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IMPORTERÓW RÓWNOLEGŁYCH
PRODUKTÓW LECZNICZYCH

Lodz, 8th May 2008

Reply to the document of the Enterprise and Industry Directorate General regarding the proposal regarding improved protection of patients from the risk related to counterfeit medicines for human use, submitted for public consultation on March 11th, 2008.

The Association of Parallel Importers of Medicinal Products (SIRPL) is pleased with the opportunity to take part in the consultation organised by Enterprise and Industry Directorate General in connection with work conducted on preparing new solutions aimed at combating counterfeit medicinal products in the pharmaceutical supply chain.

We ardently support the Commission's efforts aimed at completing a detailed analysis of the growing problem of counterfeit medicinal products, and undertaking effective steps aimed at eliminating the phenomenon. Counterfeit drugs are a major risk to public health. They are also a major issue from the point of view of operation of the European pharmaceutical sector. Reaching a position in common regarding this issue by representatives of the industry and by employers is of key importance for maintaining security of the European pharmaceutical distribution chain.

Hence, we are trying to take active part in the debate on security of supply chain in Europe. We also emphasize the efforts of the parallel distribution industry to safeguard the supply chain against counterfeit or substandard quality product.

Considering the above, we are concerned about some of the propositions included in the document issued for public consultation by the Enterprise and Industry Directorate General on March 11th, 2008. We cannot support regulations effecting in restricting competition resulting from parallel import on the market of patent-protected medicines. Likewise, we cannot endorse proposed solutions, which detract public opinion's attention from real threat of street sales or illegal trading on the internet.

Introduction

Association of Parallel Importers of Medicinal Products was established in September 2006, as a professional and representative forum authorised to represent the position on parallel import in Poland and in Europe. It includes 19 ordinary members and 7 supporting members. Since October 25th, 2007, the Association of Parallel Importers of

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IMPORTERÓW RÓWNOLEGŁYCH
PRODUKTÓW LECZNICZYCH

Medicinal Products, has been chaired by Tomasz Dzitko, President of Delfarma, which has been a leader in parallel import in Poland.

All products distributed by members of SIRPL have Polish or European regulatory approval and are only distributed within the European Economic Area, through official distribution channels comprising authorised pharmaceutical wholesale warehouses and pharmacies.

Priorities in SIRPL's activities are:

- safeguarding free flow of medicines and allowing patients to fully exercise their freedom of choice;
- promoting and supporting the development of parallel import of medicines among the society, in particular among doctors, pharmacists, patients and pharmaceutical industry businesspeople, as the only price competition for drugs subject to patent protection, and a way to introduce innovative drugs on the Polish market, at accessible prices;
- ensuring that authorities responsible for healthcare policy accept and support the development of parallel import, so as to leverage patients and national budget benefits.

Parallel import of medicinal products in Poland became possible as the country joined the European Union on May 1st, 2004. First medicines from parallel import appeared in Poland in November 2005. To date, more than 200 permissions have been issued for marketing of drugs from parallel imports. Every year, parallel import brings tens of millions of zlotys in savings for the patients.

In 2007 alone, patients in Poland saved over 30 million zlotys thanks to parallel import – 5 million of that amount is the balance of direct savings resulting from lower prices of drugs from parallel import, 25 million result from indirect savings arising from the manufacturers' decreases of prices in response to parallel import. The price pressure imposed on producers of innovative drugs stirs competitions, thus bringing savings for customers. Imported medicines are several percent, up to more than ten percent cheaper in Poland than drugs distributed the traditional way. Their emergence on the market causes producers to reduce prices for their products even as much as by 50 percent.

In the amendment of the act on healthcare services financed from public money, which came into force on October 31st, 2007, parallel importers became included among

entities allowed to apply for entering the cheaper drugs on lists of refunded medicines, and for establishment of official price. Refunding of drugs from parallel import entails more savings – not only for patients, but also for the National Health Fund – the public paying authority.

Security of the distribution channel vs. risk of counterfeit drugs in parallel distribution

SIRPL affirms with all responsibility, that the supply chain in parallel trading is secure. As the Main Pharmaceutical Inspector, Zofia Ulz, emphasised during the "Medicines trading security" conference (April 10th, Warsaw) legitimate channels of drugs distribution in Poland, including parallel import, are secure, and no cases of counterfeit drugs entering legitimate trading have been found. Such success results from a large number of regulatory inspections, which the distributors are required to perform, as well as the obligation for distributors to employ qualified staff – warehouse managers, whose actions guarantee appropriate quality and effectiveness of inspections. Parallel import is an activity that is regulated by law, legitimate and subject to full control. As emphasised by Zofia Ulz, it is unfair to give an impression as though this were not the case.

Parallel importers, who are required to open each external packaging in order to repackage or label products, while doing so also check the direct packages of drugs for any damages. On many occasions, this has allowed detecting many quality faults of the imported products (documentation pertaining to damaged and substandard products is included – **Annex 1**).

While they cannot guarantee discovery of very skilfully counterfeit products, visual inspections, combined with keeping a strict record of series, provide an additional efficient barrier to stop counterfeit or substandard products.

The effectiveness of such a profile of securities is confirmed by the fact, that counterfeiters have little economical motivation to enter their products into trade through parallel distribution channels. There are several factors contributing to this. Firstly, sizes of batches in parallel distribution are small, therefore a sudden increase of quantities would be highly suspicious. Secondly, products in parallel trading are sold at lower prices, even though preparing them for sales is more costly. Thirdly, packages of imported products are more difficult to counterfeit. The rhetoric of statements regarding cases of counterfeiting products in Europe, and alleged connections of this phenomenon

with parallel import, should be subject to prudent assessment with consideration of evidence and documents provided by supervising authorities.

Each product is approved twice in parallel distribution. First, a full marketing authorisation is issued for its trading in its country from which it is exported, and then in the country of import an approval is issued for parallel import. Each company which repackages or labels products in parallel trading, has a production permission – similar to that which the original producer obtains; it employs a qualified person – warehouse manager; and is subject to binding guidelines and periodic inspections performed by supervising authorities. Additionally, importers in parallel trading are required, pursuant to case law of the European Court of Justice (ECJ), to make a complete sample of the product prepared for sale available to the owner of the trademark in the member state of destination of supply, before such medical product is introduced on the market. This gives the producer an opportunity to speak and to submit any reservations.

SIRPL believes that collaboration between industries, as well as working together with governments and pharmaceutical authorities, is a key factor in combating counterfeit drugs. In working together, legitimately operating partners in the supply chain may assist in maintaining integrity and security of pharmaceutical distribution in Europe.

Withdrawing a product from the market, and adherence to security rules

The parallel distribution sector is capable of withdrawal of a product from the market in the exact same way, as drug producers themselves.

If withdrawing a product from the market is performed in the source country, wholesalers in the given country are required to notify their trading counterparts, to whom the given pharmaceutical product has been sold, including parallel distributors in other countries.

A parallel importer's withdrawal of a product from the market is a part of Standard Procedure of Good Distribution Practice. The immediate step is to secure the product in inventory, and to notify customers on the domestic market, to whom the product has been supplied, of the fact of withdrawal. As parallel importers also work according to Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP), they are obliged to keep protocols of deliveries made to each recipient, with series number, validity date, quantity supplied etc. The withdrawn product is received and accepted at the parallel importer's storage location, and secured as appropriate. The product is

stored in original packages, and the products in inventory, which have not yet been repackaged, may be returned to the foreign wholesaler, from whom it was purchased.

In Poland, only one case has been reported to date, of a drug from parallel import being withdrawn from trading. Applicable procedures were smoothly and effectively performed in the case of a series of Postinor-Duo, which the Main Pharmaceutical Inspector decided to withdraw upon application of the responsible entity (description of the procedure of withdrawal of a medicinal product from trading is attached herewith as **Annex 2**).

Presented henceforth are comments of the Association of Parallel Importers of Medicinal Products to proposals included in the document issued on March 11th, 2008, by the Directorate General Enterprises for consultation with entities concerned.

4.3.1. Improving packaging integrity, prohibition of repackaging

To introduce a medicine on the market, a parallel importer must adapt its packaging for local requirements, in accordance with conditions of the permission to market, local regulations and rulings of the European Court of Justice. Polish authorities insist upon repackaging of medicinal products into new boxes, into which intact internal packages are inserted, along with leaflets for patient in the mother tongue. In Poland, repackaging is considered to be definitely more friendly for patients, and is found to fully respect the owners' rights to trademarks.

In our opinion, repackaging of medicinal products in parallel import, with a view to building patients' confidence in drugs and improving their own safety, should become a rule applicable in all countries of the European Union, as well as for drugs subject to central registration. Limitations resulting from trademark protection should not put industrial property rights above patients' safety. Requiring repackaging of medicinal products from parallel imports, and verifying regulations resulting from the right to trademarks would also be desirable in the context of parallel importers' fulfilment of requirements regarding Braille inscriptions on packages.

Repackaging of medicinal products occurs at many stages in pharmaceutical distribution. In case of parallel import, it is a typical and necessary step – without labelling the box or repackaging of the drug into a new package, parallel import is impossible. Repackaging of the product is a necessary condition for obtaining access to the market in the target country. So require authorities in countries of import.

Neither a prohibition of repackaging, nor applying protective stickers, can ensure sufficient protection against counterfeit drugs entering the distribution chain. Criminals counterfeit not only packages, but also stickers and holograms. In practice, a ban on repackaging would put an end to parallel import. That would be a step out of proportion with the objectives assumed. Especially so, as no connections can be demonstrated between parallel import and the increasing threat from counterfeit drugs. One should not expect, therefore, that implementing regulations of such kind will ensue with an advancement in combating the phenomenon.

Experiences so far indicate that parallel import performs the function of an additional quality control. Repackaging, and the accompanying visual inspection of the product, allows substandard or damaged products to be spotted. Thus, the probability that the patient will receive a counterfeit drug is reduced, rather than increased, as pharmaceutical companies will insist.

It is in the repackaging process that the only quality inspection occurs of the drug after leaving the producer's factory. It is a process that is equally secure as the packaging process performed by the producer, as it is performed according to the same guidelines of Good Manufacturing Practice (GMP). Therefore it is not possible for original packages to come in the hands of counterfeiters. The packages are destroyed.

From the point of view of risk assessment, it is difficult to find arguments to justify the claim that the risk caused by the repackaging process differs depending on the location in which it is performed, and of increased threat from parallel import. Prof. Zbigniew Fijałek, Director of the National Drugs Institute, warns in the *Przegląd Farmaceutyczny* magazine (vol. 3) and Manager Apteki (April 2007) – *What is worst is generalizing and vilifying the phenomenon. Parallel import is conducted legally, and if it entails evident savings, I'm in favour, as long as it is properly controlled. The repackaging should be performed in accordance with GMP procedures. One needs to note where the critical points are, as regards the possibility for counterfeit drugs to be entered into circulation, in the prolonged path from producer to patient. In this, we need to bear in mind, that in particular cases, a counterfeit product may come from the producer packaging the product – e.g. counterfeit tablets repackaged into original packages.*

In our opinion, the European Commission should perform a very careful risk assessment, and collect evidence from different sources, without succumbing to biased arguments of pharmaceutical companies, which have been making efforts for years to rule parallel import from the market.

4.1.4. Establishing a common database

Parallel importers in Poland, like other distributors, record series numbers of outgoing products. This way, it is possible to track the movement of a medicinal product in distribution, from the producer, all the way to the pharmacy shop. The effectiveness of the process is confirmed by the case of effective withdrawal from market of Postinor-Duo (**Annex 2**).

Establishing a common database is not necessary. If, however, such database were to be established, costs of establishing it should be considered, as well as matters of protecting personal information. It should be specified in detail, who would administer the database, and who would be allowed to access what data. Otherwise, it could be captured for commercial purposes and used to control the distribution chain in contradiction of the idea of free competition. Unfortunately, a risk also exists of such information coming in the hands of criminals involved in the trade of counterfeit medicines.

4.1.5 New system of packaging of medicinal products

Parallel importers support the idea of assigning individual numbers to packages of medicinal products, on condition, however, that solutions are put in place which would prevent using information so gathered for purposes of fighting against parallel import.

4.5.2. Increasing transparency of distributors

SIRPL supports the idea of issuing GDP certificates after each consecutive inspection at the distributor's side, and of establishing a central database of certified distributors.

Summary

Parallel import in Poland fully complies with the requirements which the European Commission puts in place for the "secure European chain of distribution". We believe that introducing a ban on repackaging would be a measure aimed against parallel import, and would undermine competition on the medicines market. It will not contribute towards improving patients' safety in terms of protection from counterfeit drugs, while it will distract the attention from real threats emerging from illegal trading, which is beyond control of pharmaceutical authorities. We are open to collaboration and

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STOWARZYSZENIE
IMPORTERÓW RÓWNOLEGŁYCH
PRODUKTÓW LECZNICZYCH

discussion with the European Commission regarding effective solutions in combating counterfeit drugs. By this we mean such solutions as would not compromise competition and the interest of patients, but would contribute to their safety.

President of SIRPL

Tomasz Dzitko

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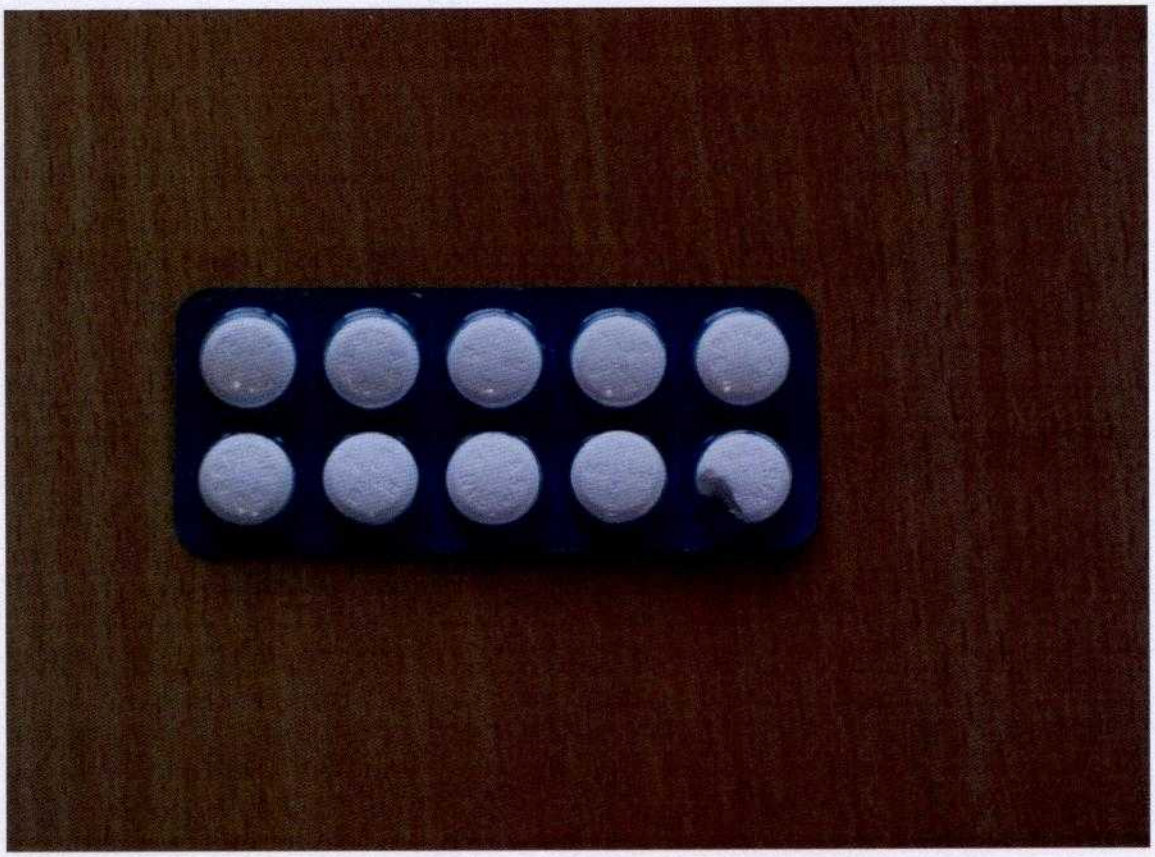
Annex 1

Faulty Goods Record:

- Product: Aspirin
- Manufacturer: Bayer Hellas
- Source Country: Greece
- Date received: 09.02.2007
- Batch No: BTA5D21/1
- Expiry Date: 04.01.2007
- Problem: Damaged tablet in the intact blister
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record:

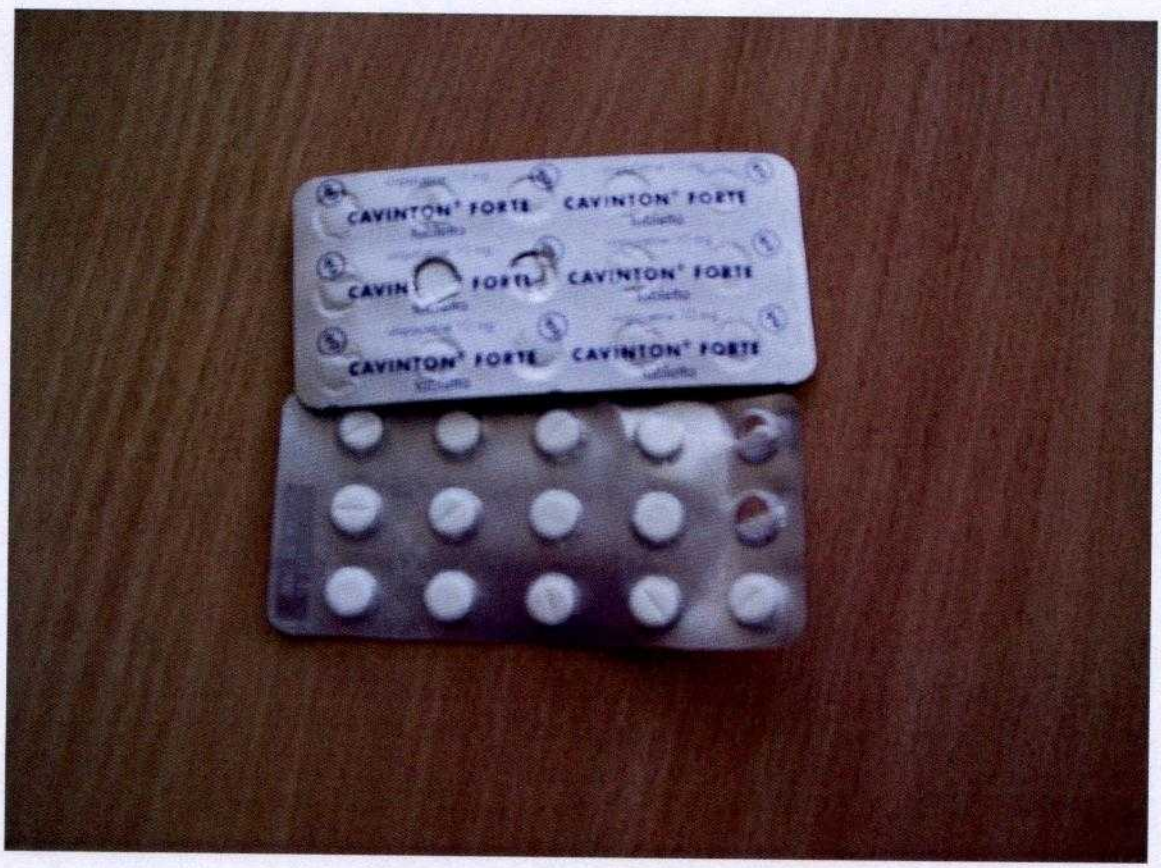
- Product: Bactrim Forte
- Manufacturer: Roche Neuilly- sur -Seine Cedex
- Source Country: France
- Date received: 03.01.2008
- Batch No: F1001
- Expiry Date: 10.2011
- Problem: Damaged tablet, batch number and expiry date are lacking
- Sample retained: Yes
- Scan taken: Yes

Faulty Goods Record

- Product: Betaserc
- Manufacturer: Solvay Pharma
- Source Country: Greece
- Date received: 11.02.2008,07.04.2008,28.11.2008
- Batch No: L0801003 ,L082009,L0709057
- Expiry Date: 01.2013,02.2013,09.2012
- Problem: Lack of inscriptions on blister and lack of tablets in blister
- Sample retained: Yes
- Scan taken: Yes

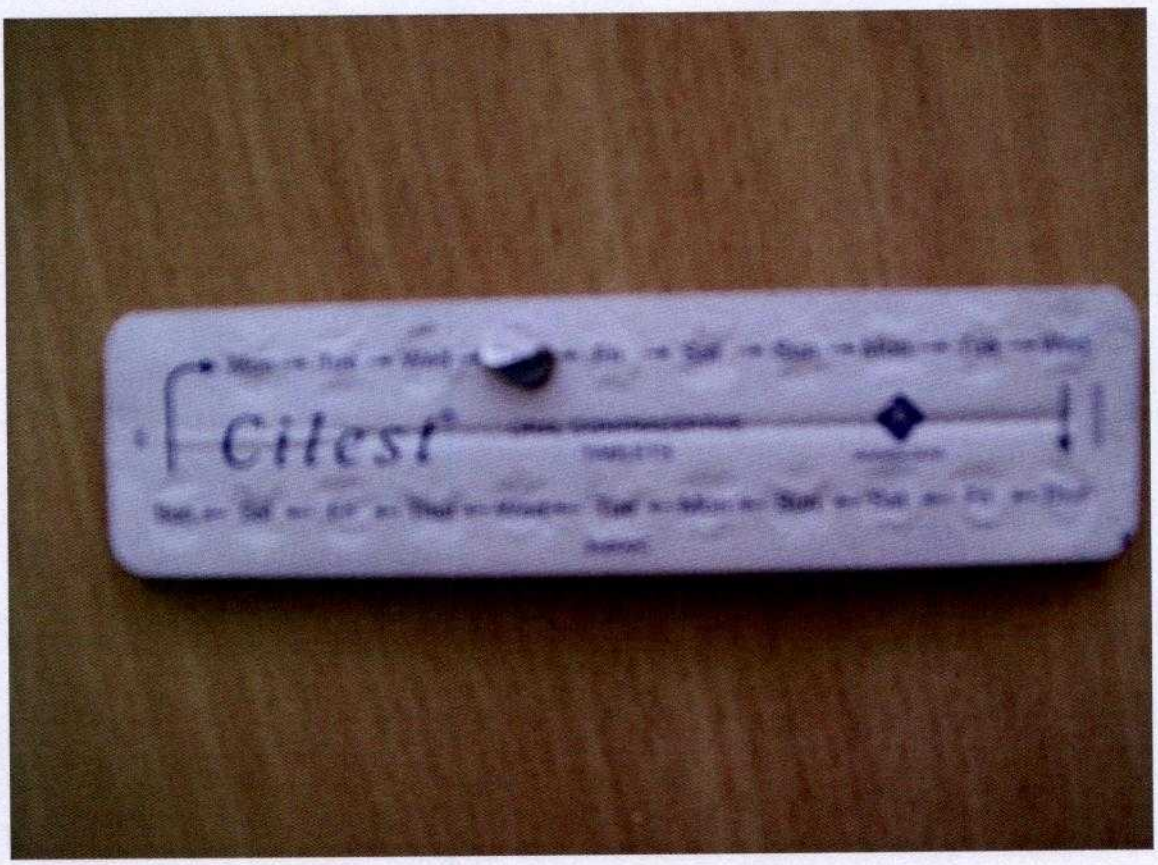
Faulty Goods Record

- Product: Cavinton Forte
- Manufacturer: Richter Gedeon Rt
- Source Country: Hungary
- Date received: 25.02.2008
- Batch No: T7A388
- Expiry Date: 10.2007
- Problem: Damaged blister
- Sample retained: Yes
- Scan taken: Yes



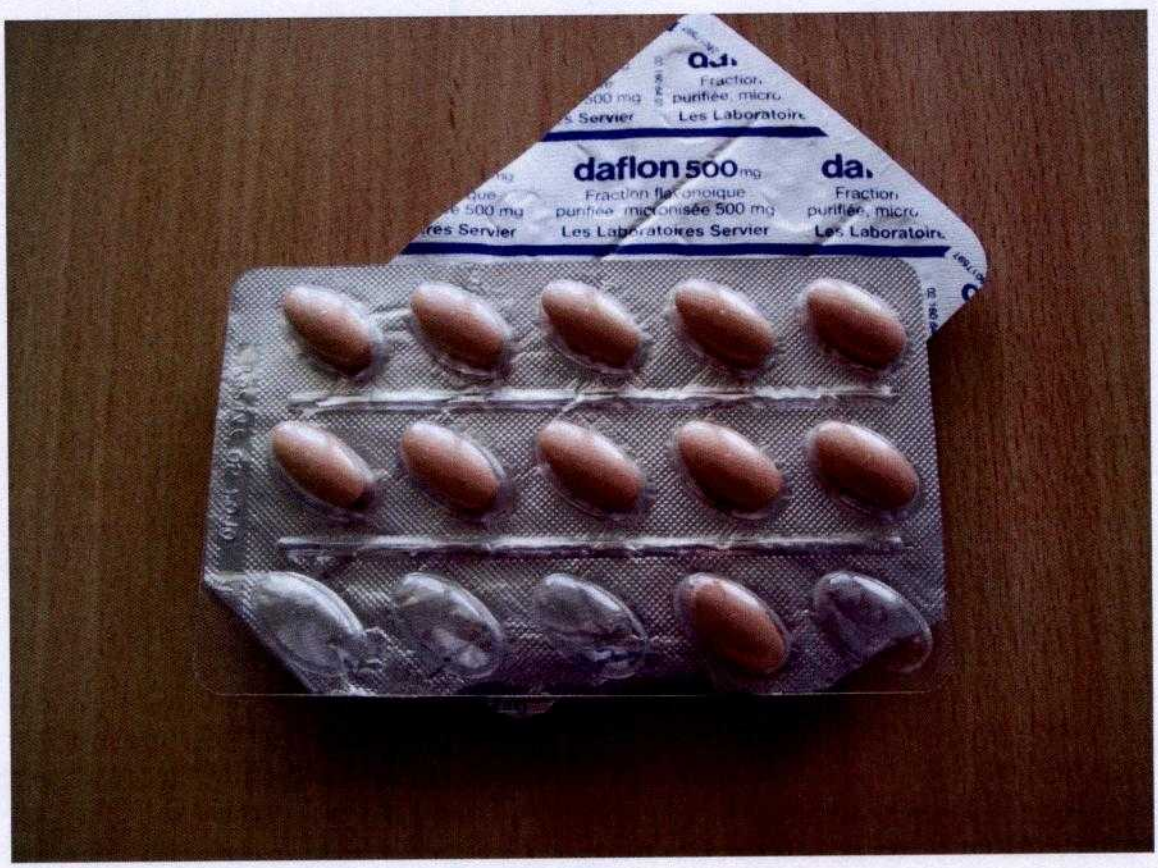
Faulty Goods Record

- Product: Cilest
- Manufacturer: Janssen Cilag Ltd
- Source Country: The United Kingdom of Great Britain
- Date received: 08.02.2008
- Batch No: 7JS0E00
- Expiry Date: 10.2007
- Problem: Damaged blister
- Sample retained: Yes
- Scan taken: Yes



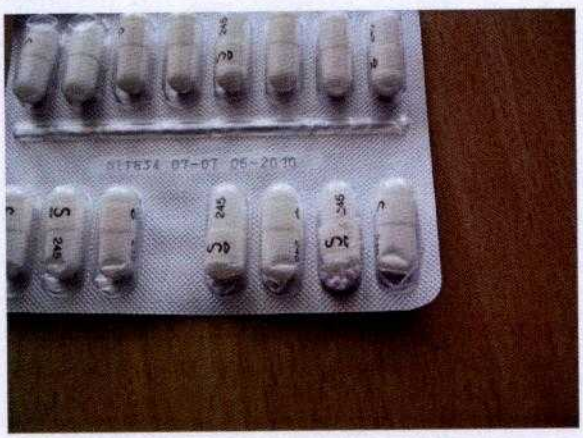
Faulty Goods Record

- Product: Daflon (Detralex)
- Manufacturer: Laboratoire Servier
- Source Country: Spain
- Date received: -
- Batch No: 762147
- Expiry Date: 05.2010
- Problem: Lack of several tablets, damaged blister
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record

- Product: Duspatalin
- Manufacturer: Laboratoire Solvay
- Source Country : France
- Date received: 04.02.2008,11.03.2008,04.12.2007
- Batch No: 611633,611634,611452
- Expiry Date: 05.2010,06.2010,05.2010
- Problem: External box is burst tablet is crumbled and blister is damaged
- Sample retained: Yes
- Scan taken: Yes

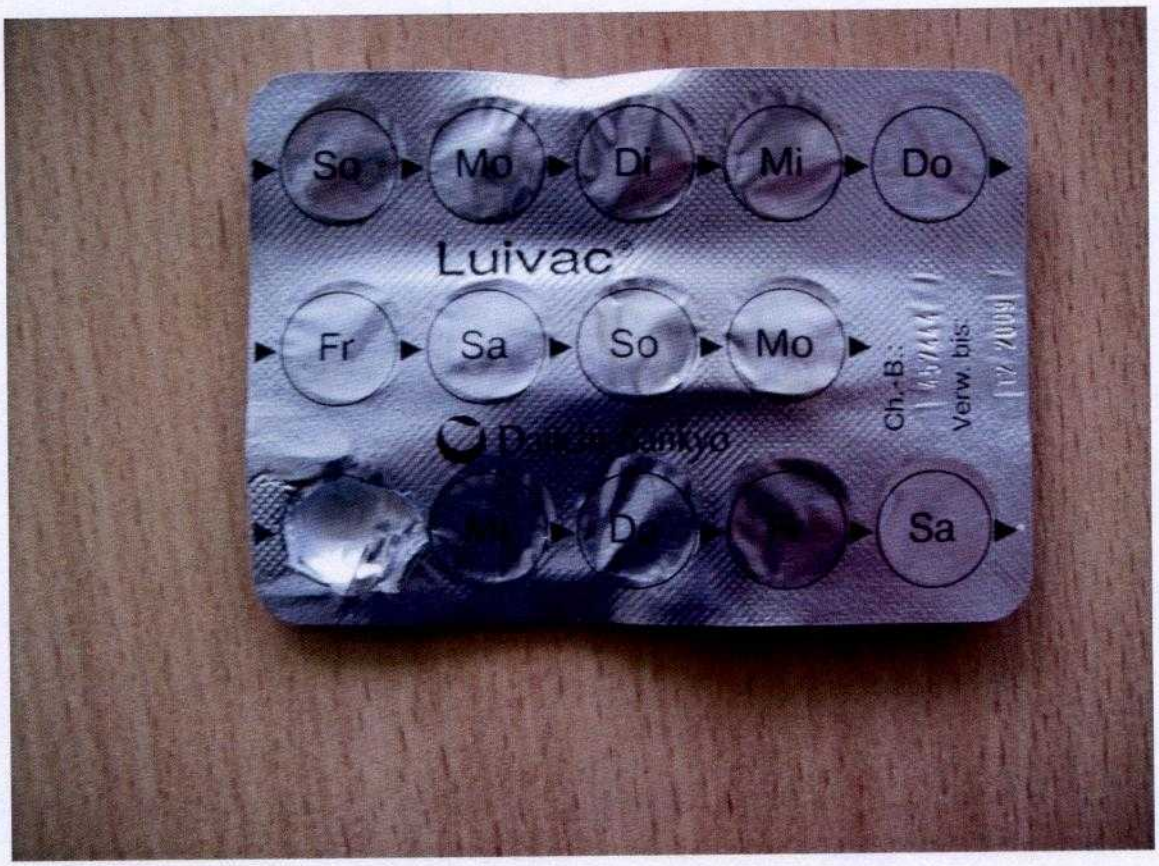


Faulty Goods Record

- Product: Fenistil Gel
- Manufacturer: Novartis Consumer Health
- Source Country: Greece
- Date received: 31.12.2007
- Batch No: L7C189
- Expiry Date: 02.2010
- Problem: External box and tube are damaged
- Sample retained: Yes
- Scan taken: Yes

Faulty Goods Record

- Product: Luivac
- Manufacturer: Daiichi Sankyo Austria
- Source Country: Austria
- Date received: 25.03.2008
- Batch No: 457444
- Expiry Date: 12.2009
- Problem: Lack of tablet
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record

- Product: Nootropil
- Manufacturer: UCB Pharma
- Source Country: Spain
- Date received: 14.05.2007,10.07.2007
- Batch No: A001,A007
- Expiry Date: 02.2011,05.2011
- Problem: External box is burst and blister is damaged
- Sample retained: Yes
- Scan taken: Yes

Faulty Goods Record

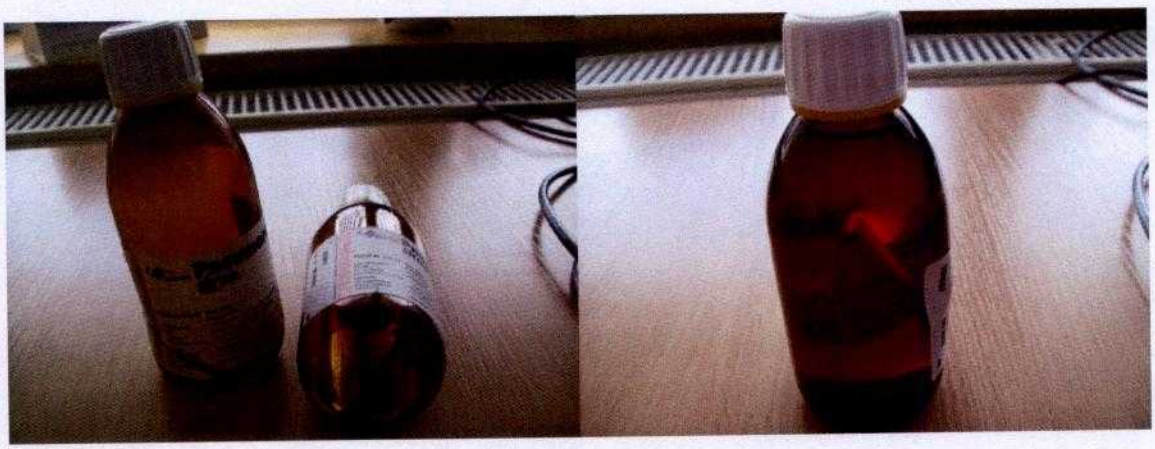
- Product: Olfen Gel
- Manufacturer: Mepha Lda
- Source Country: The Czech Republic
- Date received: 08.10.2007
- Batch No: 0651510
- Expiry Date: 11.2009
- Problem: External box and tube is crumpled
- Sample retained: Yes
- Scan taken: Yes

Faulty Goods Record

- Product: Pimafucort
- Manufacturer: Astellas Pharma
- Source Country: The Czech Republic
- Date received: -
- Batch No: Illegible
- Expiry Date: Illegible
- Problem: Tube is cracked
- Sample retained: Yes
- Scan taken: Yes

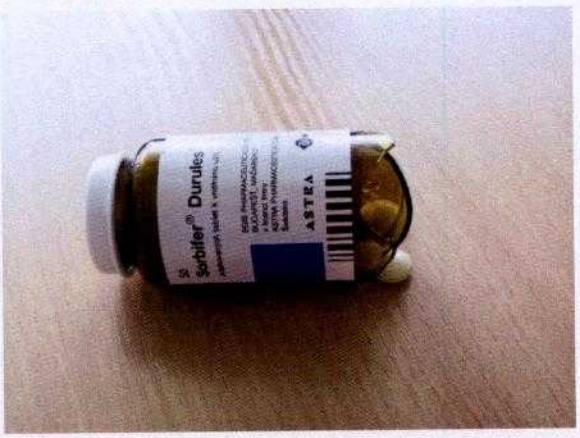
Faulty Goods Record

- Product: Pneumorel
- Manufacturer: Les Laboratoires Servier
- Source Country: France
- Date received: - --- ---------- 05.07.2007,13.11.2007
- Batch No: 764632,762261,784537,789380
- Expiry Date: : 07.2009,06.2009,04.2010,05.2010
- Problem: Lack of contents in bottle, crumpled bottle, poured contents
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record

- Product: Sorbifer Durules
- Manufacturer: Egis Pharmaceuticals
- Source Country: The Czech Republic
- Date received: 15.02.2008
- Batch No: D954N1107
- Expiry Date: 11.2010
- Problem: Bottom and cap of bottle are broken(cracked)
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record

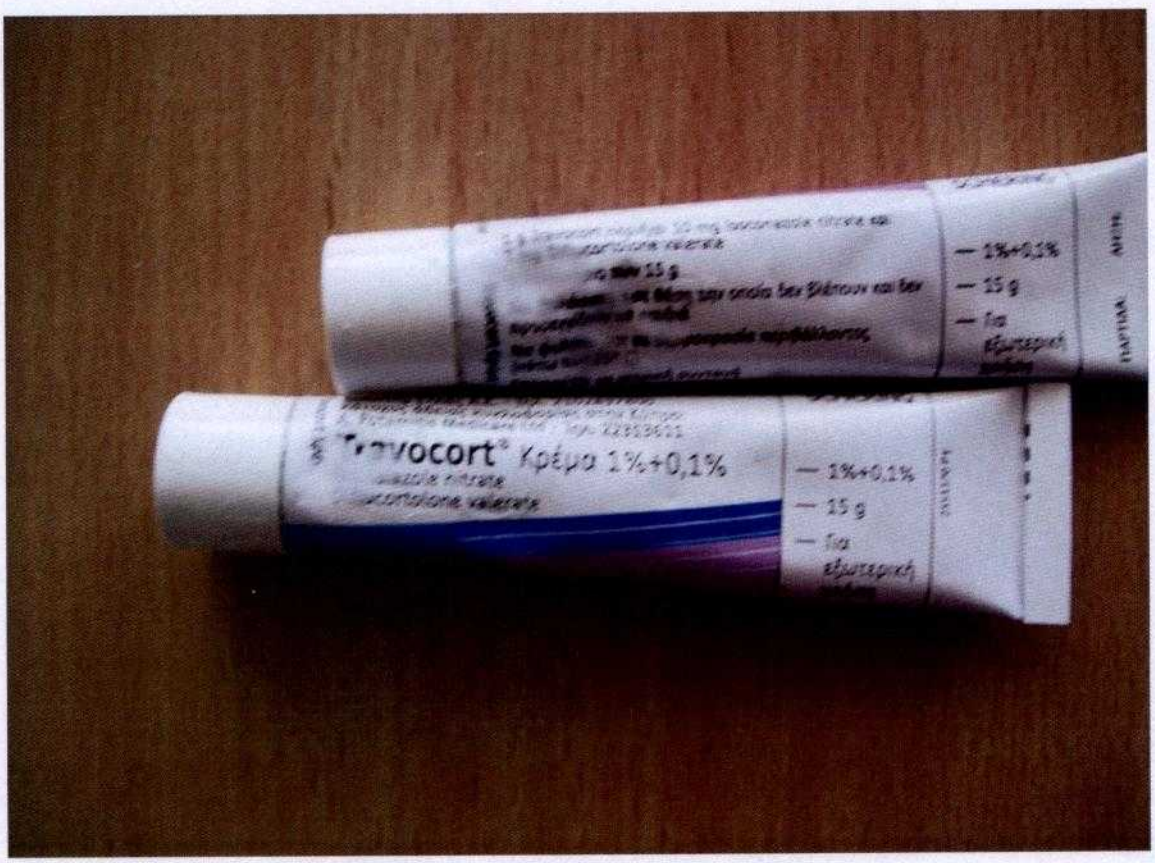
- Product: Sudafed
- Manufacturer: Laboratoire GlaxoSmithKline
- Source Country: France
- Date received: 26.11.2007
- Batch No: G9309
- Expiry Date: 08.2009
- Problem: Damaged blister
- Sample retained: Yes
- Scan taken: Yes

Faulty Goods Record

- Product: Tanakan
- Manufacturer: Beaufour Ipsen Pharma
- Source Country: The Czech Republic
- Date received: 05.10.2007
- Batch No: S358
- Expiry Date: 07.2010
- Problem: Lack of part tablet
- Sample retained: Yes
- Scan taken: Yes

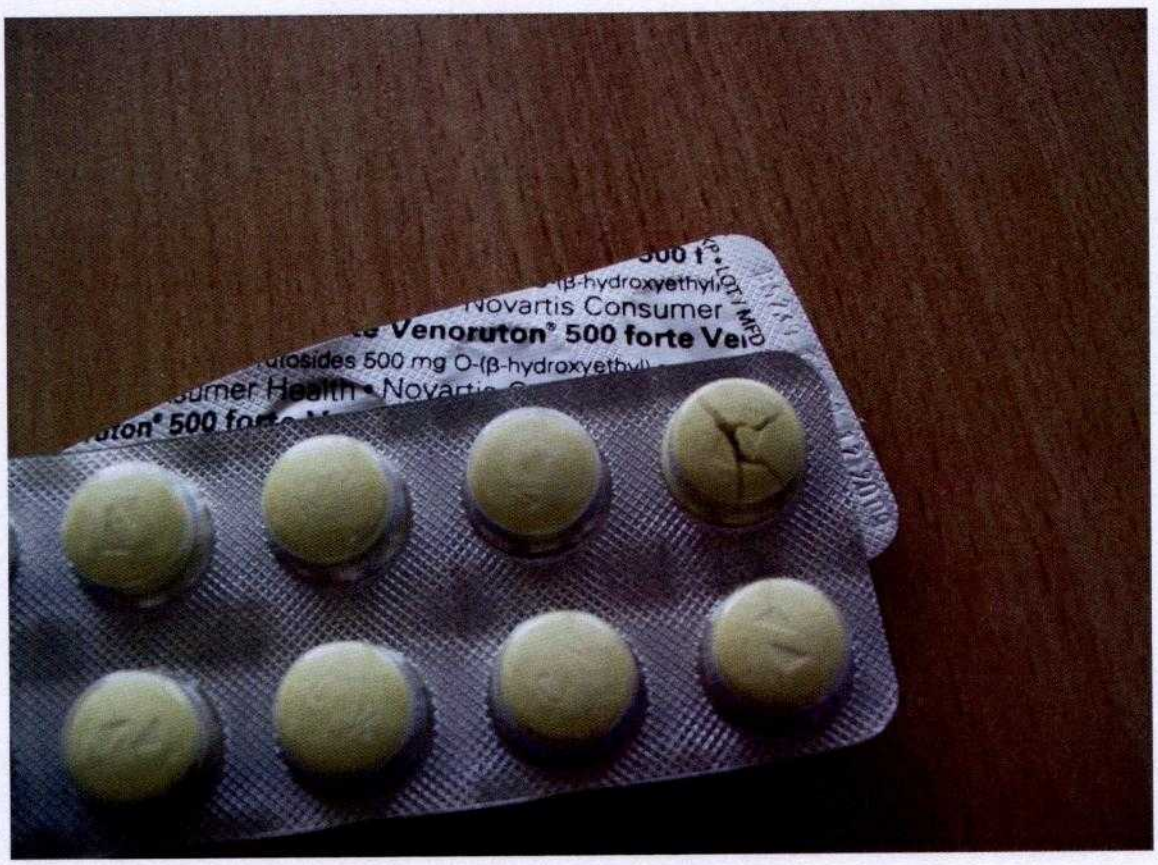
Faulty Goods Record

- Product: Travocort
- Manufacturer: Schering Hellas
- Source Country: Greece
- Date received: 22.01.2008
- Batch No: 73142A
- Expiry Date: 09.2012,09.2012
- Problem: Tube is cracked
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record

- Product: Venoruton
- Manufacturer: Novartis Hellas
- Source Country: Greece
- Date received: 04.04.2007
- Batch No: B5207
- Expiry Date: 09.2009
- Problem: Crumble tablet
- Sample retained: Yes
- Scan taken: Yes



Faulty Goods Record:

- Product: Voltaren Emulgel
- Manufacturer: Novartis Pharmaceutica
- Source Country: France
- Date received: 07.05.2007
- Batch No: W6378
- Expiry Date: 03.2010
- Problem: External box and tube is damaged
- Sample retained: Yes
- Scan taken: Yes

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STOWARZYSZENIE
IMPORTERÓW RÓWNOLEGŁYCH
PRODUKTÓW LECZNICZYCH

Annex 2

Withdrawal from trade of the medicinal product Postinor-Duo by parallel importer Delfarma Sp. Z o.o.

Timetable of actions

On **December 4th, 2007**, the Main Pharmaceutical Inspector (MPI) received a decision from the responsible entity, Gedeon Richter Ltd., of withdrawal from trading of two series of Postinor-Duo (750 µg tablets) due to inaccuracies found in informative printed matter.

On **December 5th,** 2007, MPI issued a decision to withdraw the medicinal product from trading.

On **December 6th,** 2007, the Delfarma wholesale warehouse – a parallel importer – notified pharmaceutical wholesale warehouses of withdrawal of medicinal product, asking those to launch the process of withdrawal from sales of specified series of the medicinal product, so as to ensure stock present in warehouses and pharmacies. At the same time, Delfarma appealed the MPI's decisions, upon the argument that information on leaflets was fully compliant with the permission for parallel import. The recipients undertook safeguarding actions related to withdrawal of medicinal product from trading, and sent reports as appropriate to Delfarma.

On **December 7th,** 2007, Delfarma prepared a report of the actions taken. The series withdrawn were moved from inventories to quarantine.

On **January 24th, 2008**, MIP repealed the appealed decision regarding withdrawal of Postinor-Duo from trading, of which Delfarma notified its recipients.

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