PRACTICAL GUIDE TO ECODESIGN IN PHARMACEUTICAL PACKAGING

SIGRE

Medicamento y Medio Ambiente

Index

1 Introduction to the Guide

THE VALUE OF MEDICAL PACKAGING

Humberto Arnés
Chairman of SIGRE
Managing Director of Farmaindustria

The pharmaceutical industry is the main driver of research in our country. Thanks to investments in R+D, previously deadly diseases are now considered chronic, and have even been eradicated; our life expectancy and quality of life have improved, generating social value and bringing wealth to our society.

The combination of these medical, social, and economic factors and innovation are what define the real value of medicine in a modern and developed society. But, at present, medicines without their packaging are inconceivable and the value the packaging provides is unquestionable.

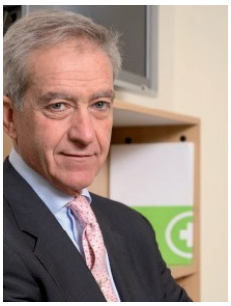
The value of medicines' packaging lies, first of all, in its two-fold protective function. On the one part, it protects the properties and qualities of the medicine, and on the other part, it protects users' health through the information provided for the medicine's correct use and conservation.

The packaging also guarantees the medicine's traceability and ensures it is of legitimate origin, defending consumers' rights against potential counterfeits.

Also, packaging is one of the most visible proofs of the pharmaceutical industry's concern for the environment, thanks to the application of preventive measures to minimise its environmental impact.

Our objective as a sector is for medical packaging to incorporate new environmentally-friendly attributes from the moment of its design, thereby reinforcing, if possible, the value of the medicine it contains.

"Currently, medicine without its packaging is inconceivable and the value that packaging provides is unquestionable"



ONE STEP FURTHER TOWARDS A SUSTAINABLE CONTAINER

Juan Carlos Mampaso
Managing Director of SIGRE

SIGRE has been the entity responsible for driving and coordinating the five Packaging Prevention Business Plans developed by the pharmaceutical industry between 2001 and 2014.

In each one of them, the effort made by the pharmaceutical industry, through successive preventive measures applied to packaging and centred on reducing its weight and volume, have allowed us to surpass the original objectives and to obtain magnificent results.

Evidence of this is that, if we compare the weight of packaging for sale, grouping and transport, used in 2014, with that in 2000, there has been a reduction of 22.85%.

Having practically concluded this stage, it is time to reflect on and study the way of continuing to innovate to open up new lines of action that allow the sector to maintain its pioneering role, anticipating and preparing for new legislation.

Through the publishing of this Guide, our aim is to take a step further and provide the sector with a broader vision of ecodesign actions that can be applied to packaging, based on an analysis of its environmental impact throughout its life cycle.

This vision opens up new prospects and areas of action to ensure medical packaging is increasingly sustainable.

We hope that the content of this Guide serves to inform and stimulate leaders in this sector and that their work serves to demonstrate publicly the pharmaceutical industry's firm commitment to caring for the environment.

"By publishing this Guide, we aim to move forward and to provide the sector with a broader vision of eco-design"

2 What has been done in pharmaceutical packaging prevention?

For the last 15 years, the pharmaceutical industry has been implementing and developing action plans to prevent at source the quantity of medical packaging materials placed on the market and to promote the recycling of packaging waste. These are known as the pharmaceutical sector's Packaging Prevention Business Plans.

This environmental commitment of the pharmaceutical laboratories and their efforts to incorporate the sustainable aspect into their packaging is reflected in the following actions and results obtained:

5

Packaging Prevention Business Plans from 2000 to 2014

- ✓ **15 years working on packaging prevention**
- ✓ **Objectives fulfilled**
- ✓ **2015-2017 Plan in progress**

1,763

prevention measures applied by pharmaceutical laboratories to their packaging throughout this period

- ✓ **Reduction in packaging weight**
- ✓ **Improved recycling**
- ✓ **Minimisation of the environmental impact**

22.85%

reduction in the weight of pharmaceutical packaging (sale, grouping and transport)

429

million containers have incorporated environmental improvements

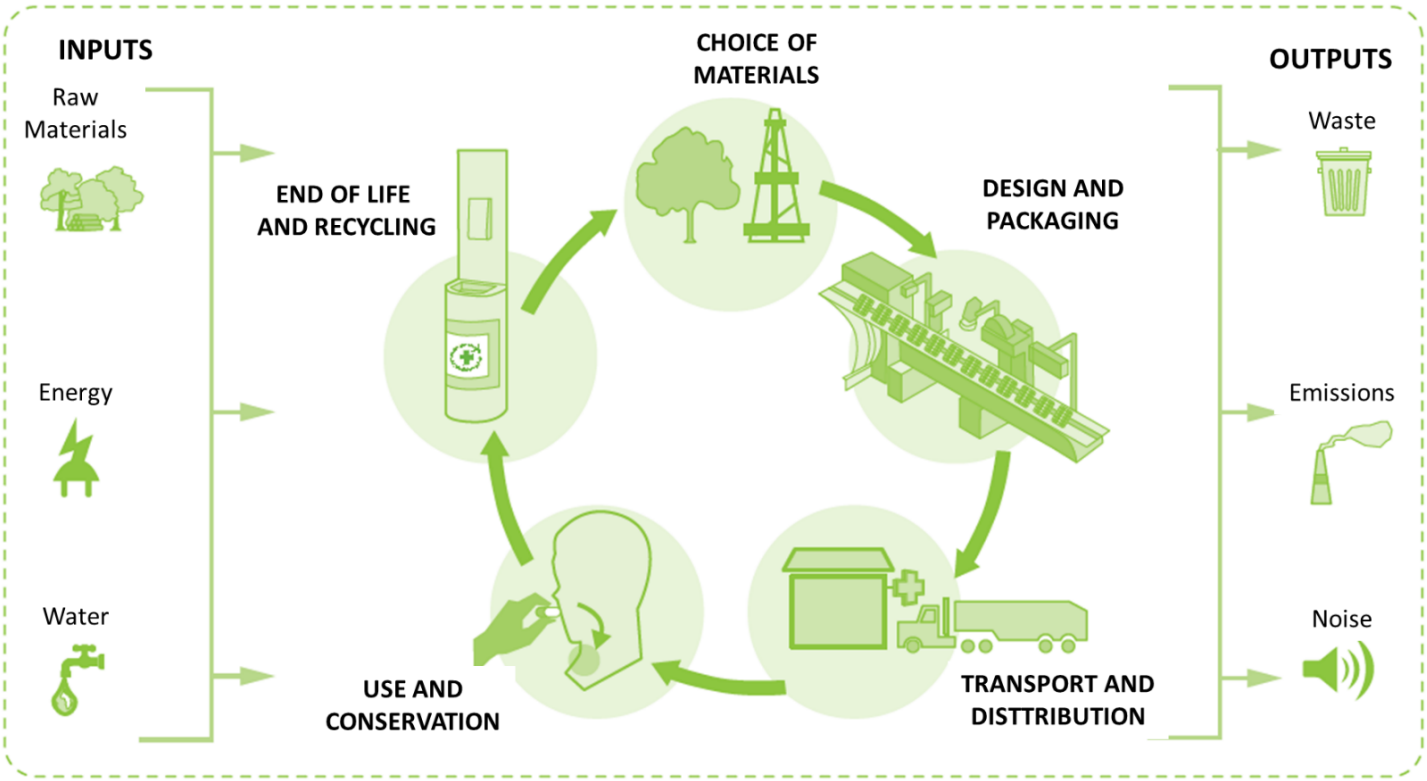
The pharmaceutical industry has spent years developing prevention programmes to reduce the environmental impact of their packaging

3 What is ecodesign?

Ecodesign is a design methodology that analyses environmental impacts throughout packaging's life cycle.

The global environmental impact of pharmaceutical packaging requires an analysis of all raw material, energy and water inputs and waste, emissions and noise outputs in each stage of the packaging's life cycle, from choice of materials through to end of life.

STAGES IN THE LIFE CYCLE OF PHARMACEUTICAL PACKAGING



The type of each medicine conditions the ecodesign of its packaging to guarantee correct dosing, use and conservation

4 Benefits of ecodesign in pharmaceutical packaging

ECONOMIC

- Reduced costs of packing, production and distribution
- Improved productivity
- Optimised resources

MARKET

- Differentiation from other laboratories
- Access to markets that demand sustainable products

ENVIRONMENTAL

- Reduction in the use and consumption of raw materials and energy resources
- Reduction of the global environmental impact

"Change is inevitable. Growth is optional"

John C. Maxwell

"Environmentally friendly markets will grow by 125% by 2020"

Federal Ministry of the Environment. Germany. 2009

QUALITY

- Excellence in products and operations
- Fostering the qualification of personnel across different disciplines
- Continual improvement in line with GMP (Good Manufacturing Practices)

LEGAL AND REGULATORY

- Guarantee of national and international compliance
- Anticipation of future legislative and regulatory developments

INNOVATION

- Competitive advantage versus other laboratories
- Environmental management leaders

IMAGE

- Improved perception of the Pharmaceutical Industry among patients, the Administration, etc.
- Sustainable brand value

5 Steps to be taken

1 CONSTITUTION OF THE WORK TEAM

- Choose a coordinator and a multidisciplinary team from the company areas involved: dosage forms, production, environment, quality, procurement, marketing, logistics, etc.

WORK TEAM DEFINED

2 CONTAINER SELECTION

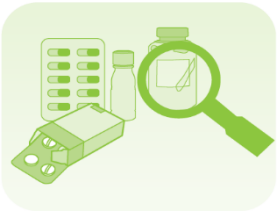
Ecodesign of a new container:

- With the medicine as the starting point having an established pharmaceutical form, identify the packaging possibilities best suited to the medicine in question.
- Check the compatibility of the different materials and select the types of packaging to be analysed
- Describe the components of each type of packaging and gather details regarding: materials, power consumption, costs...

Ecodesign of an existing container:

- Based on the packaging under study, describe its main components
- Collect information on each stage of its life cycle in relation to: materials, power consumption, costs…

PACKAGING SELECTED AND DATA COLLECTED



3 ENVIRONMENTAL ANALYSIS

- Carry out an environmental assessment of the packaging applying a life cycle perspective
- Identify the stages with the highest environmental impact to define potential actions
- Use as a starting point the ecodesign initiatives provided in the guide and develop one or several lines of action together with the team

AREAS OF IMPROVEMENT IDENTIFIED

To be successful in ecodesign, Management must promote it and involve all of the company's departments

4 FEASIBILITY STUDY

- Analyse the feasibility of the contemplated lines of action bearing in mind the medicine's requirements, legislation, costs, or changes in the process, among other aspects
- Quantify improvements that can be made for each studied action

POTENTIAL SOLUTIONS ANALYSED

5 SELECTION AND IMPLEMENTATION OF ACTIONS

- Select, describe and plan actions to be implemented and integrate them with the company's procedures pursuant to legislation and GMP (Good Manufacturing Practices)
- Put the actions into practice, informing the parties involved (staff, suppliers…)

SELECTION AND IMPLEMENTATION: ECODESIGNED CONTAINER

6 ANALYSIS OF RESULTS AFTER IMPLEMENTATION

- Analyse results relating to: reduction in materials, cost optimisation, improvements in processes, sales outcomes, improved perception among patients and sector professionals, etc.
- Review and quantify the improvements achieved following a determined marketing period

RESULTS

7 COMMUNICATION

- Communicate improvements achieved, both internally and externally

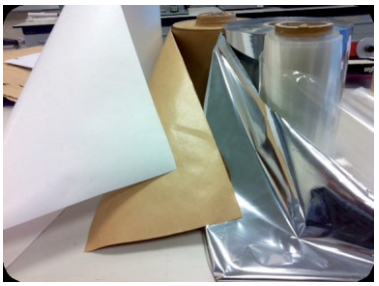
DISSEMINATION

The “green container” is not only an image, but also a path towards being a more competitive, sustainable and socially responsible organisation. Ecodesign is the tool to achieve this.

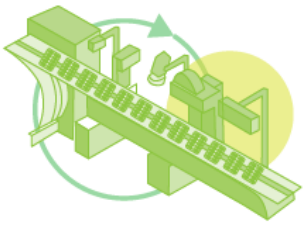
6 What ecodesign initiatives can be applied?

IN THE CHOICE OF MATERIALS

The choice of the different materials, their quantity and resulting environmental impact are considerations that allow us to optimise available natural resources in the manufacture of pharmaceutical packaging.

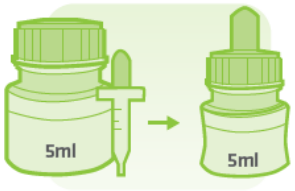


AREAS OF ACTIVITY	LINES OF ACTION	INFLUENCE ON OTHER LIFE CYCLE STAGES
Decrease in weight and/or volume 	• Reducing weight • Reducing thickness • Reducing size • Reducing the quantity of material used • Minimising empty spaces • Eliminating superfluous elements	**Design and packaging** • Ensuring packing and filling processes are correct • Verifying that assembly operations are efficient **Transport and distribution** • Comparing the quantity of packaging required for grouping and transportation • Verifying the packaging's resistance throughout the distribution cycle
Use of materials with a lower environmental impact 	• Replace the packaging material with one having a lower environmental impact • Minimise the heavy metals content of the packaging material • Use materials that require less water and energy consumption • Choose renewable materials • Foster the use of recycled materials • Use accessory elements with a lower environmental impact: inks, adhesives, glues... • Work with local suppliers (reduced transport distance)	**Use and conservation** • Checking whether administration and conservation of the medicine is adequate **End of life and recycling** • Revising the quantity of waste to be generated • Verifying whether recycling is possible and the separation of the container's components • Verifying that the appropriate waste collection and management systems are in place and available
Simplification of the materials 	• Reduce use of different types of materials for the same packaging • Improve separability	

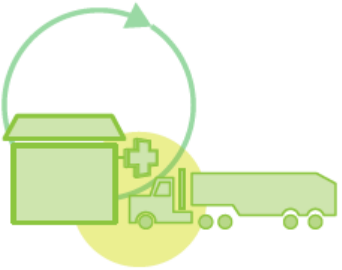


IN DESIGN AND PACKAGING

Design changes associated to optimising the container's material and/or volume in addition to improvements in the packaging process are solutions that minimise the environmental impact of the containers

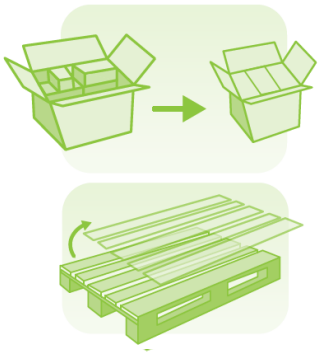
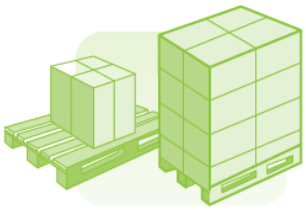
AREAS OF ACTIVITY	LINES OF ACTION	INFLUENCE ON OTHER LIFE CYCLE STAGES
Optimisation of packaging design 	•Reduce the size of the packaging by redistributing the medicine and/or accessory components •Reduce the size of the container and/or its components through changes in design •Reduce sealing surfaces •Use packaging with improved container/content ratios •Reduce/eliminate printed surfaces •Use less bonding elements •Design containers that provide for swift and efficient assembly	**Choice of materials** •Confirm that the environmental impact is lower •Examine the packaging material's capacity to be sealed •Check compatibility between the material used and the packaging process **Transport and distribution** •Check whether modularity is improved •Review the weight/volume of packaging for grouping and transportation •Verifying the container's resistance throughout the distribution cycle **Use and conservation** •Check whether the medicine's administration and conservation is adequate •Note whether the packaging opens and closes correctly •Check that the reduction in printed surfaces does not alter the patient's understanding of the information **End of life and recycling** •Minimise the quantities of packaging waste generated •Analyse the components' separability
Optimisation of packaging processes 	•Improving the efficiency of the filling and dosing system through the container's design •Designing containers and choosing materials that increase the speed of the packaging process •Using automated packaging (containers and self-assembling packaging) •Adapting packaging technologies to the container materials and pharmaceutical forms •Selecting packaging processes that require minimum consumption of power, water and other materials	

What ecodesign initiatives can be applied?



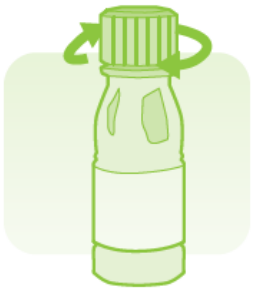
IN TRANSPORT AND DISTRIBUTION

Organising sales units in group packaging and optimising transport and distribution operations help to reduce the environmental impact and use of available resources

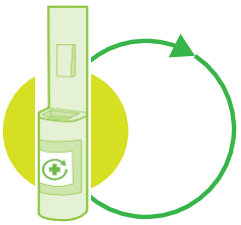
AREAS OF ACTIVITY	LINES OF ACTION	INFLUENCE ON OTHER LIFE CYCLE STAGES
Optimisation of grouping and transportation 	•Adapting the size of grouping packaging to the number of transported sales units •Using lighter packaging •Using reusable packaging •Adapting the quality of the packaging to the actual load •Eliminating and/or reducing superfluous elements (edge guards, cardboard sheets, filler material…) •Adapting the design of the sale container to the packaging used for transport	**Choice of materials** •Check whether the quantity of material is reduced •Make sure that the demand for power and fuel is reduced **Design and packaging** •Revise adequate handling of grouping packaging •Check that production times are optimal with use of reusable elements •Revise volumes and quantities transported **Use and conservation** •Check that the medicine and its packaging arrive at the destination in a proper condition **End of life and recycling** • Verify whether the quantity of material is the minimum possible
Modularity/ manipulation of cargo on pallets 	•Redesigning container groupings according to orders •Increasing the quantity of medicine transported on pallets (use of software for the optimisation of pallet mosaics) •Use modular transport packaging, folding, detachable…	
More sustainable transport 	•Optimise cargo space •Optimise transport routes •Use more environmentally-friendly means of transport: multi-mode (rail, sea), run on renewable energy sources (biodiesel), or having a low environmental impact (electric vehicles) •Using modern vehicle fleets •Choosing professional transport services with implemented environmental management systems	

IN USE AND CONSERVATION

The most appropriate environmental packaging solution must facilitate or maintain correct administration of the medicine by the patient and conservation until expiry of its shelf life

AREAS OF ACTIVITY	LINES OF ACTION	INFLUENCE ON OTHER LIFE CYCLE STAGES
Optimisation of the medicine's administration and conservation 	•Adapt opening and closing systems to the patient's general profile •Optimise auxiliary elements, such as dosing devices or accessories, for administration of the medicine •Design containers to optimise storage space •Improve the ergonomics of the container while using the least possible quantity of material •Introduce systems that guarantee no ha ndling or counterfeiting of the medicine, compatible with the packaging material	**Choice of materials** •Check whether the quantity of material used is reduced or the global environmental impact **Design and packaging** • Verify the capacity for processing with the opening and closing systems used •Examine that the container's empty spaces are minimal •Check that ergonomic improvements in the container do not interfere with the efficiency of the packaging process **Transport and distribution** •Check that there is no deterioration in sale containers or loss of medicine during transport operations •Confirm the resistance of the packaging for grouping and transportation throughout the distribution cycle **End of life and recycling** •Check whether less packaging waste is produced •Revise whether the quantity of unusable medicine is reduced
Extend the useful life/reuse 	•Use refillable/reusable containers •Improve the design of closures, and also use reversible opening and closing systems •Use materials with improved barrier properties •Use packaging with additional functions to that of their initial use	
Modification of the information support 	•Introduce new information systems with a lower environmental impact	

What ecodesign initiatives can be applied?



END OF LIFE AND RECYCLING

Reducing the quantity of medicine that is not usable, minimising generated container waste and favouring appropriate management will reduce environmental impacts and the consumption of natural resources

AREAS OF ACTIVITY	LINES OF ACTION	INFLUENCE ON OTHER LIFE CYCLE STAGES
Use of recyclable 	•Use of materials with existing and available recycling processes •Reducing the quantity of materials used •Simplifying the types of materials used in one same container	**Choice of materials** •Check whether changes to a more recyclable material might affect the safety of the medicine •Check that materials do not have a high global environmental impact •Verify whether it will be possible to recycle the materials used **Design and packaging** • Verify that the packaging materials used can be processed •Check the functioning of new bonding systems in the packaging process •Confirm that improvements in separability do not interfere with the usual packaging process **Transport and distribution** •Examine that transportation is optimised for the management of generated waste **Use and conservation** •Check whether the quantity of unusable medicine in the container is reduced
Optimisation of recycling processes 	•Improve effective emptying of the containers •Improve recycling compatibility of the materials used (label and container…) •Reduce elements that can prevent recycling such as: coatings, bonding elements (adhesives) •Use materials that are easy to separate •Identify the container's type of material	

7 Examples

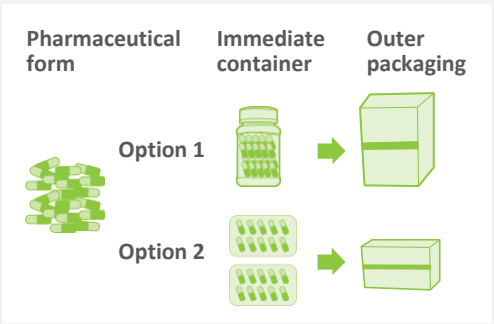
ECODESIGN OF A NEW PHARMACEUTICAL CONTAINER

CONTAINER SELECTION

Ecodesign of packaging for a new medicine formulated in 20 pills for oral administration, requiring cold storage. The most environmentally friendly container is chosen, from among those that are compatible with the medicine and its pharmaceutical form. Two possibilities are considered:

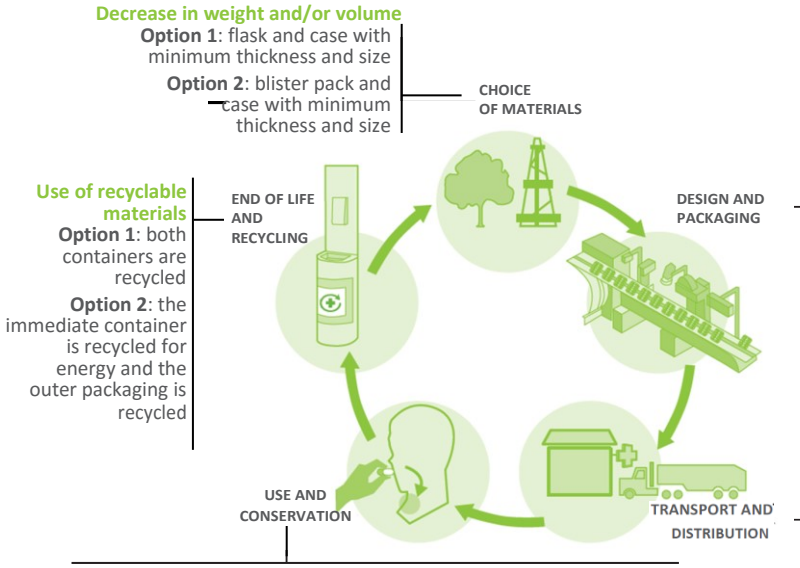
- **Option 1**: vial with a plastic body and lid (HDPE)
- **Option 2**: blister pack (PVC-Al)

The outer packaging (case) is designed to adjust to the dimensions of the immediate container. At the same time, grouping packaging is selected that is appropriate for the sale unit.

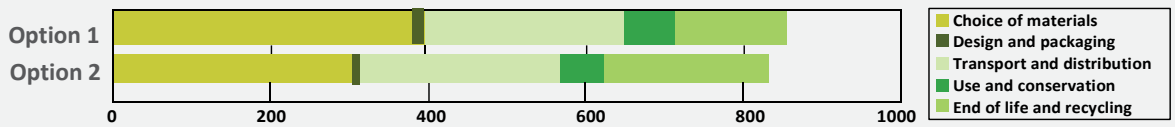


AREAS OF ACTIVITY AND LINES OF ACTION

Next, in the different stages of the life cycle we identify, as an example, some of the areas of activity and lines of action that could be applied with a brief description and quantification of each ecodesign initiative.



ENVIRONMENTAL IMPACT: CARBON FOOTPRINT ANALYSIS (measurement unit in kg CO_2-eq.)



Based on the results obtained from the Carbon Footprint analysis taking 10,000 units as reference and using the IPCC (Intergovernmental Panel on Climate Change) impact method, option 2 is selected as having the lowest environmental impact.

RESULTS (comparison between option 2 and option 1) *

- Reduction in global weight of the material: 11%
- Reduction in sales containers transported per pallet: 2%
- Carbon footprint reduction: 2%
- Cost reduction: 16%

**Only some of the possible indicators have been quantified*

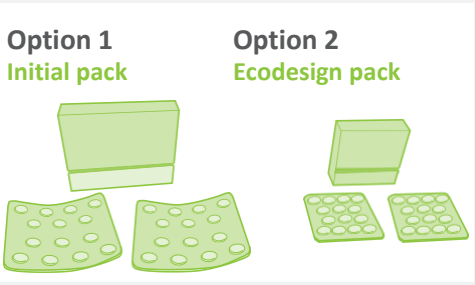
Examples

ECODESIGN OF AN EXISTING PHARMACEUTICAL CONTAINER

CONTAINER SELECTION

Redesign of the immediate container for a medicine comprising two blister packs of 14 pills each.

Among the possible initiatives for the ecodesign, it has been chosen to reduce the weight and volume of the blister packs, optimising empty spaces between pockets. This makes it possible to reduce the dimensions and weight of the outer packaging (case), adjusting it to the new size of the blister packs.



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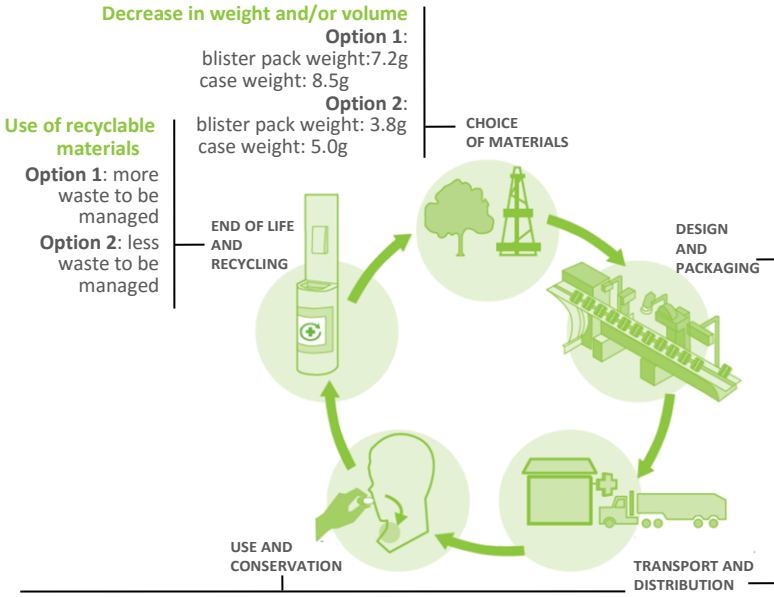
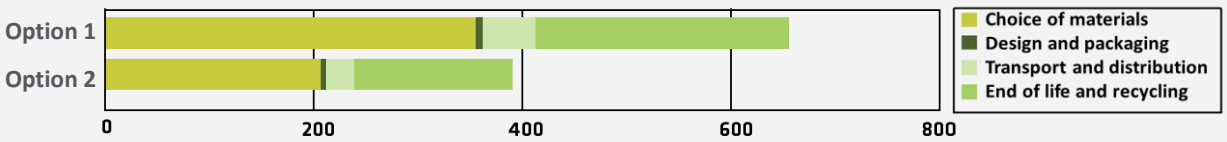


ENVIRONMENTAL IMPACT: CARBON FOOTPRINT ANALYSIS (measurement unit in kg CO_2-eq.)



Based on the results obtained from the Carbon Footprint analysis taking 10,000 units as reference and the IPCC (Intergovernmental Panel on Climate Change) impact method, it is verified that option 2 has the lower environmental impact.

RESULTS (comparison between option 2 and option 1) *

- Reduction in global weight of the material: 38%
- Increase in sales containers transported per pallet: 113%
- Carbon footprint reduction: 40%
- Cost reduction: 43%

**Only some of the possible indicators have been quantified*

8 How do we communicate ecodesign?

INTERNAL COMMUNICATION 	**SUSTAINABILITY** 	• Reduction of the container's environmental impact • Lower consumption of natural resources and reduced waste generation
	PROCUREMENT 	• Savings in the costs of packaging materials • Introduction of environmental criteria in the selection of suppliers
	LOGISTICS 	• Time savings through reductions in the number of groupings • Reduced fuel consumption
	MARKETING AND SALES 	• Sustainable brand value • Differential sales pitches • Responsible company image
	QUALITY 	• Continual improvement • Improved workforce awareness and participation
EXTERNAL COMMUNICATION 	**PATIENTS** 	• Environmental awareness • Socially responsible company
	PHARMACIES 	• Optimisation of space • Improved pharmacy image for the patient
	ADMINISTRATION 	• Anticipating fulfilment of future environmental obligations
	HEALTH SECTOR 	• Commitment to society's wellbeing

Ecodesign must be incorporated into the brand's value and communicated

9 Where can we find further information?

ADDITIONAL SUPPORTING INFORMATION OF INTEREST

ECODESIGN MEASURES AND ACTIONS

- Technical guide to pharmaceutical packaging ecodesign. 2015. SIGRE. www.sigre.es
- Pharmaceutical sector Packaging Prevention Business Plan 2015-2017. www.sigre.es
- Catalogues of ecodesign initiatives for pharmaceutical sector packaging. SIGRE. www.sigre.es
- Éco-conception des emballages. Comment aller plus loin? Guide Pratique acteurs du médicament. 2013. ADELPHE.www.adelphe.fr
- Sector guide to ecodesign. Containers and packaging. 2009. IHOBE. www.ihobe.net

ENVIRONMENTAL ANALYSIS

- Tool for the environmental assessment of packaging. Bilan Environnemental des Emballages. bee.adelphe.fr
- Open tool for Life Cycle Analysis. www.openlca.org/openlca
- Free Life Cycle Analysis tool for plastic and bioplastic materials. www.lca2go.eu

ENQUIRIES RELATED TO THE GUIDE AND ITS APPLICATION:

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This guide has received technical advice from ITENE, Instituto Tecnológico del Embalaje, Transporte y Logística (the National Institute of Packaging, Transportation and Logistics).

The paper used to print this document contributes to an environmental impact reduction of:

87 kg of waste

9 kg of greenhouse gases

100 km of travel in a standard car

2,042 litres of water

187 kWh of energy

142 kg of wood

This guide has been printed on paper with FSC green certification. CO_2 emissions associated to its publishing and distribution have been neutralised by means of CO_2 emission offset projects.

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