducing pharmaceutical costs.

"Pharmaceutical imports are politically desired."

Imported medicinal products are currently the only source of competition for patented medicines. According to the German government, such imports save statutory health-insurance funds around 200 million Euros per year.

Yet these savings are only possible because the sector ensures compliance with the necessary safety standards. All medicines originating from parallel and re-imports are original products from the respective pharmaceutical manufacturer (and are thus subject to the latter’s quality controls) and are sourced by wholesalers operating within the EU.

"Parallel imports currently represent the sole source of competition for patented medicines."

VAD members have checked the authenticity of the medicines they supply from the very beginning. In the thirty years of pharmaceutical imports to Germany, there has not been one known case of import of counterfeit medicines.

Parallel and re-imports have successfully established themselves on the pharmaceutical market and make an important contribution to reducing costs in the healthcare sector. Even if the industry is keen to speak of a “grey market” in order to convey an impression of dubious legality, it must be recognized that pharmaceutical imports are politically desired, and make a contribution to reducing pharmaceutical costs.

Since its foundation, the German Association of Pharmaceutical Parallel Distributers (VAD) has campaigned successfully for high safety and quality standards in the import of pharmaceutical products.

Since then, VAD has established successful links to political decision makers, the relevant stakeholders and, of course, its own members. Without such relationships between people, it would be impossible to guarantee the high safety and quality standards so vital to pharmaceutical distribution.

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Commitment to safety in pharmaceutical distribution

This is of fundamental importance for us as pharmaceutical wholesalers. We can only cooperate with partners who share and support our high standards of safety and quality. Only under these premises is it possible for us to distribute imported medicines to our customers.

“We as wholesalers only work with partners who share our high quality standards.”

On the other hand, cost pressure in the pharmaceutical trade will probably continue to grow. All involved in the distribution of medicines will be faced with a number of new tasks. However, I am convinced that pharmaceutical importers will continue to proactively contribute to the safe supply of medicines and tackle the challenges ahead in a responsible manner.

“Not a single case of counterfeit medicines has been known since the inception of parallel trade.”

VAD has a more than successful track record of representing the interests of pharmaceutical importers in Germany. However, this task will not become any easier. On the one hand, the demands placed on pharmaceutical distribution are set to increase. The continually rising number of medicines available in Germany and the increasingly individual nature of medical care and higher patient demands have enlarged the product range. Within this process, pharmaceutical innovations often have a short shelf-life, tight storage temperature ranges and a high value of goods, all result-
Patient benefits

In the age of globalization, the German pharmaceutical market needs to open itself to imports in order to provide economically justifiable prices. However, such a development cannot be allowed to usher in a fall in standards. Reputable players in this process such as the VAD take measures to ensure that risks are minimized.

Wolfram-Arnim Candidus
President of the German Society for the Insured and for Patients
(Präsident der Deutschen Gesellschaft für Versicherte und Patienten e.V., DGVP)
The quality of pharmaceutical provision in Germany is very high. Nevertheless, this has recently been undermined by discount contracts and tenders from the statutory health-insurance funds. This has two aspects: on the one hand, it results in delays in the delivery of drugs to the patients; on the other, the necessity to provide different medicines per company and patient burdens pharmacists with unnecessary bureaucracy.

"The quality of pharmaceutical provision in Germany is high, but has been undermined in recent times."

Important in this context are new developments in prescription behaviour. Although doctors prescribe certain prescription-only medicines, directives from the statutory health-insurance funds mean they do not always know which drug the patient actually receives. Nevertheless, the doctors retain liability for their decisions – an untenable situation for both patients and doctors.

It is vital that the questions of pharmaceutical provision and the future shape of the health-care system calculates for the aspect of globalization. Germany is still the world’s leading exporter, a positive factor for our economic and social development. Nevertheless, it is vital that we do not close ourselves off from the import of products and services. This also applies to in the area of pharmaceuticals.

For patients, an effective and efficient system of pharmaceutical provision must fulfil the following criteria: 1. certified quality 2. high availability 3. economically justifiable prices.

Current developments in the German health-care service are producing low prices without supervision of treatment efficiency. This satisfies the demands by those in government and in the health-insurance industry for reducing costs and minimizing services, but does not satisfy the requirements of patients.

This situation is compounded by the influence (the legality of which is not entirely accepted) of the German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care), which undertakes “cost-benefit evaluations”, designed to reduce costs as intended by politics and the SHI system. These evaluations purport to be balanced, yet do not guarantee sufficient patient involvement. At best this restricts or at worst, even prevents the correct and sufficient provision of pharmaceuticals.
Patient benefits

“The health-care system must be open to the import of products and services.”

Parallel importers already use the opportunities provided by the free movement of goods in Europe and in so doing, promote competition on the pharmaceutical market. It is clear that parallel trade also brings considerable advantages for patients. Cheaper imported drugs reduce treatment costs, without reducing the level of service, since the drugs are identical.

Indeed, patients even make a double saving: reduced costs mean both stabilized insurance contributions and less co-payment at the pharmacy.

In order for patients to enjoy the full advantages of parallel trade, two conditions need to be given:

Firstly, both patient and doctor need to be assured that the imported drugs pass German licensing standards. Identicality with the German reference product is guaranteed by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Federal Institute for Drugs and Medical Devices). Indeed, a product can only be distributed in Germany after strict testing and licensing by the BfArM. Safety considerations also include the packaging text, package inserts and other information. Especially the repackaging of imported products has the potential to confuse patients – the importers need to provide both reliable alternatives and comply with the strict specifications.

Secondly, it is vitally important for patients that the drugs they need are easily and quickly available in pharmacies. Parallel trade must ensure swift despatch and permanent availability.

At present, there is danger of a “grey market” for medicines. Current price pressure and the promises of a growth market contribute to this possibility. This development can only be contained if the safety criteria of medical treatment is controlled and maintained in a sustainable fashion.

“Patients profit in various ways from cost savings resulting from parallel trade.”

Reputable associations such as the VAD need to ensure that risks to patients do not develop in the first place. This is possible by motivating those in the sector to maintain high quality standards and by offering support, so that all the stages in the process from purchase to transport, repackaging and storage follow the highest standards.
“Reputable associations such as the VAD ensure that patient risks do not develop in the first place.”

Furthermore, it is necessary to observe international regulations in order to prevent high-quality products from being excluded from the market. The financial and health interests of patients are not served by price harmonization resulting from national or international price controls.

We should continue to be open to market forces – whilst ensuring the highest of quality standards and excluding risks for patients – to enable us to take advantage of the benefits of a free market.
Using all distribution channels

Pharmacists in Germany consider themselves responsible for providing their patients with both expert advice as well as high-quality products. However, medicines also need to be affordable, and parallel imports provide an increasingly utilized alternative. Moreover, in terms of quality, they match those drugs produced in Germany in every respect.

Wolfgang Simons
President of the Marketing Association of German Pharmacies, regional spokesman for LINDA Pharmacies in the Cologne area
(Präsident des Marketing Verein Deutscher Apotheken e.V., MVDA e.V., Regionalsprecher LINDA Apotheke Gebiet Köln)
The parallel trade sector has undergone considerable change since its inception. Where imported medicines were previously delivered in undersized packages and with copied package inserts, the level of professionalism displayed by today’s parallel imports means that it is impossible to differentiate between imports and domestic products.

The concerns of many pharmacists – whether the long transport routes really allow for savings, or whether the cold chain can be actually maintained – have also proven themselves to be unfounded. Long co-operation between MVDA pharmacists and German pharmaceuticals importers has matured into a partnership of mutual trust.

“Thanks to strict safety regulations, pharmacists no longer have any objections to dispensing the more affordable parallel imports.”

This is due in no small part to the sharpened licensing and safety regulations to which imported pharmaceuticals are now subjected. Thus medicines imported from other EU states need to satisfy not only the German Arzneimittelgesetz (AMG) (German Medicines Act), but also strict European regulations.
In terms of quality and safety, imported pharmaceuticals are equal to those produced for the German market. Price differences between EU states enable the sale of these products at greatly reduced prices. Where possible, we draw the attention of our customers to more affordable import alternatives – a choice appreciated by an increasing number of customers.

“An increasing number of customers are coming to appreciate the advantages of parallel imports.”

The statutory health-insurance system has also discovered the potential for savings provided by imported medicines and has therefore campaigned for the introduction of a quota designed to the amount of such drugs dispensed in pharmacies.

The GKV-Gesundheitsreformgesetz (SHI Healthcare Reform Act) of 2000 incorporated this regulation into existing social legislation (§ 129 para 1 Sozialgesetzbuch V – SGB V – Social Code V). Since 2002, it has been designated that at least five percent of all finished drugs dispensed have to be imported products, specifically those bringing a saving of at least 15 percent or 15 Euros compared to the German reference product. This is an important saving in particular for the chronically ill.

For example, all products now contain a German package insert as a matter of course. Thanks to various regulations governing product labelling, the origin of all pharmaceuticals packaging can be retraced quickly and easily. The immediate packaging remains entirely intact anyway.

Even if the original medicine has already been licensed for distribution in Germany, imported pharmaceuticals are subject to separate verification by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Federal Institute for Drugs and Medical Devices) or the Paul-Ehrlich-Institut in order to ascertain their therapeutic indenticality with the original. Only after satisfying all quality requirements does the BfArM issue a license for distribution on the German market.

“Where possible, pharmacists draw the attention of their customers to more affordable import drugs.”
“The basis for the safe use of imported products remains competent advice.”

We as pharmacists have a special responsibility to provide patients with a level of competent and high-quality advice that merits their trust.

“Thanks to professional logistics, even rare imports can be made available quickly.”

Ordering non-stocked drugs is no longer a problem and thanks to professional logistics they can be obtained within 1–2 days.

The basis for the safe use of imported products remains competent advice. Inappropriate media reports and sensationalist propaganda about bootlegged drugs have unsettled many patients and have brought parallel trade an undeservedly bad reputation.

In such a situation it is necessary to differentiate between the criminal activities of illegal internet pharmacies selling counterfeit and smuggled drugs from outside the EU and registered pharmacies who sell entirely legal medicines which have been subjected to exhaustive and repeated official checks.
Reducing medicines expenditure

Parallel trade is an instrument with which statutory health insurers can reduce their spending on medicines. In order to make a significant contribution to this however, parallel traders need to improve their service in terms of price gap, medicine safety and availability.

Rolf Steinbronn
President, AOK PLUS – statutory health insurance for Saxony and Thuringia
(Vorsitzender des Vorstandes, AOK PLUS – Die Gesundheitskasse für Sachsen und Thüringen)
Spending on pharmaceuticals has increased noticeably. According to information from the Deutsche Apothekerverband (DAV) (German Pharmacists’ Association) in 2007, the statutory health-insurance funds spent an approximate 25.6 billion Euros on medicines, representing an increase of around 1.95 billion Euros in comparison to the previous year – an increase of more than eight percent.

A long-term decrease or reversal of this tendency is unlikely. This trend is exacerbated by an increase in the number of total prescriptions and the selection of newer, more expensive and innovative medicines instead of much cheaper established drugs. In 2006 for example, the increase in turnover for the statutory health-insurance funds resulting from this trend amounted to over 900 million Euros.

“Reducing costs in the statutory health-insurance sector requires reductions in pharmaceutical expenditure.”

In order to reduce costs in the long-term, statutory health-insurance funds need to reduce expenditure on pharmaceuticals. A step in this direction could involve the increased use of cheaper original products originating from parallel trade. To realize significant savings, the AOK believe that parallel traders also need to play their part.
Reducing medicines expenditure

By introducing ever-more new medicines into their product range, the companies had to a certain extent, shot themselves in the foot, as the price gap related to non-imported versions of these agents is sometimes so marginal that opting for parallel products is not as attractive.

The government shares this view. It has specified that five percent of all drugs sold by pharmacies must be imported products – yet this figure only includes those with a price difference to the equivalent German product of 15 percent or 15 Euros.

“The statutory health-insurance funds can play their part by concluding discount contracts.”

The statutory health-insurance funds also need to play their part. Since 2003, the government has passed legislation allowing them to negotiate special conditions with pharmaceutical companies within the framework of discount contracts, and in so doing, buy large quantities of pharmaceuticals at lower prices. This is also possible for parallel imports. AOK takes regular advantage of this option: in 2007, we were able to secure price reductions of up to 37 percent within the framework of discount contracts for more than 40 groups of agents. In doing so, we have made a contribution to ensure the future of high-quality pharmaceutical provision at affordable prices.

We will remain dedicated to this aim over the coming years – especially in view of the likelihood that the continued budgetary deficits will continue to have a negative financial impact on the health-insurance funds.

“Parallel trade should concentrate on the distribution of those products which guarantee a significant price saving and availability.”

In addition, the current debate is complicated by questions regarding the safety of medicines, counterfeit drugs and compliance, which is significantly reduced by unattractive packaging. In order to remain competitive, the traders should concentrate on a small number of products for which it is possible to guarantee availability and a significant price difference. Accordingly, medicines should be repackaged in a way that leaves no room for misunderstandings.
“As one of the largest statutory health insurers, we work together with reputable companies who provide only licensed products.”

In our 125 year history, AOK has stood for both safety and comprehensive medical provision. With 25 million clients, we insure almost a third of the population, and as the largest society, thus carry a special responsibility for the health of the nation. In terms of pharmaceutical provision, we therefore work exclusively with reputable companies who, providing only licensed products, ensure the highest of standards in manufacture and distribution. In this way, we are able to guarantee our members high-quality provision whilst reducing costs.
Opinion:
Safe provision of imported pharmaceuticals

Parallel imports can be used to reduce expenditure within the statutory health-insurance system. Nevertheless, control mechanisms need to be refined in order to rule out danger to health from imported pharmaceuticals. Disproportionate restrictions to parallel trade would, however, be counter-productive.

Dr. Marlies Volkmer
Member of the German Parliament, rapporteur on pharmaceuticals, SPD healthcare working group (MdB, Berichterstatterin für Arzneimittel der Arbeitsgruppe Gesundheit der SPD-Bundestagsfraktion)
Increasing expenditure within the statutory health-insurance system is a pressing problem to which the government needs to react. Expenditure on pharmaceuticals increased by 6.7 percent per insured person in 2007 compared with the previous year. Medical progress and demographic developments will only add to this problem. In order to address this trend, we need to take advantage of every opportunity presented to optimize medical provision.

"We need to take advantage of every opportunity presented to optimize medical provision."

An important instrument in this process is the import of cheaper pharmaceutical products. Pharmacists in Germany are legally required to dispense imported pharmaceutical products. The estimated potential for savings lies between 300 and 400 million Euros per year. The proportion of imported drugs in the total turnover of statutory health-insurance funds has steadily increased in previous years. In 2007, 8.9 percent of all drugs paid for by the statutory health-insurance funds were imports. This represents a turnover of 2.5 billion Euros.

The indirect savings brought about by imports are even greater. Denmark, Malta and Germany are the only EU member-states in which pharmaceutical companies are free to set prices for drugs themselves. Moreover, certain products are not subject to any upper price limits for reimbursement via the statutory health-insurance funds. These are often precisely the drugs for which the highest prices are charged in Germany.

"The indirect savings possible through the use of imported pharmaceuticals are enormous."

Importers, on the other hand, are able to use price advantages gained through cheaper purchases on other markets. German patients benefit directly from cheaper drugs in pharmacies, but also indirectly by savings in their insurance premiums, which, furthermore, is conducive to contribution stability.

Parallel trade prevents manufacturers from demanding excessive prices in Germany for non-reference-priced drugs. Competition with the importers leads to reduced prices, providing a direct benefit for statutory health-insurance funds.
Opinion: Safe provision of imported pharmaceuticals

“Competition with the importers leads German manufacturers to reduce their prices.”

The SPD parliamentary group in the German Bundestag welcomes the new draft directive. This directive has the potential to contribute to safeguarding both public health and the functioning of the single market in pharmaceutical products.

The European Commission directive proposals from December 2008 took account of member-state criticism of the initial commission proposals. These stipulated that breaking of the original manufacturer seal should only be permitted for the licence holder or the end-consumer. All repackaging activities without the permission of the licence holder would have become illegal. In view of the significance of parallel imports and the functioning of the single market, such a ban on repackaging would have been disproportionate.

In view of the significance of parallel trade, a ban on repackaging would have been entirely disproportionate.
Opinion:
An essential instrument for restricting expenditure on pharmaceuticals

Growing expenditure on pharmaceuticals represents an increasing burden on the health system. This can be ascribed for instance to the high cost of patented medicines. Parallel trade can work to reduce costs and generate more competition on the pharmaceutical market.

Biggi Bender
Member of the German Parliament, Health spokesperson, The Green Party (MdB, gesundheitspolitische Sprecherin Bündnis 90/Die Grünen)
The costs of some drugs are simply incomprehensible."

This applies to innovation in particular. The introduction of new agents generates astronomical price increases, even if these developments bring only little improvement in comparison to established medicines. Thus for example, the conflict over the use of the medicines Lucentis and Avastin for the treatment of old-age blindness attracted great attention. Whilst an injection with the established Avastin costs 50 Euros, a comparable dose of the new Lucentis amounts to 1500 Euros. Such price increases cannot be explained with differing costs for research and development.

"Innovative pharmaceuticals often generate astronomical costs."

The certainty that expenditure on pharmaceuticals will increase is not necessarily cause for pessimism. The fact that improvements to medical technology enable us to treat illness better than before is something for which we should be grateful. After all, providing the best possible health provision is the Raison d’être of every healthcare service.

Moreover, increased prices for pharmaceuticals could produce savings at other stages of the healthcare system. If for example an outpatient drug-based therapy prevents an expensive hospital stay, this could result in considerable cost savings.

Nevertheless, we need to consider the question of increasing pharmaceutical prices, as many are just not comprehensible. This applies to many over-the-counter drugs. That twenty Aspirin cost four Euros less in a Greek pharmacy than in a German cannot be explained by higher personnel costs.
Opinion: An essential instrument for restricting expenditure on pharmaceuticals

“Lively competition is an important step towards the goal of a long-term reduction in pharmaceutical prices.”

Such savings are miniscule in comparison with the unrestricted price increases in patented agents. The core problem is that the prices in Germany are individually set by the manufacturers and there is no incentive for them to sign discount contracts concerning patented ingredients with SHI funds. Discount contracts with insurance funds play no role in this area.

In view of this, we welcome the provision included in the last healthcare reform introducing a cost-benefit analysis for expensive pharmaceuticals. Based on this, insurance funds should now be able to set limits for patented pharmaceuticals.

Nevertheless, the reform did not change the regulations stipulating that pharmaceuticals are reimbursable (i.e. can be prescribed to publicly insured patients) immediately after licensing. The parties negotiating the reform were unable to agree on a “fourth hurdle” which would make this reimbursability dependent not only on proving the safety, effectiveness and quality of a drug but also a suitable cost-benefit relationship.

“The cost-benefit evaluation introduced by the recent health reform is a welcome development.”

Once a drug has been declared as reimbursable at the price set by the manufacturer, changing this status or even altering the price to be paid will be possible in only a handful of exceptional cases. As a result, the development of prices for patented drugs will continue in its current form without any relationship to medical requirements.
Within this situation, parallel trade of pharmaceuticals will continue to have great significance for statutory health-insurance funds, not least due to the direct savings (estimated at around 250 million Euros) which it is set to bring. Even greater savings are expected from price competition, which it should introduce on an otherwise competition-free market.

“The government should not pay too much notice to the claims of the pharmaceutical industry.”

The pharmaceutical industry is considerably disturbed by parallel trade. The government should not pay too much notice to such complaints. Access to therapeutic progress must remain affordable: this need has priority over safeguarding the profits of what is an already highly profitable business segment.
Opinion:
Stimulating competition in the healthcare sector

Since its inception, the legal framework regulating parallel trade has become even more complex and unclear. Future alterations must create an appropriate balance between state intervention and reinforcing competition. The goal is to create a dynamic and flexible pharmaceutical market.

Daniel Bahr
Member of the German Parliament,
Health spokesman of the FDP parliamentary party
(MdB, gesundheitspolitischer Sprecher der FDP-Bundestagsfraktion)
pharmacies and statutory health-insurance funds foresees a 5 percent minimum sales quota for imports. These turbulent developments reflect the differing estimations of the effects of pharmaceutical imports.

“Imports cause pharmaceutical firms to reconsider their pricing policy.”

Pharmaceutical imports are a viable practice because of price differences between states, which themselves are caused by a number of different factors. These include differences in taxation, costs of manufacture, but also the various price regulations applicable in various countries. In this way, it is possible to sell trademarked medicines on the German market at a lower price compared to products produced directly for the German market. German drug manufacturers thus have cause to reconsider their pricing policies, if imports reach a specific market share.

The conditions under which pharmaceuticals can be imported to Germany were subject to considerable and repeated change in recent years. The aim of these undertakings was to use pharmaceutical imports in order to bring a change in prices in those areas where the absence of generics results in monopoly situations.

“Pharmaceutical imports stimulate competition on the German drugs market.”

The obligation for pharmacies to sell imported drugs established in 1989 was abandoned in the mid-1990s within the framework of the seventh alteration law to the Sozialgesetzbuch V (SGB V) (Social Code V). This reversal was necessitated by free-market concerns. The health reform of 2000 reintroduced this provision, which was again modified by the GKV-Modernisierungsgesetz (SHI Modernization Act) to the effect that sales of imported drugs became compulsory if they represented a saving in comparison to the original medicine of at least 15 percent or 15 Euros. Moreover, the framework agreement concluded between
Opinion: Stimulating competition in the healthcare sector

The research-based pharmaceutical companies are especially affected by this situation and complain that it could undermine the mid to long-term viability of Germany as a location for pharmaceutical production. The core of their complaint: no industry is able to maintain production under interior economic conditions, when faced by competitors able to undercut domestic prices through purchasing the same product in a third country at a price fixed by the state. A state distribution guarantee for such products represents a further unfair advantage.

“Negative effects of engineered price competition must be prevented.”

In order to prevent negative consequences resulting from engineered price competition, it is necessary to pay attention to the conditions under which pharmaceuticals are imported. A controversial topic is whether there should be a minimum quota for the distribution of imported pharmaceuticals. It is first necessary to resolve the question as to whether the imported medicines would be able to compete on the German market without such a provision (equal attractivity is assumed) or whether this would result in legal problems. We also need to take into account how the provisions regulating imported pharmaceuticals are to be integrated in the overall regulatory framework of a market which is already clearly over-regulated.

“The overregulation of the healthcare market undermines market dynamism and growth.”

With an annual expenditure on medicines of around 28 billion Euros, pharmaceuticals assume a prominent position in the German healthcare system. By using regulatory intervention, the government has made repeated attempts to reduce the financial burden on the statutory health-insurance funds. The success was only short-lived. Various government decisions in other areas – such as the increase in V.A.T. – has even had the opposite effect, resulting in rising expenditures.
The current regulatory jungle is almost impenetrable even for experts. The permanent addition of new provisions has lead to a chaos of overlap and feedback mechanisms. Such overregulation ultimately affects the dynamism and growth potential of the German pharmaceutical market.

“The state should provide a framework, not regulate every detail.”

The FDP parliamentary party demands the adoption of a competitive approach to the pharmaceutical market. Good, affordable healthcare provision is a priority but it is also necessary to secure the future of Germany as a location for pharmaceutical manufacturing, in which innovation pays off. This requires the consistent application of competition law in order to prevent the misuse by individuals of a market-dominating position. Such a programme also requires the restriction of national interventions on the necessary level. The state should restrict itself to providing the legal framework of market activity, leaving the market-players to resolve the details.
Financing and participating in the EU healthcare market

In order to remain viable, the healthcare systems in the EU member-states need to reduce their expenditure. Parallel trade can make an important contribution towards this aim. European decision-makers need to produce financially viable social structures – if necessary at the cost of losing regional business locations.

Günter Danner
MA, PhD, deputy director German Social Insurance Representation in Europe and consultant to the board of Techniker Krankenkasse
(Stellvertretender Direktor der Europavertretung der Deutschen Sozialversicherung und Persönlicher Referent des Vorstands der Techniker Krankenkasse)
Germany is the only EU state with a health insurance scheme that allows its richer citizens to opt out of the system. A further peculiarity is the emphasis placed on in-kind transfers at the point of delivery. Social models with traditional reimbursement of previously “officially” fixed tariffs – such as France, Belgium or Luxembourg – have retained this in core, but as in the case of France, they have been replaced by new electronic methods of direct accounting.

All EU systems are subject to enormous cost pressure, caused not as some would have us believe by increasing life expectancy, but due to the effects of medical progress combined with acute income problems. It cannot be expected that expenditure on healthcare will undergo a significant reduction in the near future. A whole series of reforms and “cost-containment laws” have attempted to delay this development with often only short or medium term success.

"Pharmaceutical research is expensive but an important part of medical progress."

Spending on pharmaceuticals remains a central topic for a number of reasons. The well-known interface between social provision and “big business”, local facilities and in some places, global concerns, contributes to this. Moreover there is an ill-defined yet pervasive distrust of this industry, especially its world-famed representatives.
Financing and participating in the EU health-care market

On the other hand, despite all “me too” problems, fundamental and hope-inspiring innovations are still being developed. Pharmaceuticals are very expensive but they are an essential area of medical progress.

“The savings potential of parallel imports is considerable.”

On a EU level, the question of pharmaceutical provision affects not just social policy; industrial and research policy is also involved. “Brussels” is and remains primarily a deregulating economic model. The term “EU social model” is designed to reconcile, but suffers from the fact that it is not particularly well defined. The so-called re-imported pharmaceuticals play a significant role within this context. In countries without a positive list for pharmaceuticals and thus with a much more open-market access to the local socially-financed medicines, the savings produced are considerable.

The AOK Bundesverband (AOK Federal Association) in Germany estimated such savings made in 2007 at around 200 million Euros. The statutory health-insurer Techniker Krankenkasse alone saved around 13 million Euros. These can hardly be considered as significant sums when compared with overall budgets, but are significant when we consider how quickly additional expenditure adds up.

“Social systems generally have little leeway for additional cost savings if they want to ensure patient access to excellent provision.”

Social systems generally have little leeway for additional cost savings if they (as we do) seek to ensure patient access to excellent provision. Critics at some point lack clear leadership from Europe. They emphasize that in the conflict of interests between national economic policy and ensuring financially viable social structures, there is a tendency toward preferring the interests of the market.

“Increased European regulation does not necessarily produce better results.”

Growth and securing the future of industrial locations are key concepts. They make sense, but must not be allowed to neglect or endanger social justice, an important part of European political culture, which only nowadays is beginning to come into discussion in America. The
diversity of access to drugs is important, especially in weaker systems. More “Brussels” in the health-care market is not necessarily a guarantee for improvement for a problematic market. Europe represents our common future in many senses; but it is important that we deal carefully with the change involved in this process. We must not risk tried and tested instruments before having found convincing alternatives.
Interview with VAD

Edwin Kohl, the president of the German Association of Pharmaceutical Parallel Distributers (VAD) comments on the development, challenges and future of parallel trade in Europe.
What are the reasons for this success? What are the advantages of parallel imports?

Parallel imports reduce the costs of medicine. Patients experience direct benefits from this practice by paying less for the same product when visiting the pharmacist. Parallel imports have an even greater effect on statutory health-insurance funds, to which drugs represent a large and increasing expenditure and which suffer even more greatly under the effects of expensive drugs. Parallel trade generates noticeable savings.

What represents a realistic savings volume?

The statutory health insurance funds estimate that the healthcare system could save a total of 388 million Euros by using parallel imports. As medicines are comparatively expensive in Germany, we enable many medicines to be sold at an average saving of 10 percent.

What influence do parallel imports have on the overall pharmaceutical market?

In addition to the direct cost reductions, parallel and re-imported medicines have the effect of stimulating price competition in what is otherwise a highly regulated market environment. This applies especially to the patent-protected market segment. The introduction of, or even the mere announcement of parallel imported medicines, brings the manufacturers of German equivalents to reduce or at least maintain prices.

The parallel and re-import of medicines to Germany is a practice with a thirty year history. How has the branch developed since its inception?

To our great satisfaction, parallel trade has developed into a successful niche market. Starting this practice thirty years ago represented an uncertain risk. It was by no means certain that the European internal market would develop so quickly and as successfully as it did. Today, German pharmacies sell around 60,000 medicines per day originating from parallel trade. Employment has also benefited: an extra 3000 jobs owe their existence to this branch of the market.

What was the role played by the European single market and its stepwise realization?

A decisive role: the common market and its realization of the four freedoms made parallel trade possible in the first place. National laws and regulations were subject to increasing harmonization in areas such as pharmaceutical testing, licensing and safety regulation. In this way, parallel trade was able to take ever-greater advantage of the price gap between national pharmaceutical markets in order to provide patients in Germany with more affordable medicines of identical quality.

What influence do parallel imports have on the overall pharmaceutical market?

In addition to the direct cost reductions, parallel and re-imported medicines have the effect of stimulating price competition in what is otherwise a highly regulated market environment. This applies especially to the patent-protected market segment. The introduction of, or even the mere announcement of parallel imported medicines, brings the manufacturers of German equivalents to reduce or at least maintain prices.

The parallel and re-import of medicines to Germany is a practice with a thirty year history. How has the branch developed since its inception?

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What is the role played by the VAD?
We understand our role as ensuring that those in government, authorities and the public are aware of the social and economic profits derived from parallel trade and re-imports. As part of this, it is in our interest that all our activities are coherent and transparent. As our branch represents only two percent of the European market, our means are restricted. Yet we believe that the advantages of parallel trade will prove convincing in the long-term.

The safety of imports is the subject of repeated doubts. How do you guarantee the safety of imported pharmaceutical goods?
To start with, it is necessary to realize that the medicines which we distribute are trademarked drugs verified by the BfArM for their therapeutic identicality with their German counterparts. In order to satisfy all legal requirements, the drugs need to be repackaged after being imported. They are then labelled according to German law and are provided with a German package insert. This serves the needs of patient information and eliminates the risk that the medicines are administered incorrectly. We as distributors are subject to the same legal requirements as pharmaceutical manufacturers and require a formal manufacturing license. This is obtainable only after passing extensive tests and is subject to regular controls.

How do you see the future for your branch?
The single European health market is in a very early phase of development. I am sure that we can expect very interesting times. The markets will become ever more integrated and the rules will be harmonized. This will provide great opportunities for parallel trade. We also hope to
take greater advantage of the Eastwards expansion of the EU. In view of the difficult condition of European health systems and current demographic developments, cost reduction of high quality provision is of ever-increasing significance.
Parallel importing is a success story. Generating billions in turnover, it creates new and secure jobs and provides the German healthcare system a direct savings volume of around 200 million Euros. The savings resulting from the competition which it stimulates are estimated as being significantly higher. The significance of pharmaceutical imports has also received political recognition and receives support, for instance through the dispensing obligation of parallel imports.
If the trade of parallel imports was still a small niche market in the 1970s, the model increasingly established itself in the 1980s and 1990s and now generates billions in turnover. The effects are also to be felt on the job market: around 3000 people have been ensured a safe position in a branch with a strong future.

In 2008, parallel trade sold 45 million packages of medicines. From 1998, the cumulative number registered an impressive 329 million packages. This amounts to an extrapolated 25 million packages despatched from the importer’s warehouses between 1998–2008. It is a striking statistic that up to now, there has not been a single registered case of counterfeit drugs.
How drugs come from the manufacturer to the patient

*An original pharmaceutical imported from an EU member-state to Germany
Parallel importers purchase original pharmaceuticals in an EU member-state and import them to Germany. Cheaper purchase prices enable the importers to sell the medicines to German wholesalers at a cheaper price, thus providing lively competition to manufacturers producing for the German market. The parallel importers are subject to the same strict licensing and pharmaceutical regulations as apply to original manufacturers.
Glossary

A **Aut-Idem-Regulation**: This ordinance requires pharmacists to dispense a cheaper article when choosing between two compounds with identical agents, as long as the prescribing doctor has not specified that replacement of the drug is not to be permitted.

B **Blister**: Medicines are enclosed by so-called push-through packs also known as blisters.

C **Cost-benefit evaluation**: This instrument was launched within the framework of the GKV-Wettbewerbstärkungsgesetz (GKV-WSG) (SHI Competition Re-enforcement Law) in order to make pharmaceutical provision more cost-effective. Medicines should no longer be assessed just according to their therapeutic benefit, but also in view of their price-performance ratio. The Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) (Institute for Quality and Efficiency in Healthcare) founded in 2004 conducts the scientific analyses that provide the basis of the decisions made by the Gemeinsame Bundesausschuss (G-BA) (Federal Joint Committee) over which drugs to pay for.

D **Discount contracts**: Since 2003, health-insurance funds are permitted to conclude discount contracts with pharmaceutical manufacturers in order to reduce expenditure on pharmaceuticals. The funds issue provision contracts for particular medicines and the manufacturer offering the lowest price is given the monopoly of supply.

E **EudraVigilance**: The central computer database is operated by the European Drug Agency since December 2001. It collects EU-wide information regarding the undesirable side-effects of licensed medicines. The data is only available to official bodies. Pharmaceutical manufacturers only have access to the information which they submit themselves.
European Medicines Agency (EMEA): Located in London, the EMEA is the European institution responsible for the scientific evaluation of licensing applications as well as the monitoring of drug safety. Based on the evaluations of the EMEA, the European Commission decides on the licensing for the entire EU single market on the basis of a “centralized procedure”. As a co-ordinating institution, the agency gathers information about the evaluation, licensing and monitoring of drugs within the EU and makes them available to the authorities in the member-states.

Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM): The federal authority under the Federal Ministry of Health is responsible for the national licensing of pharmaceuticals as well as their registration and risk monitoring.

German Medicines Act (Arzneimittelgesetz, AMG): The law over the trade in pharmaceuticals regulates the production, clinical testing, licensing, dispensing and controlling of drugs. All the requirements made in this area apply to both manufacturers as well as parallel importers.

Generics: These imitation compounds use the same agents as original medicines but can be manufactured and sold more cheaply. A generic may only be distributed after the patent of the original has expired.

Good Manufacturing Practice (GMP): Strict standards are set for the quality of the production sequence. The GMP is specified in corresponding directives and guidelines and is applicable for all medicine including imported drugs.

Immediate packaging: The term refers to the packaging coming into immediate contact with and enclosing the medicine, thus protecting it from external influences.

Imported pharmaceuticals: Imported pharmaceuticals are bought from wholesalers in particular EU countries and then imported in a third EU country e.g. Germany. The importers take advantage of the price differences between the country of origin and the target land. It is common to differentiate between parallel imports and re-imports depending on the location of manufacturing.

Import quota: Pharmacies are obliged to ensure that a minimum of 5 percent of their sold stock is covered by parallel imports. Only those products which fulfil the price gap clause are included in this statistic.

Manufacturing licence: According to § 13 AMG, pharmaceutical manufacturers in Germany require a manufacturing licence in order to produce medicines. Parallel importers also require a manufacturing licence from the state authorities before they are permitted to start distribution of parallelly imported drugs. These licenses permit the parallel importers to label the imported medicines in accordance with the AMG and pack them in the package sizes usually prescribed in Germany.
Me-Too drugs: These medicines, also known as analogue compounds copy a licensed and patented medicine with only minor deviations to the original. This allows them to be patented as a new product.

Parallel distribution: Pharmaceuticals participating within a special procedure conducted by the European Medicines Agency can be licensed for the entire EU. Possession of such a licence obviates the need for individual licences from each member-state and the product can be distributed parallelly in all EU member-states.

Parallel importer: The business area of parallel importers is the parallel import of medicines. In order to store medicines, re-label them in German and where necessary, provide new packaging, these importers require a manufacturing licence in accordance with § 13 AMG. Parallel importers are also required to fulfil all further requirements of the AMG for the manufacture and distribution of medicines. For instance, parallel importers always have a qualified person (§ 15 AMG), a manager responsible for the graduated plan (§ 63a AMG) and an information executive (§ 74a AMG).

Parallel imports: The great majority of pharmaceuticals produced for the German market are manufactured in other European member-states. As these products are brought to Germany by both the manufacturer and importers, the product is called a parallel import.

Pharmaceutical Prescribing Efficiency Act (Arzneimittel-versorgungs-Wirtschaftlichkeitsgesetz, AVWG): The law which came into force on 1 May 2006 specified various alterations to the Arzneimittel-Preisverordnung (Drugs Price Ordinance) with which the annual SHI expenditure on pharmaceuticals should be reduced. The measures include reductions in the reference price as well as an exemption of co-payment on low-priced drugs.

Pharmacovigilance: The term refers to the continuous and systematic monitoring of the safety of pharmaceuticals. The European legal foundation is provided by directive 2001/83/EC. Information regarding side-effects is collected from all member-states and stored in the central database EudraVigilance. In Germany, the AMG obliges all pharmaceutical companies to document and notify the authorities of all undesirable side-effects.

Price gap clause: The clause refers to the selling of cheaper imported pharmaceuticals. According to the clause, the final price for the insured patient has to be at least 15 percent or at least 15 Euros lower than the price for the respective German drug. Imported medicines satisfying this price difference can be used to fulfil the import quota.

Re-import: Re-imports are pharmaceutical products manufactured in Germany and exported to other EU countries. They are then purchased in these countries at a lower price and re-imported to Germany. The price difference enables the re-importer to undercut prices for products distributed directly in Germany.
SHI Competition Re-enforcement Law (GKV-Wettbewerbsstärkungsgesetz, GKV-WSG): The main provisions of the law from 1 April 2007 concern the strengthening of competition between the statutory health-insurance funds, a stronger emphasis in healthcare on cost-benefit evaluations as well as the reform of private health-insurance.

SHI Modernization Act (GKV-Modernisierungsgesetz, GMG): This law from 2004 designed to modernize the statutory health-insurance system, reorganized the financing of the SHI. For example, a flat rate “surgery charge” for a doctor’s visit was introduced and the levels of co-payments by the patient increased. The price gap clause is of particular significance for parallel trade.

Specific mechanism: The new EU members having joined within the scope of the 2004 and 2007 expansions are subject to the “specific mechanism”. Most of the states have no equivalent to the patent laws valid in West-European states. However, as the accession of these states means that the introduction of a drug by a patentee in the new state results in exhaustion, the patentee cannot use the patent to prevent a parallel import in the old member-state, the freedom of the movement of goods anchored in the EU treaty is restricted by the “specific mechanism.” The specific mechanism is specified in the accession treaty.

Therapeutical identity: Parallel and re-imported pharmaceuticals match trademarked pharmaceuticals licensed in Germany in terms of their composition and effect i.e. they have identical contents and an identical therapeutic effect. This identicality is verified in Germany by the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) (Federal Institute for Drugs and Medical Devices).