

European Union

Program Overview: Eleven European Union member nations have pharmaceutical take-back systems, all of which allow residents to drop unwanted pharmaceuticals at pharmacies. More than half of the European nation systems are operated by the pharmaceutical industry or by pharmacies; the rest are paid for by municipalities. Each country has a different approach to managing these programs.

Five countries (Belgium, France, Luxembourg, Portugal, and Spain) have take-back schemes operated by the pharmaceutical network as a whole. The remaining six countries (Denmark, Finland, Germany, Italy, Sweden, and U.K.) only conduct take-back programs through pharmacies in collaboration with a public or private waste contractor. Of these 11 nations, two have had particular success in the past two decades. These include:

Italy: In the late 1980's, Associazione Indennizzo Resi (Ass Inde) was established in Italy as an independent company to run an inter-sector agreement to refund the distribution chain, on behalf of pharmaceutical manufacturers, for the cost of expired, damaged, or recalled medicines. Italy's take-back program involves collection at more than 16,000 pharmacies. The program operates on a six-month cycle. Every January and July, wholesalers and pharmacies clear their shelves of out-of-date or damaged stock and draw up an inventory on a designated form. The pharmaceutical products are transported by a licensed carrier to Ass Inde's offices in Rome, where the packaging materials are separated, sealed in bags, quarantined for six months, and then shredded. The products themselves are incinerated.

France: France operates a structured, industry-funded system for recalling pharmaceutical waste. The system is run in a collaborative manner between manufacturers (265), wholesalers (6), and community pharmacies (22,590), but without any refunds. The scheme, run by an association known as Cyclamed, has both an environmental and a humanitarian aim. Through their local pharmacy, households are invited to return all unused medicines and packaging, even empty packs. Bags and leaflets handed out at the time of dispensing and window stickers and posters reinforce this message. Partially used, expired, or damaged stock is placed by the pharmacist in a "destroy" box. Products that could possibly find use by medical charities in France or overseas are stored in a second box. When full, the "destroy" boxes are picked up by a wholesale company on its delivery rounds and put into an isolated, closed container at the warehouse. Wholesalers then arrange for a waste contractor to collect containers when full for incineration.

The scope of take-back schemes is normally limited to medicines when the system is financed by pharmacies or municipalities. Where industry must comply with national regulations deriving from the packaging wastes directive, then the take-back scheme is expanded to packaging (including empty packs); this is financed by industry.

Key Motivation: The 11 member nations that currently support pharmaceutical take-back programs believe these programs have significant practical value in terms of drug safety, the environment, economics, and in the sense of partnership they bring to members of the medicines of the supply chain.

Organizing Body: The take-back schemes implemented throughout the European Union are primarily organized by the European Federation of Pharmaceutical Industries and Associations

(EFPIA), which is composed of 28 national pharmaceutical industry associations and 44 leading pharmaceutical companies throughout Europe.

Partners: Europe's take-back programs are also organized with the aid of the European Commission Directorate General Environment. The Environment DG is one of 36 Directorates-General and specialized services which make up the European Commission. Its main role is to initiate and define new environmental legislation and to ensure that measures which have been agreed upon are actually put into practice in the Member States.

Cost: When operated by the pharmaceutical network as a whole, costs are apportioned between pharmacists, wholesalers, and industry according to their role in the distribution system: industry consequently pays for external costs (mainly incineration) with the exception of Luxembourg, where no pharmaceutical industry exists and the Ministry of the Environment consequently pays for these costs.

When operated by pharmacies only, the system is financed by municipalities (Finland, Italy, and U.K.), pharmacies where they are responsible by law (Denmark and Sweden), or by industry (in Germany where products have to bear costs related to recycling of packaging wastes).

Under Italy's take-back system, the major expenses (data from 1999) are as follows:

- Television advertising = US \$863,578
- Incineration = US \$844,403
- Waste Transport = US \$614,111
- Waste Containers = US \$556,538
- Other forms of Communication = US \$422,163

Outcomes:

Italy: By 2000, more than 132 million unwanted packages of pharmaceuticals had been collected for safe disposal. Products with a shelf life of five years are reimbursed at 70% of the purchase price; those with a shelf life of two years or less, and all damaged goods, are reimbursed at 100%. In 1998 alone, about US \$39,218,821 was refunded to the country's 280 wholesalers and 16,000 pharmacies. Refunds covered about five million of the approximate seven million packs returned that year.

France: 1995 was the first year the system was in place. Since that time, the quantity of pharmaceutical waste collected yearly has increased. In 1995, 13,800,000 pounds of unwanted/expired medications were collected. By 1998, the annual total had risen to 20,600,000 pounds. While the majority of the collected medications were incinerated, in 1998, 1,926,000 pounds were redistributed to poor people in France. Ten charities benefited overall, with three accounting for 84% of the total weight: Order of Malta (790,000 lbs), Pharmaciens sans Frontieres (616,000 lbs), and Terre d'Amitie (212,000 lbs).