EDITION







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EDITORIAL

David Daroux

President of Leem's Permanent Eco-Design Task Force

Companies Association (Leem, Les entreprises du médicament) has been closely involved in a joint project as part of the Grenelle Environment Round Table. To extend and strengthen its environmental performance commitments, the association signed a new improvement agreement with the French Minister of Health and the Environment, for the period from 2012 to 2014. The agenda includes work on the drug product lifecycle, particularly research on minimising the environmental impact of packaging through eco-design.

Eco-design can be introduced early in a project, during a new product launch, or as part of a continuous improvement system, leading to a discussion on how to improve packaging performance and innovation while reducing environmental impacts.

With support from Adelphe, Leem provided its members with an introductory guide to eco-design in 2010 and assigned a permanent task force to the topic, which I'm honoured to oversee.

Faced with the ever-increasing challenges presented by this issue, Leem and Adelphe wanted to combine their efforts in order to publish this Eco-Design Guide to Drug Packaging, which provides useful information and guidelines to professionals in the pharmaceutical industry to help guide them in their eco-design efforts. 99

Noëlle Guillerault

Managing Director of Adelphe

In our management of the sorting, collection, and recycling of household packaging in France, we have long encouraged our members to think about the environmental factors associated with packaging.

In 2011, with the new authorisation granted by the government, Adelphe made a commitment to

the objectives of reducing packaging at the source as part of a larger initiative on ecodesign.

We believe that eco-design should be viewed as an opportunity to address today's environmental challenges, while also being innovative and reducing costs at the same time.

That's why Adelphe is here for you as you too make the commitment to help the environment, promoting best practices for reducing packaging at the source.

After forming a successful partnership with Leem and publishing an introductory guide on eco-design, we decided to work again with your association on this operating guide tailored to the drug packaging sector.

In order to continuously improve its services, Adelphe provides you with tools throughout the guide, which will help you improve the eco-design of your packaging. **99**

ECO-DESIGN OF PACKAGINGHow can we improve?

GUIDE FOR THE PHARMACEUTICAL SECTOR

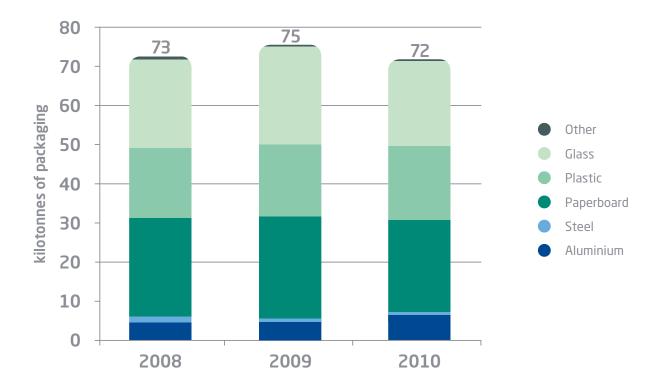
WHY START?



In the household sector, packaging represents an average of 8% of all carbon content consumed each year by the French. But the environmental impact varies greatly depending on the type of packaging involved, ranging from 3% to nearly 33%¹.

In the drug industry, the number of boxes sold between 2008 and 2010 has remained steady. Meanwhile, the tonnes of packaging put on the market has changed little during that time.

Little effort has been made toward reducing packaging weight or volume, and the French still circulate a little more of **70,000 tonnes of drug packaging** each year.



A study of drug packaging material deposits shows that **paperboard is the most common, accounting for 36% of total tonnes of deposits**. Plastic has increased by 7% in two years, while glass is down 9%².

Packaging cannot be separated from products because it serves essential functions, especially in pharmaceuticals. For example, packaging protects products, allows them to be tracked, provides general information and safety information to patients, and more.

Because of its importance, it is reasonable to question whether there is still more that can be done about the environmental impact of packaging. Improvements are indeed possible, and an increasing number of companies are exploring eco-design.

An eco-design initiative involves thinking about environmental criteria as early as the design phase of packaging or when improving existing packaging, for the purpose of reducing the impact of the packaging on the environment while maintaining its original functions.

Implementing such an approach also benefits your entire business structure.

Did you know?

Between 2008 and 2011, the number of companies in the industry who are investing in eco-design for drug packages has quadrupled³.

¹ Source ADEME 2012 - The Carbon Content of Shopping Carts Today.

² Source Adelphe - Consumer Data 2011.

³ Source Leem 2011 SCR Report - A study of 43 companies, representing more than 60% of the sector.



CONTROL YOUR COSTS

Reducing the consumption of raw materials and energy during production and optimising logistics are both actions that yield economic benefits for your company. Decreasing the weight of materials also reduces Green Dot contributions.

STAY COMPETITIVE

By offering a new perspective on your products, eco-design will drive innovation.

CREATE VALUE FOR YOUR PRODUCT

Eco-design enhances your company's environmentally-friendly activities.

INVOLVE YOUR TEAMS

The extensive reach of eco-design projects (marketing, R&D, logistics, etc.) motivate your teams around a new central focus.

COMPLY WITH REGULATIONS

The "Packaging and Packaging Waste" directive (94/62/EC) requires companies to make an effort to reduce packaging at the source, limit heavy metals, and use packaging that can be recovered at the end of its life, all actions that play a role in eco-design.

IPSEN'S ACTIONS

ECO-DESIGN

TO....

Why have you adopted eco-design?

Ipsen is a firm believer in the importance of the environment, health, and safety. The integration of eco-design and prevention into Ipsen's HSE strategy was driven mainly by a desire among HSE professionals to build general awareness about this topic through Leem.

What actions have you put into place?

In terms of reducing at the source, we have been working at the Dreux industrial site to lower how much aluminium goes into a line of medicine bags, and we have reduced the weight of cardboard boxes.

We have also replaced insulated cases with refrigerated trucks, which saved 2,000 insulated cases in 2009, and on larger scale, we optimised our pallet layout to improve efficiency during transport.

Other actions have been initiated in 2012. For example, we are working with our vendors to limit the packaging used for packaging materials delivered to our site.

What benefits has your company seen from eco-design?

By motivating our teams internally (purchasing, quality, methods, HSE, etc.), the eco-design actions that have been put into place have resulted in real economic benefits for our sites.

Are there any projects in the pipeline?

The principles of eco-design and reduction of packaging at the source are integrated into our new product manufacturing plans from the very beginning. For any new drug that comes along, we are optimising the size of the sales unit for palletisation. Our vision in terms of packaging eco-design has shifted from a short-term vision to a long-term vision.



WHERE DO WE START?

Use the following industry-specific eco-design checklist to help you get started.

Key principles

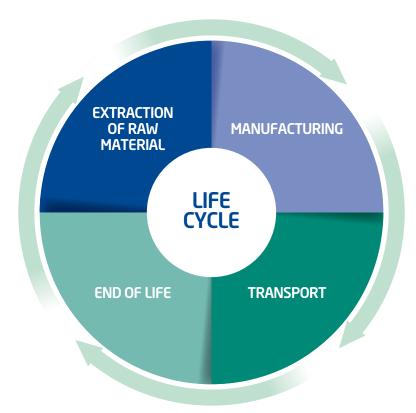
Follow the two key principles below for each guidelines of eco-design:

- **ENSURE THAT YOUR PACKAGING COMPLIES** with regulations governing packaging.
- AVOID TRANSFERRING POLLUTION BETWEEN DIFFERENT PACKAGING SYSTEMS (UVC, SECONDARY, AND TERTIARY)
 by confirming that a change or improvement to one aspect of packaging results in an overall improvement.

Checklist guide

Eco-design guidelines included in the checklist are organised:

• by stages of the packaging lifecycle. The lifecycle includes all stages in the life of the packaging: the extraction of raw materials used in packaging, the shaping of the packaging, the steps involved in transporting the empty or filled packaging, and the lifecycle of the packaging once it becomes waste. Each stage is shown here as a segment of the wheel.



• by level of difficulty of the suggested actions:
 ★ Easy
 ★ Affordable
 ★ More complicated

Some areas of eco-design may require a change to the Marketing Authorisation (AMM, Autorisation de Mise sur le Marché). These can be identified by the last column in the checklist.





EXTRACTION OF RAW MATERIAL

FOCUS OF WORK	DIFFICULTY	ASK YOURSELF	EXAMPLES OF INDUSTRY-SPECIFIC ACTIONS	MA CHANGE	V		
Weight / Volume	*	Can we reduce the weight of our boxes?	Focus on the weight of the box to come up with the appropriate packaging				
	***	Can we make the contents thinner to reduce the weight of our packaging?	Review the thickness of bottles and the size of stoppers	To be determinated			
	***	Can we reduce how much needs to be packaged for more consistent produce quantity?	Freeze-dry the product or make it concentrated	To be determinated			
	***	Can the volume of packaging be reduced relative to the size of the product?	Check that the blister pack is not too big Minimize empty space in boxes	To be determinated			
	Refer to the best practices guide on "source reduction", available at http://reduction-emballages.adelphe.fr						
Packaging techniques	*	Can we eliminate part of the packaging without jeopardising the protection of the product?	Eliminate fillers inside the box Study whether cardboard trays and racks are required				
	**	Are packaging surfaces being used as efficiently as possible?	Reduce the width of seals Review overlap techniques Use shorter flaps for boxes				
	***	Is it possible to reduce the amount of waste generated by safety seals?	Limit the use of tabs or covers Research alternatives to peelable blister packs	To be determinated			
Waste	***	Can we maximise the product's return rate for patients?	Focus on the design of the contents or on the selection of materials to allow the patient full use of the product (liquid, cream and powder)	To be determinated			
reduction	***	For the packaging of products used only in part, is the reclosing system ideal?	Check the performance of reclosing systems Modify the packaging so that the product stays good longer	To be determinated			
	*	Are recycled materials being used in the packaging system? If not, can they be used?	Use cardboard boxes made from recycled fibres Look into food safe recycled materials	To be determinated			
	**	Can the materials in use be sorted and collected in France? If not, can the recyclability of the packaging be improved?	Refer to the sorting guidelines to identify packaging that can be recycled				
Materials	***	Can packaging using multiple layers or multiple materials be eliminated?	Opt for packaging that uses just one material and/or layer in order to: -Facilitate the recycling of incoming packaging in sorting guidelines -Reduce the steps involved in assembly and, likewise, energy consumption	To be determinated			
	***	Have we verified that there is nothing to prevent recycling?	Refer to Adelphe's list of recycling disruptors Avoid using a tagger seal for a PET bottle, for example	To be determinated			
	See the guide on recycling disruptors http://www.adelphe.fr/entreprises; "Documentation Utile"						



FOCUS OF WORK	DIFFICULTY	ASK YOURSELF	EXAMPLES OF INDUSTRY-SPECIFIC ACTIONS	MA CHANGE	V
Production techniques	**	Have packaging production and assembly processes been optimized?	Minimise production line energy losses		
	**	Are there minimal and/or strategic drops in production?	Adjust the sizes of what goes into the line (sheets of cardboard, reel widths, etc.) relative to the limits of production machines Recycle internal drops in production		
Supplier	*	Has the weight of packaging been compared against what competitors are offering with the same level of packaging performance?	Add a weight check when selecting suppliers		
	*	When selecting new packaging, has it been determined that the new packaging provides at least the same level of environmental performance as the old packaging did?	Add an environmental check when selecting new packaging (percentage of recycled material included, recycling of drops in production etc.)		
	**	Can we reduce the distance required for transport?	Prefer local suppliers		
	***	In general, has there been an effort made to make the size of packaging consistent?	Limit how many sizes and/or colours are being used	To be determinated	
	**	Is it possible to reduce the amount of additives used in the packaging's finish?	Reduce the amount of ink and/or the number of colours Reduce the amount of glue		
Finish	**	Can more environmentally-friendly ink be used?	Opt for water-based ink with low migration potential		
	**	Can more environmentally-friendly glue be used?	Opt for water-soluble glue Consider using solvent-free glue		







FOCUS OF WORK	DIFFICULTY	ASK YOURSELF	EXAMPLES OF INDUSTRY-SPECIFIC ACTIONS	MA CHANGE	V
	*	Can we reduce the weight of packaging used for transport?	Reduce the weight of boxes and separator material Reduce the amount or thickness of shrink-wrap Opt for lighter pallets		
	**	Has multipack packaging been adjusted to the size of the product being transported?	Eliminate all empty space		
Distribution	**	Can bulk or transport packaging be reused?	Reuse insulated cases Reuse pallets		
	**	Can palletisation be improved so as to increase how many products are transported at a time?	Go over palletisation plans (number of grouped cases on each layer, number of layers, etc.)		
	*	Has a supplier been selected who is committed to being environmentally responsible?	Include an environmental check when selecting suppliers (carbon reduction program, ISO 14001 certification, EMAS, etc.)		
Transport	**	Has work been done to optimise transport?	Eliminate trips involving empty trucks Work on the number of rotations made by trucks		
	***	Can alternative or less polluting modes of transport be used?	Consider using boat or rail transport		



	FOCUS OF WORK	DIFFICULTY	ASK YOURSELF	EXAMPLES OF INDUSTRY-SPECIFIC ACTIONS	MA CHANGE	V
Packaging end of life	*	Do patients have information on how to recycle packaging?	Provide information about sorting the packaging for recycling, for example on the medication instructions (p.14)			
	***	Is it possible to separate the components of the packaging for easier recycling?	Make packaging components easier to separate	To be determinated		

HOW CAN ECO-DESIGN EFFORTS BE EVALUATED?



Overview of lifecycle assessment

Lifecycle assessment (LCA) is a standardized method of quantifying a product's environmental impacts over its entire lifecycle, producing several environmental indicators as results.

MULTIPLE STAGES

This multiple stages approach prevents pollution from being transferred between the stages of the packaging lifecycle. For example, selecting a more environmentally-friendly raw material for packaging may reduce its recyclability and therefore increase its end-of-life impacts. This is why it is important to consider the entire lifecycle of the packaging.

MULTIPLE CRITERIA

Some impacts garner intense media interest. For a complete analysis, it is absolutely essential to consider all of a product's impacts. For this reason, the lifecycle assessment includes multiple indicators to measure environmental impacts, including:

The "Greenhouse Gas Emissions" indicator covers global warming potential.

Greenhouse gases are gaseous compounds that absorb infrared radiation emitted by the Earth's surface. Their increased concentration in the Earth's atmosphere is thought to be a factor behind recent global warming. Greenhouse gases are all measured in terms of their CO₂ equivalent, by weighing their warming potential.

Did you know?

Carbon dioxide (CO_2) is the second most common greenhouse gas in the atmosphere, behind water (H_2O). That makes it the biggest anthropogenic contributor to the greenhouse effect.

Methane (CH₄) is another greenhouse gas, with 21 times the heating potential of CO₂.

The "Water Consumption" indicator is calculated from water sampling and waste water. It is expressed in ml.

The "Non-Recovered Packaging Waste Production" indicator measures the number of tonnes of residual packaging waste. Such waste is not recovered by recycling or waste-to-energy.

The "Depletion of Non-Renewable Resources" indicator represents the consumption of non-renewable fossil and mineral resources, describing their loss on the land. A natural resource is considered to be non-renewable or exhaustible when its rate of consumption exceeds its rate of creation.



DECISION SUPPORT TOOL

The LCA can also be used to compare multiple packaging solutions in terms of their environmental impact. This comparison focuses on a single function, meaning that the packaging being compared must provide the same service to the user, including the same quantity of product for the same duration of time.

An LCA can be performed using various tools, some more sophisticated than others. They are easy to learn and may or may not be specific to a particular industry. Adelphe/Eco-Emballages has developed its own tool, called BEE, which is specific to packaging.

The Adelphe/Eco-Emballages LCA tool: BEE



BEE (Bilan Environnemental des Emballages [environmental impact of packaging]) is an eco-design packaging tool. It is used to evaluate the environmental impact of the entire packaging system based on the four indicators listed above.



BEE also provides:

- · Packaging templates for easier project import
- Reports for summarising the results of the project
- A page for managing teamwork

And coming soon:

- A checklist for implementing eco-design processes
- The BEE critical review to confirm its robustness and compliance with LCA standards

BEE is available as an intuitive and user-friendly web interface: **bee.adelphe.fr**

Available to everyone free of charge.

VOCABULARY

The packaging system can be defined a number of ways, depending on the sector.

In BEE, the **Consumer Sales Unit (CSU)** is the packaging in direct contact with the product (blister pack, bottles, pill boxes, bulbs, bags, etc.) and the contents of the packaging (case, boxes, etc.). The consumer sales unit therefore includes all of the packaging the patient receives.

Multipack packaging is known as **secondary packaging** (e.g. Regular Slotted Case), and **tertiary packaging** is used to describe transport and delivery packaging (e.g. pallets).

LCA results: Example obtained with BEE

In 2011, a laboratory put an eco-design process into place for a line of bottle/pill packaging. The process made it possible to redesign the traditional system to develop a more eco-designed solution. The following itemizes the environmental benefits of those actions.



BASELINE SOLUTION

Actions taken

- Elimination of a non-recycled LCA component
- Reorganisation of items in the box
- Improved pallet layout

Impacts on the characteristics of the LCA packaging

- Volume reduced by two-thirds
- Weight reduced by 15%
- Greater potential recyclability



ECO-DESIGNEDSOLUTION

By comparing the LCA results of the baseline solution and the eco-designed solution, we can measure the benefits of the actions taken. The LCAs were performed with BEE.

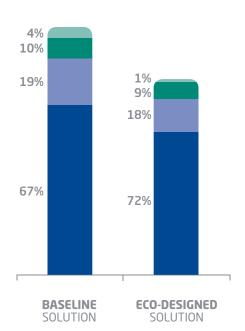
IN TOTAL: A 20% REDUCTION

With the eco-designed solution, the "Greenhouse Gas Emissions" (-25%) and "Depletion of Non-Renewable Resources" (-20%) indicators show a significant reduction in environmental impacts. The actions taken have provided a tangible environmental benefit.

Did you know?

In LCA, a difference of more than 15% between two environmental assessments is considered significant. Such a difference indicates that the actions taken have had a tangible effect.

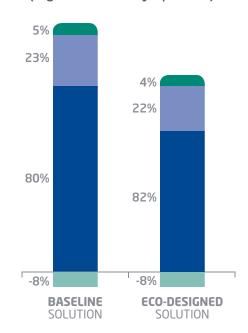
GREENHOUSE GAS EMISSIONS (in grams of CO, equivalent)





DEPLETION OF NON-RENEWABLE RESOURCES

(in grams of antimony equivalent)





A CLOSER LOOK AT THE "GREENHOUSE GAS EMISSIONS" INDICATOR

Reducing the weight and volume of the consumer sales unit can reduce the overall impact over all stages of the lifecycle and for the entire packaging system (consumer sales unit, secondary packaging, and tertiary packaging). Source reduction results in less materials used for the consumer sales unit and a smaller box, which in turn allows for more boxes in each bulk case, fewer cases overall (secondary packaging), and fewer pallets (tertiary packaging) for the same number of transported products.

Finally, eliminating a non-recycled item for the consumer sales unit can greater reduce the end-of-life impact.



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HOW TO PROMOTE YOUR ACTIONS?

In terms of environmental communication, it is important to focus great care on the content of messages. Adelphe provides several tools to help you prepare your environmental messages.

FOR YOUR SUSTAINABLE DEVELOPMENT AND ACTIVITY REPORTS

Always compare the environmental impact of packaging with the impact of the product/packaging combination, and tailor your communication strategy to the target audience (patient, distributor, government, etc.).

Eco-Emballages has published a guide to help you understand your results and your commitment to packaging in sustainable development and activity reports.

The guide is available at:

http://www.adelphe.fr/entreprises; "Documentation Utile"



TO PRESENT YOUR LIFECYCLE ASSESSMENTS

In order to be an external communication topic, a lifecycle assessment must be reviewed by a group of independent experts, according to applicable standards (ISO 14040 series).

TO HIGHLIGHT YOUR SOURCE REDUCTION ACTIONS

Adelphe and Eco-Emballages have a website you can use to state your source reduction actions.

You may also choose to share your best practices and receive a bonus in your annual declaration*.

The site is available at:

http://reduction-emballages.adelphe.fr

Pairs committee won actions de réduction d'emballage 8 partager les bonnes pratiques In a martine d'un le beune se cette de 2) de cette de 1,000 de 1,000

TO GUIDE PATIENTS IN SORTING

Patients are always looking for easy-to-use tools to help with sorting. To address this need, Adelphe, Leem, and Cyclamed have developed the "Info-tri Médicaments" for drug packaging.

This turnkey tag is available to companies in the industry. It can be used to affix sorting guidelines to packaging elements for example on the instructions, with or without content.

By affixing this "Info-tri Médicaments", companies can earn a bonus toward their annual packaging declaration*.

For more information on the "Info-tri Médicaments" guide, visit: www.adelphe.fr/entreprises



Did you know?

Unlike in other sectors, drug packaging waste is handled by two separate organisations:

- If the packaging is completely empty: it should be sorted according to local guidelines, using the Adelphe system.
- If the packaging contains leftover drugs: it is considered unused drugs and must be returned to a pharmacy, using the Cyclamed system.

^{*} See the eligibility requirements in the 2012 Declaration Guide: www.adelphe.fr/entreprises/la-declaration







ADELPHE

Find all of the tools discussed in this guide and other Adelphe services to help with your eco-design processes at **www.adelphe.fr/entreprises**

FRENCH PHARMACEUTICAL COMPANIES ASSOCIATION

Find out what your association is doing at www.leem.org

FRENCH PACKAGING COUNCIL

Learn about how the French Packaging Council is preventing packaging waste, and visit the discussion forum for packaging professionals at **www.conseil-emballage.org**

CEREC/COTREP

Read reviews about packaging recyclability from CEREC (Packaging Recyclability Evaluation Committee) and COTREP (Technical Committee for the Recycling of Plastic Packaging), two expert technical committees on package recycling. **www.cerec-emballages.fr** and **www.cotrep.fr**

ADEME

Contact ADEME (French Environment and Energy Management Agency) for assistance with your environmental processes. **www.ademe.fr**





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