Sustainable Packaging Guide for the pharmaceutical sector

Vereniging Innovatieve Geneesmiddelen / Bogin / Neprofarm / KNMP

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Disclaimer:
This guide has been prepared with the utmost care, but if you come across any inaccuracies we would like to hear from you so that we can adjust them.

Version: 2019

Introduction

Approximately 417 million packages are put on the market every year in the Netherlands. This concerns 260 million packages of prescription medicines and 157 million packages of self-care products.

Medicines make a valuable contribution to society and are essential for the daily functioning of many people. At the same time, medication and its packaging have an unavoidable impact on the environment. Sustainability is becoming an increasingly important topic, because of climate change, environmental pollution and depletion of raw materials.

The most critical requirement for medical packaging is obviously patient safety and product efficacy. Packaging is necessary to protect a medicine against external influences, such as light, moist and temperature. It makes it possible to transport medicines, to dose them easily and to track & trace them.

Besides all the requirements the packaging has to meet, there are still many options to reduce the amount of material used and improve recovery and recycling. This guide provides insights, tips and tools to make your medicine packaging more sustainable.

European Strategy

Action on Plastics was identified as a priority in the 2015 Circular Economy Action Plan, to help European businesses and consumers use resources in a more sustainable way. In this context, the European Strategy for Plastics in a Circular Economy, adopted on 16 January 2018, aims to transform the way plastic products are designed, produced, used and recycled in the EU. In 2015, the Commission already proposed that by 2025 at least 55 % of all plastics packaging in the EU should be recycled.

On June 14th 2018 Directive EU/2018/852 was published amending Directive 94/62/EC on packaging and packaging waste. This amendment is part of the European Union's framework regarding circular economy.

In parallel to a number of definition changes, other important adaptations were introduced. Member States should take measures to incentivise the take-up of reusable packaging and to achieve a reduction in consumption of packaging that is not recyclable and of excessive packaging.

New minimum goals for recycling:

- at the latest by December 31st 2025 at least 65 weight percent of all packaging waste is recycled (50 weight percent of plastics);
- at the latest by December 31st 2030 at least 70 weight percent of all packaging waste is recycled (55 weight percent of plastics);

Member States should put in place adequate incentives for the application of the waste hierarchy including economic instruments and other measures.

Figure 1: Waste hierarchy (EU Directive)

Sector Innovation Plan on Sustainable Packaging (The Netherlands)

In the Framework Agreement for Packaging 2013-2022, the national government of The Netherlands, municipalities and the packaging industry agreed on several measurements to improve the sustainability of packaging. One of the measurements is the drawing up and execution of sector innovation plans.

The Sector Innovation Plan 2019-2022 for the Pharmaceutical sector is formulated by a cooperation of the Association Innovative Medicines, BOGIN, Neprofarm and KNMP, representing the following companies in the supply chain.

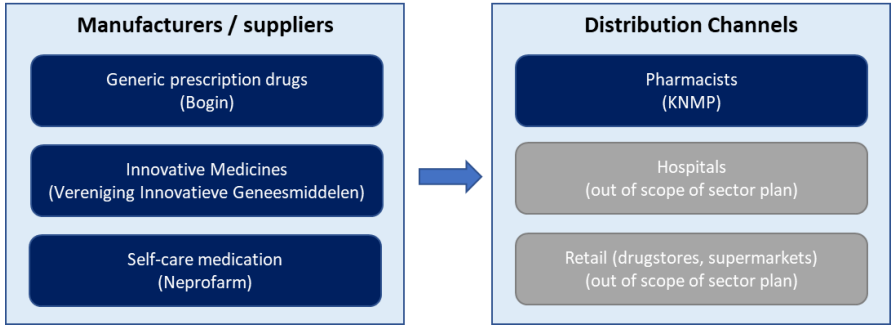

Figure 2: Stakeholders and supply chain

In the Sector Innovation Plan 2019-2022 the pharma sector formulated the following general ambitions:

1. Prevention and reduction the wastage of medicines and packaging and reducing the emission of medicine waste in the environment
This means optimizing the use of medicines, so that waste of product and packaging is prevented and the amount of medicine residues in the surface water is reduced. Preventing drug wastage also prevents the use of packaging because it is inextricably linked.

2. Sustainable and circular procurement of packaging
This means cooperation in the chain to reduce the quantity and weight of packaging and to opt for circular packaging with the lowest possible environmental impact.

In the Sector Plan the following six objectives have been formulated:

1. Prevention of medicine wastage
2. Increasing the collection of unused medicines
3. Improving the recycling of collected packaging
4. Preparing a Sustainable Packaging Guide
5. Increasing the percentage of FSC / PEFC certified paper and cardboard for transport packaging
6. Paper leaflets will be replaced by a digital version in the long term

The Sustainable Packaging Guide

This Guide is the result of objective 4 of the Sector Innovation Plan. It shows how you can pack more sustainably, explained with various examples. It can be used by buyers, packaging producers and other parties involved in (the packaging of) medicines. You can also share the guide with your supplier, so that he can make sustainable choices.
Every chapter starts with the goals and a checklist with general ideas for your packaging, followed by examples of specific sustainable packaging solutions.

In this Guide we use the following definitions for three types of packaging:

- *Primary packaging* is in direct contact with the medicine. Examples are blisters/strips, flasks and tubes.
- *Consumer packages* bundle one or more primary packages and contain information about the medicine. For example, it concerns the box around a tube or a box with several blisters in it. The consumer packaging is the packaging that is sold over the counter.
- *Transport packaging* bundles several consumer packages, so that they are transported safely. It concerns boxes, but also pallets that carry multiple transport packaging.

1. Prevention

Goal of the sector is to reduce the wastage of medicines and related packaging with 20% in 2022. This has to be done by a combination of measurements, both on the production side as the issue side at the Pharmacies.

Medicine wastage is a major problem. In the Netherlands approximately €40 million of unused medicines are being thrown away every year. Medicines are inextricably linked to the packaging in which they are contained. When medicine waste is prevented, the related packaging and material waste is also prevented.

An important condition in this respect is that the government and other parties such as health insurers, when making policy, take environmental aspects into account. And that decisions for future purchasing will not only be based on the price but also on the sustainability of products.

Waste can be prevented both on the production side and on the issue side of medicines.

Prevention medicine wastage	
1.1	**Matching the packaging quantity to the user**; Make it possible to distribute packages in different quantities, when the prescribed dosage varies. Avoid using too large packages for medicines that are not used regularly, which may endanger the shelf life and wastage by users..
1.2	**Optimizing logistics and shelf-life**; Optimizing the shelf-life criterium for delivery can save a lot of medicine and packaging waste;
1.3	**Re-issue** – Investigate the possibilities for introducing an re-issue system for unused expensive medicines.

1.1 Matching the packaging quantity to the user

A large quantity of medicines is destroyed because the patient does not use them. In addition, profit can be gained through the proper use of medicines and through the development of innovative therapies that make customization possible for patients such as personalized medicine. These new therapies have a beneficial effect on the environment because they enable more effective treatment.

Investigate whether the medicines will be redistributed later in a different form. For example, when the tablets are repacked in a baxter roll after being pressed out of a blister, it is desirable to examine alternative (bulk) packaging.

Case: Baxter roll

The baxter roll or medicine box is a good example of promoting therapy compliance - the use of medicines becomes very easy. At the same time, additional material is used when the medicines that were previously in a blister are repackaged in a baxter roll.

If the medicines for baxter rolls are delivered in bulk packaging (pots) this can save a lot of blister materials and costs.

Case: Fixed Dose Combination (FDC) - Janssen

With 'Fixed Dose Combination (FDC)' two or more active pharmaceutical ingredients (API's) are combined in one dosage form (vb. capsule or tablet). This reduces the amount of packaging per patient related to the therapy with 50% or more per year. FDC products are typically used by Janssen when the therapy requires a combination of drugs, such as in the treatment of HIV-1. EVIPLERA™, REZOLSTA™, SYMTUZA™ and JULUCA™.

1.2 Optimizing logistics and shelf-life

The shelf life of a product is recorded in the registration file, when the raw materials are weighed, the clock starts running, from that moment the shelf life starts to expire.

Health insurers, wholesalers and pharmacists often make the requirement that the product must have a shelf life of at least 12 months when purchasing. This results in a lot of waste. The expectation is that an average saving of 20% can be

achieved if this requirement is adjusted, particularly in combination with a good logistics system.

Case: Optimizing logistics - Janssen

By centralizing its European drug distribution, Janssen was able to optimize the required stock. This makes just-in-time packaging processes possible from a bulk stock of tablets. This leads to a reduction in waste since the shelf-life of medicines in stock is exceeded much less frequently, which also leads to packaging reduction.

Case: Optimizing shelf-life criterium - TEVA

TEVA has calculated that it has to destroy 447,100 packages annually because wholesalers want a remaining shelf life of 12 months. If a shelf life of 9 months would be used for resale, this means that 174,720 packages would have to be destroyed less. This means a saving of 39%. When checking with Mylan and Aurobindo, this also appears to be the case. It is estimated that a total of around 4500 packs of generic medicines must be destroyed per day as a result.

1.3 Re-issue systems

Re-issue systems can be considered for expensive medicines. Pharmacists estimate that it costs around 30 euros per box to get it "safe" back again in the drawer. Furthermore, it will have to be considered how the 'back declaration' should be organized (when issued in first line), how the medical file will be put back in order and perhaps also the reason why someone stops. Most expensive medicines will be delivered via hospital pharmacy.

Case: Re-issue system for unused medicines – UMC Utrecht

During her PhD research, Charlotte Bakker evaluated an implemented re-issue system for the post-exhibition prophylaxis package (PEP) to prevent HIV. The UMC Utrecht has been using this system for five years in the HIV medication that students take to Africa. They only need it if they cut or puncture and therefore run the risk of an infection. In all other cases, the packages, € 800 each, are returned to the UMC for reuse.

PEP was provided in a sealed bag with a temperature logger to record the storage temperature. It could be reissued as:

- The sealed bag was returned unopened;
- The outer packaging and blister were undamaged;
- The medicine was stable for at least 6 months;
- The medicine was stored below 35 ° C.

Over a period of almost four years, 379 students received a PEP package; more than 75% of them had already been spent on other students. This saved € 225,000 (The costs of the re-issue system amounted to € 15,000). A cost saving of 74%.

Source: Pharmaceutisch Weekblad, 51/52, December 21, 2018

2. Reduction

Goal: The sector aims for the optimum product/packaging combination that is meeting all legal and other requirements.

Reduction of packaging materials	
2.1	**Optimizing the primary packaging;** See if the amount of material per package can be reduced: Is all the material needed to meet the quality and safety requirements? This is not only environmentally beneficial, but also ensures that you need less material, which provides economic benefits. Tune the secondary package to the usual number of primary packages contained in it. This prevents unnecessary cardboard use and medicine wastage.
2.2	**Optimizing the secondary packaging;**
2.3	**Optimizing the transport packaging;** Make use of thinner and lighter materials without compromising the functional requirements.
2.4	**Digital Product Information;**

In Europe approximately 80% of all tablet and capsules are packed in blister strips and retail cartons.

2.1 Optimizing the primary packaging

The most commonly used primary packaging is the blister, which is an efficient and safe way to pack pills. Sometimes blisters are bigger than necessary and the weight of the materials can be reduced by using thinner plastic and aluminium foil.

- Make use of thinner and lighter materials without compromising the functional and legal requirements.

Case: Reduction – blister

Keystone Folding Box Co., a designer and manufacturer of paperboard packaging solutions, has responded to calls for reduced plastics in packaging. The company's Ecoslide-OTC™, a paperboard pack for Over-The-Counter medication eliminates the need for larger plastic peel/push blister packs. Ecoslide-OTC™ allows manufacturers to eliminate up to 50% of plastics used in conventional blister packs.

2.2 Optimizing the secondary packaging

Folding boxes, the most important consumer packaging in the industry, have been made smaller and thinner already to save material. For example, many folding boxes have gone from 250 grams cardboard to 210 grams cardboard (reduction of more than 15%). Due to the legal requirements for the provision of information (text in a certain font size and different languages on boxes and in the package leaflet) in combination with technical requirements for the thickness of the cardboard (in order to protect the product optimally and to keep braille tangible without having braille in it combination with too thin cardboard leads to holes in the packaging), the industry sees limited potential to save even more material in this area.

- The weight and volume of the packaging should match the minimum amount needed to maintain the legally required level of safety, hygiene and acceptability for the consumer.

Case: Reduction – folding boxes	
	Many folding boxes have gone from 250 grams cardboard to 210 grams cardboard (reduction of more than 15%).

2.3 Optimizing the transport packaging

Corrugated carton boxes are often used for storage and transportation purposes. Optimization is possible by contacting your supplier.

Case: Reduction – transport box	

2.4 Digital Product Information

Digital package leaflets can replace paper package leaflets, provided that legislation and regulations allow this. In the longer term (2030) the sector aims to replace the paper leaflets with digital alternatives. This applies to all products with the exception of self-care products, because these products are not always provided by a pharmacy that can still provide the required information. This will have a major positive impact on the environment, because a lot of paper is saved, and smaller boxes are possible.

- Role of Pharmacists …

Pilot: Digital Patient Information Leaflets – e-PIL
The e-PIL project has been launched by the pharmaceutical industry in Belgian and Luxembourgish hospitals. In this project, the Patient Information Leaflets for certain medicinal products marketed on the Belgian and Luxembourgish markets will no longer be included in paper format inside the medicinal product's packaging, and instead will only be available online on controlled websites. Although the package leaflet is not considered as a packaging component under EU packaging legislation, it is a potentially reduction of the environmental impact of our medicines.

3. Recycling

Goal: As soon as technology and regulations make this possible, we want to use 100% recyclable packaging, such as recyclable blisters, vials and other packaging.

Recycling	
3.1	**Design for Recycling**: Recycling starts with 'design for recycling'. Use the KIDV recycle check or ask your recycler how to make your packaging fit for commonly used recycling systems.
3.2	**Collection, soring and recycling;**

3.1 Design for Recycling

Recycling starts with 'design for recycling'. There are some general rules to be followed for the design of packaging:

- Use mono-materials whenever possible.
- Combine chemically compatible or jointly processable materials, if multiple materials are required.
- Use materials that are easily separated during automated recycling processes, if multiple materials are required.
- Provide material identification logo's on the packaging to make the process of identification and separation more easy.

Tool: KIDV Recycle check

The Recycle Check is a tool to one of the many choices that packaging designers, but also marketers and buyers have to make if they bring a new product or packaging on the market. The tool has the model of a decision tree.

The user will be asked a short series of questions about the material and packaging components that affect the sorting and recycling. At the end the question is answered: the packaging is good recyclable or not. The Recycle Check focuses at the entire packaging, for example a bottle with cap and label or sleeve, or a bowl with lid and label.

Blisters

The most commonly used primary packaging is the blister, which is not easily recyclable. Although it is technically possible to separate the plastic (PVC) from the Aluminium, this is not done very often.

Bottles, pots, jars and vials

There is a trend in the industry to replace glass vials with plastic in new product registrations, in which the product is stable (eg nasal sprays, cough drink). This saves costs and emissions during transport (due to less total weight) and is more environmentally friendly in production and recycling (less energy consumption). The recycling of the plastic packaging should be considered carefully.

Carton boxes

Most of the carton boxes are very easy to recycle, unless there is a plastic (PE) coating used on the board.

3.2 Collection, sorting and recycling

The recycling process starts with collecting and sorting of discarded packaging materials. Collecting un-used medicines and packaging is also preventing the amount of medicine residues in the surface water.

For some of the pharmaceutical packaging recycling is not an option, due to regulations and safety hazards.

Communication and consumer behaviour …

In a literature review conducted by HPRC, Life Cycle Assessment (LCA) studies comparing recycling to other disposal methods concluded that recycling had a lower environmental impact than landfill or incineration with energy recovery, particularly due to the benefits of avoiding virgin plastic production.

Case: MediSchoon

We use more and more medicines in the Netherlands. A small part of this enters the sewer directly through the sink. In addition, the remains of medication via urine and faeces enter the sewer. After partial purification, the medicines end up in rivers and ditches. This is bad for aquatic life and difficult for the preparation of drinking water.

MediSchoon is a region-wide program for the collection of medicine residues. In cooperation with Vitens, Wetterskip Fryslân, Province of Fryslan, Frisian Pharmacists Association, Water Alliance, GGD Fryslân and various healthcare organizations, governments and waste processors, we have made entire Friesland medicine waste free. After Friesland, work is now being done to make Groningen and Drenthe free of medicine waste.

www.medischoon.info

Pilot: Teva return box

The Teva return box is placed at Pharmacies, so consumers can have their medicine waste and empty blister packs processed safely. For this purpose, Teva Netherlands entered into a unique collaboration with the Thio Pharma pharmacies, the recycling company Renewi and the Institute for Responsible Use of Medicine. The experiences of the pharmacies participating in the pilot are positive. After a short period, people get used to this new approach.

www.teva.nl

Renewi is recycling the blisters. An important condition for recycling these strips is that they are 100% free of pills and that is still a problem.

4. Material choice

Goal: Using packaging materials with the lowest possible environmental impact

Goal: 80% of the transport packaging is FSC/PEFC certified in 2022.

Finding the most sustainable materials for your packaging is always related to the specific situation and product/packaging combination. To be sure about the environmental impact of your specific packaging it is always preferable to make a Life Cycle Assessment (LCA).

Sustainable material choice	
4.1	**Paper and board**; Use FSC/PEFC certified paper and cardboard for all transport packaging. Use recycled materials for secondary and transport packaging.
4.2	**Plastics;** In general plastics are very efficient materials for packaging purposes, but recycling can be still an issue to be solved. Avoid the use of PVC, because this is difficult to recycle and can cause problems with incineration.
4.3	**Aluminium;** Avoid the use of aluminium, because of the high energy impact of the production.
4.4	**Glass;** Glass is impermeable and protects the products very well. It is made from biobased resources, the impact of production is high, but is can be recycled very well.
4.5	**Biobased and biodegradable materials;** Biobased plastics are made from renewable resources and might have a lower environmental impact. Biodegradability is not always an advantage, because in many countries and situations waste collection infrastructure is not supporting this option.
4.6	**Other materials;** inks, coatings and other additives should be free of any hazardous substances.

4.1 Paper and board

Paper and cardboard are very sustainable packaging materials, if they are made of certified sources. The Forest Stewardship Council (FSC) and Programme for the Endorsement of Forest Certification (PEFC) are two international non-profit organizations to promote responsible management of the world's forests. They do this by setting standards on forest products, along with certifying and labeling them as eco-friendly. This certification covers both recycled fibers and new fibers (recycled or mixed resources).

Case: Ecoslide-RX

The Ecoslide-RX is a child-resistant, senior-friendly compliance package that is both eco-friendly and economical to produce. The Ecoslide-RX 3.0 carton contains no plastic, and the internal blister requires minimal film and foil. The Ecoslide-RX 3.0 is made from 100% recycled material, and uses unbleached paperboard and a clay-coated surface to store blister packaging with reduced foil and film. It is easily separated from its internal blister for recycling.

4.2 Plastics

In general plastics are very efficient materials for packaging purposes. The main issue is that they should be recyclable (see: chapter 3). The use of PVC and PS should be avoided whenever possible, because of the lack of recycling options and higher environmental impact of the incineration.

4.3 Aluminium

Aluminium is a material with a relatively high environmental impact, due to the high energy demand for the production. Avoid the use of aluminium, because of the high energy impact of the production.

4.4 Glass

The impermeable nature of glass makes it a safe form of protective packaging. In addition to being an excellent barrier against the external environment, glass containers do not interact with or alter the taste, odor or composition of the

products they contain. Glass packaging provides optimum long-term conservation of the original qualities and virtues of food and beverages.

4.5 Biobased and biodegradable materials

Biobased plastics are made from renewable resources instead of non-renewable petroleum based resources. These renewable resources can include corn, potatoes, rice, soy, sugarcane, wheat, and vegetable oil. Biobased plastics are made by creating plastic polymers from these materials, through either chemical or biological processes. **Biodegradable plastic degrades through exposure to naturally occurring microorganisms.**

4.6 Other materials

Inks, coatings, adhesives and other additives should be free of any hazardous substances.

Checklist: Healthcare Plastics Recycling Council (HPRC), 2019

Desirable materials and design practices:

- Designing with mono-material whenever possible
- Using polyolefin seals or gaskets on polypropylene bottles
- Combining chemically compatible or jointly processable plastics, if multiple materials are required
- Using materials that are easily separated during automated recycling processes, if multiple materials are required
- Using breathable plastics as an alternative to paper
- Minimizing paper labels and components
- Using water-based adhesives
- Allowing for bottles and bags to be fully drained with ease before disposal
- Providing information on contents that allows for easy identification of residual liquids
- Minimizing pigments

Less desired materials and design practices:

- Using a rubber seal on a polypropylene bottle
- Combining incompatible bioplastics and petroleum-based plastics into one product
- Welding, gluing or molding two components of unlike plastics
- Combining plastic film with paper in packaging
- Using metalized plastics, metals screws, grommets in plastic
- Using lead
- Using PVC

Appendix 1: Sources and further reading

- A EUROPEAN STRATEGY FOR PLASTICS IN A CIRCULAR ECONOMY, 2018 https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf
- EU Circular Economy Action Plan https://ec.europa.eu/environment/circular-economy/index_en.htm
- DIRECTIVE (EU) 2018/852 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018L0852&from=EN
- Brancheplan Duurzaam Verpakken - Farmacie en zelfzorggeneesmiddelen (NL) https://www.kidv.nl/item/8742
- KIDV Recyclecheck
- **Healthcare Plastics: Guidance for Recyclers**, Healthcare Plastics Recycling Council (HPRC), 2019.
- **Environmental Impacts of Recycling Compared to Other Waste Disposal Methods**, Healthcare Plastics Recycling Council (HPRC), September 2015. http://www.hprc.org/environmental-impacts-of-recycling.

European Standards Organisation	Reference and title of the harmonised standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of superseded standard
CEN	EN 13427:2004 Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste		
CEN	EN 13428:2004 Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction	EN 13428:2000	2005-02-19
CEN	EN 13429:2004 Packaging - Reuse		
CEN	EN 13430:2004 Packaging - Requirements for packaging recoverable by material recycling		
CEN	EN 13431:2004 Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value		
CEN	EN 13432:2000 Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging		