

TESTIMONY TO HHS TASK FORCE ON DRUG IMPORTATION
14 MAY 2004
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SECRETARY GENERAL
EUROPEAN ASSOCIATION OF EURO-PHARMACEUTICAL COMPANIES

Mr Chairman, Task Force members.

Thank you for inviting the European Association of Euro-Pharmaceutical Companies to submit its views. With over 70 member firms from 16 European countries, the EAEPCC is the professional representative body for parallel exporters and importers in medicines – collectively we call these parallel traders - in Europe.

Ours is an industry that in its best-ever year, 2002, shipped 140 million packs of prescription medicines, such as this sample, safely and efficiently across national borders within the EU's internal market.

Parallel trade exists because of inter-state price differences, but it simply would not happen if after meeting his costs the parallel trader did not pass on a large part of the price differential to the payer, which in Europe is mainly the various national health insurance schemes. Direct savings to these schemes and to patients for 2002 in just 5 EU countries were independently quantified at the equivalent of \$745 million. Indirect savings, through parallel trade's competitive effect in an otherwise monopolistic market is likely to even higher, according to the study.

20+ years' experience in Europe has conclusively shown that pharmaceutical parallel trade is safe. It can be strictly limited to genuine products that have been approved for marketing to common, high EU standards, and produced by the same, original brand manufacturers as the domestic version. There has never been one confirmed case of a counterfeit drug reaching a patient in Europe as a parallel import.

Parallel trade would fit in well with US free market principles. One of the reasons why governments in the UK and Germany – the two largest markets for incoming parallel trade – have been able to avoid introducing manufacturer price controls for new, innovative drugs is that use of parallel trade by pharmacists is officially encouraged there.

Parallel trade, as found in Europe, is very different from personal importation – whether by mail order, via the Internet or on foot – that has been the basis of US experience to date.

Ours is a mature, highly-regulated business-to-business activity. We have no direct dealings with the public, and instead supply only authorised wholesalers and/or registered pharmacies. It is the community or hospital pharmacist's professional decision whether parallel trade is dispensed to the patient or not.

With parallel trade, the product's origin, quality and storage conditions can be assured. The chain is a closed one. Only authorised products are purchased from authorised wholesalers in one EU country and sold to authorised distributors in another EU country by parallel traders that themselves are regulated by four different means.

Pharmacists purchase parallel trade because it gives them and their patients a choice as well as financial savings. It supports rather than threatens the local pharmacy infrastructure. It is suitable for all types of products, not just repeats of oral chronic medication.

As I mentioned, 2002 was our peak year. Growth in the major markets was flat in 2003 and is expected to be negative in 2004.

This is not because the demand for parallel trade is lessening or because inter-state price differences are narrowing. It is because of obstructive strategies by Big Pharma. The main problem has been the introduction over the past 2-3 years of supply quota systems by an increasing number of multinational manufacturers. Surplus stock that once was traded has been progressively eliminated. As well as hitting parallel trade, quotas have damaged the business of wholesalers and also led to product shortages, therefore impacting adversely on public health.

EAEPC, its members as well as the European association of full-line wholesalers (GIRP) allege quotas breach EU competition rules. Around 50 complaints against a total of 15 multinationals are believed to be currently pending with national and EU antitrust authorities.

We are constantly reminded that we have the support of the European Commission. Only this January, the Commission issued a new Communication reaffirming that parallel trade in drugs was entirely legal. However, antitrust investigations have to be thorough to withstand robust examination in the courts, and with manufacturers making full use of their appeal rights a single case can drag on for a decade or more.

In conclusion, Mr Chairman, while EAEPC strongly supports all those who advocate parallel importation of prescription drugs into the US, Europe is not currently the solution or alternative to supply shortages in Canada. Without any doubt, we have the know-how and proven expertise, and I would personally like to invite you and your colleagues to visit our members' facilities to check this out for yourself. But we have supply shortages of our own.

We therefore urge US lawmakers to ensure that coming importation legislation contains effective measures to penalise manufacturers that hinder free trade into the US, especially artificial volume restrictions in the countries of supply. I understand that this is indeed the case with two bills tabled recently in the US Senate. This is an encouraging development.

Thank you for your attention and I will try and answer your questions.