efpia

European Federation of Pharmaceutical Industries and Associations

EFPIA White Paper on Circular Economy





Executive Summary

- The European Commission's Circular Economy Action Plan[1], the Roadmap[2] and the European Green Deal[3] has established direction for the future approach to a sustainable business model based on circularity.
- Transition to a more circular economy requires changes throughout value chains, from product design, manufacturing and supply, to new business and market models. New ways of turning waste into resources, prolonging life of products and changes to consumer behavior are also important considerations.
- EFPIA, the research-based pharmaceutical industry is supportive of the principles of the Circular Economy Action Plan and see synergies with our aspiration to safeguard the future supply of pharmaceuticals for patients and improve human health. Implementation of a circular economy is fundamental to help limit global warming[4] and we welcome the opportunity to be part of the solution by working collaboratively with the EU in shaping the legislative framework and within our organizations to mitigate our impacts.
- The pharmaceutical industry's approach to circularity builds on our long experience in sustainability and aligns with the EU approach whilst recognizing the constraints, especially on speed of transition, from operating in a highly regulated industry. Due to the regulatory approval process for pharmaceuticals it is currently very challenging to introduce innovative changes to product manufacturing processes and supply post-approval. Circularity and regulation of pharmaceuticals should be carefully balanced. The innovation to enable circularity will drive new opportunities for growth, promote greater resource efficiency, create a more competitive economy and reduce pollutants, but it cannot be done without consideration of wider influences on our activities for example on use of secondary materials in manufacturing.

1 The European Commission, 2020 Circular Economy Action Plan https://ec.europa.eu/environment/circular-economy/pdf/new_circular_economy_action_plan.pdf
2 The European Commission, 2019, Annex - Roadmap and key actions https://ec.europa.eu/info/files/annex-roadmap-and-key-actions_en
3 The European Commission, 2020, Communication on The European Green Deal https://ec.europa.eu/info/files/communication-european-green-deal_en
4 United Nations, 2015, Paris Agreement http://unfccc.int/files/essential_background/convention/application/pdf/english_paris_agreement.pdf

1. Circular Economy – An Overview

The EU Circular Economy[5] is a key priority, pursued by the European Commission since 2015[6], that outlines the steps and measures needed to transform the EU economy into more circularity, where waste is prevented, and materials recycled and maintained for as long as possible.

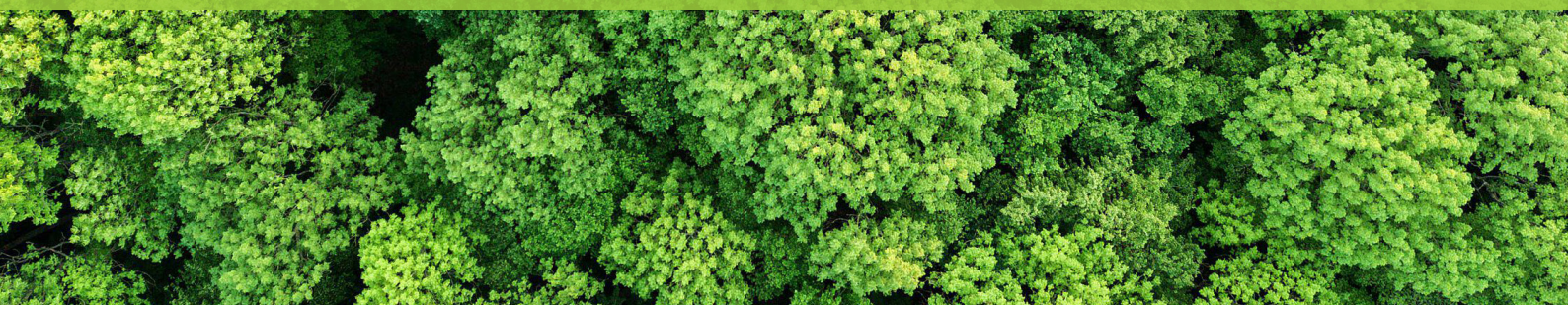
This paper provides the view of EFPIA members on the Circular Economy and confirms members support to the transition towards a circular economy based on the Final Circular Economy Package of the European Commission[7], The European Green Deal[8], the principles of the Ellen MacArthur Foundation[9] and in line with the UN Sustainable Development Goals[10].

Details on the approach of EFPIA on Climate Change, Chemicals and Pharmaceuticals in the Environment are discussed in separate papers which can be accessed on the website of EFPIA (Annex 1).

We see a circular approach as an opportunity for the pharmaceutical industry to ensure access to sustainable supplies of raw materials and energy in a resource constrained world while also providing protection against price volatility and building a more sustainable and competitive business model.

The starting point is a responsible approach based on the following principles:

- **DESIGN OUT WASTE AND POLLUTION [DESIGN FOR CIRCULARITY]**
- **KEEP PRODUCTS AND MATERIALS IN USE**
- **REGENERATE NATURAL SYSTEMS**



5 For more details, see this overview of concepts with the circular economy: https://www.ellenmacarthurfoundation.org/circular-economy/concept

6 The European Commission, 2015. Communication from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee of the Regions, Closing the loop - An EU action plan for the Circular Economy. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614

7 The European Commission, 2019. Final Circular Economy Package. Available at: https://ec.europa.eu/environment/circular-economy/

8 The European Commission, 2019. Communication on the European Green Deal. Available at: https://ec.europa.eu/info/publications/communication-european-green-deal_en

9 The Ellen MacArthur Foundation (launched 2010). Available at: https://www.ellenmacarthurfoundation.org/our-story/mission

10 The United Nations, 2015. The Sustainable Development Goals. Available at: https://sustainabledevelopment.un.org/

The innovation to enable circularity will drive new opportunities for growth, greater resource security and sustainability and a more competitive economy. However, it cannot be done by sectors in isolation and will require cross-industry and EU agency co-operation and collaboration to establish the economic and legislative framework and realise synergies.

Circular systems employ reuse, refurbishment, remanufacturing and recycling to create closed-loop systems by embedding circular principles in the design phase and by minimizing the use of resource inputs and the creation of waste, pollution and carbon emissions. In the circular economy 'waste' from one process would be the input for another.

The existing linear economic model of 'take, make, use, dispose' is neither innovative, nor sustainable. Current estimates are that we are using the world's scarce and non-renewable resources as if we have several planets at our disposal. The circular economy ("circularity") is based on a business model in which we maximise the lifetime of resources across value chains and reduce unnecessary waste and minimise environmental impacts.

Indicative circular economy opportunities available to the pharmaceutical industry

2. Circular Economy is important for the Pharmaceutical Industry

The driving motivation of the pharmaceutical industry is to improve human health and well-being[11]. Environmental protection is a prerequisite for human health. Reducing environmental degradation and pollution of air, water and soil, reducing the use of scarce resources, e.g. as water in water scarce areas, and limiting climate change to 1.5°C are all goals that will underpin health in the 21st Century[12]. Continued adoption of circular economy principles into the pharmaceutical sector will reduce material extraction, operational waste and safeguard the future supply of medicines essential for patients. The circular economy approach supports a global, sustainable economy and protects production from increased pressure on resources but recognises that there are limitations to circularity.

Design of products, processes and packaging

In the design phase, choosing sustainable, renewable or recycled materials to preserve resources and maximize product lifetimes should be an integral part of the process. EFPIA members already actively apply the principles of green chemistry to select the least environmentally damaging materials and maximise process efficiency. Eco-design principles are also fundamental to drive the development of more sustainable formulations, devices and packaging. See examples below.

Resource Efficiency

Turning waste into secondary raw materials is an option for the pharmaceutical industry to minimize the environmental impact of its activities across the entire value chain while also reducing costs in the long run. This approach is already widely adopted across the industry, especially for solvents, water and packaging materials. However, due to the high quality and purity requirements for medicines[13], regular use of secondary raw materials presents more of a challenge. Development of a market for secondary raw materials ensuring materials of adequate quality and availability should be a key area for future industry collaborations.

Value chain collaboration

In the circular economy, opportunities are considered to create greater value and align incentives through business models that build on collaboration across sectors, e.g. between products and services. EFPIA members operate global manufacturing, supply and distribution chains and the circular economy will have limited impact if not implemented in collaboration with global partners and stakeholders in the healthcare sector. By working together across sectors and within our manufacturing and supply chain, we believe we can advance human health and ensure our use of natural resources is efficient, sustainable and affordable. Hospitals, medical staff, public health bodies, patients and supply chains have an important role to play.

An EFPIA Survey in 2020 indicated that more than 90% of the respondents are willing to collaborate within areas such as packaging and shipping to identify new opportunities.

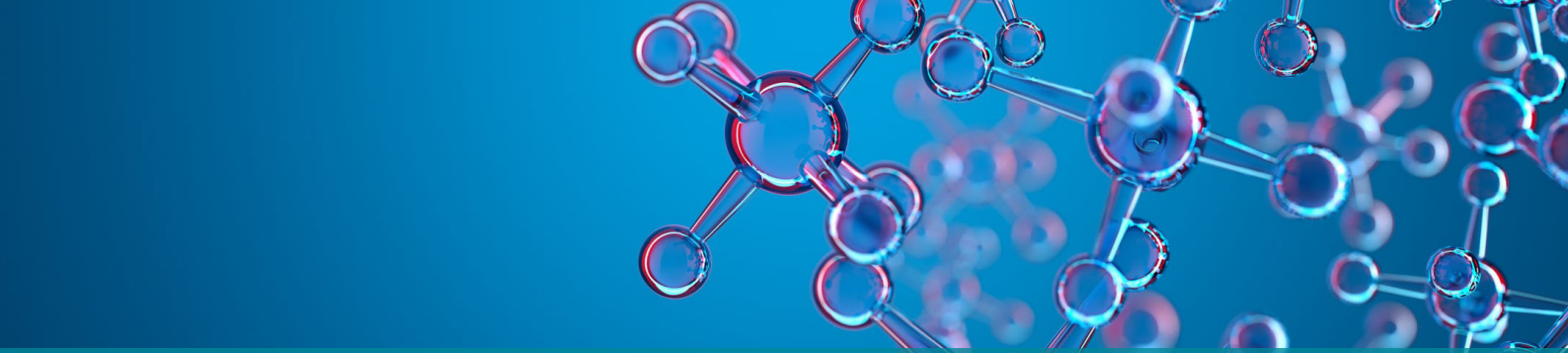
Moreover, green investments are gaining speed. Global investors are increasingly focused on the environmental strategies of the companies they invest in. This is illustrated by the high number of signatories (3,038) by April 2020, that have signed the UN-backed Principles for Responsible Investment (PRI[14]).

11 EFPIA, The European Federation of Pharmaceutical Industries and Associations, 2018. Building a healthier future for Europe. Available at: https://www.efpia.eu/manifesto/

12 The Ellen MacArthur Foundation, 2019, Completing the Picture https://www.ellenmacarthurfoundation.org/assets/downloads/Completing_The_Picture_How_The_Circular_Economy-_Tackles_Climate_Change_V3_26_September.pdf)

13 The European Medicines Agency, Quality guidelines. Available at: https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/quality-guidelines%20s

14 PRI, Principles for Responsible Investment, Signatories. Available at: https://www.unpri.org/



3. The Regulatory Landscape

As a provider of life-saving medicines to the EU market, the pharmaceutical industry is subject to unique, and often inflexible regulation which may challenge circular economy initiatives. Whilst the EU Circular Economy Action Plan has improved clarity, it will take time to address conflicting regulatory expectations and allow the pharmaceutical industry to adapt their operating models.

Pushing for implementing environmentally friendly processes

Legislation to underpin the quality of secondary raw materials is critical to the pharmaceutical industry and a dialogue with the EMA will be needed to give confidence that the use of recycled materials, where appropriate risk assessment has been conducted, will be encouraged and not prevented through incompatible priorities and ineffective communication. The current lack of consistent quality standards1 reduces the potential to find beneficial secondary use for recovered solvents and presents barriers for EFPIA members to make use of recovered materials in manufacturing processes.

If well designed and part of a coherent policy approach, the circular economy principles would benefit the economy and environment, assisting a resource-efficient, competitive and resilient pharmaceutical industry to continue to deliver innovative medicines to improve healthcare. Any decision for regulatory changes must, though, be evidence-based and consider full product lifecycles to avoid unintended consequences.

However, in response to the EFPIA circular economy survey, 2020, 14 out of the 22 respondents identified regulatory requirements as the greatest challenge when implementing circular economy initiatives.

To facilitate circularity in the pharmaceutical industry, it is important that innovation (including post-approval innovation) that improves environmental performance, is encouraged and regulatory blockers are removed where possible. Statements in the new circular economy action plan show a willingness to address these challenges.

EFPIA looks forward to the outcome of the new Circular Economy Action Plan that is intended to further support and accelerate the transition towards a circular economy.

We welcome the plans to strengthen the EU market for secondary raw materials and hope for improvements concerning the safety, quality and performance of these raw materials as indicted in the 2020 Roadmap[15]. Likewise, we expect that the announced modernization of certain waste laws will facilitate the embedding of the circular principles in the pharmaceutical industry.

4. How Pharma can contribute to the Circular Economy

EFPIA members are constantly working towards cost-effective and resource-efficient innovations and a shift to a circular economy will see an expansion of innovations already taking place across the industry. It is up to the members of EFPIA to find an innovative circular economy approach based on business model options, current legislation and the circular economy principles outlined by the Ellen MacArthur foundation.

The EFPIA 2020-survey shows that the circular economy is widely prioritised by the industry, e.g. by setting circular economy targets or defining a strategy. The survey also indicates that supply chain initiatives, such as reducing CO_2 emissions by raw material manufacturing, supplier engagement and improvements in operations and designing out waste currently are the most prioritised aspects of the circular economy within the pharmaceutical industry whilst transportation is gathering increasing focus.

Providing a clear vision of a circular pharmaceutical industry and sharing examples of the circular economy in practice will help harness the innovation expertise in our sector, facilitating the design of circular principles into products and supply chains at an early stage. The opportunities available to the pharmaceutical industry are illustrated by the activities listed below which will also showcase to our stakeholders how the pharmaceutical industry addresses the circular economy.

Circular Economy opportunities and activities undertaken by the pharmaceutical industry

a. Disease Prevention

The pharma industry is increasing its focus to prevent disease and provide cures rather than long term treatment of symptoms with the associated resources usage. Successful development of vaccines, for example to prevent the virus that causes cervical cancer, not only support health and wellbeing but prevent the need for treatment of the condition and thus saves resources.

b. Create awareness

It is vital to engage key stakeholders to the pharmaceutical industry to raise awareness and seek opportunities for circular innovation. Patient behaviors in the use and disposal of prescribed medicines will further enable opportunities.

c. Product design

The Circular Economy Action Plan has identified that up to 80%[1] of products' environmental impacts are determined at the design phase and this highlights the importance of circularity in pharmaceutical research and development.

ASTRAZENECA

From single use to reusable thermal packaging

Each year, Astra Zeneca sends 60,000 products to hospitals and clinics for clinical trial distribution. It involves a huge amount of packaging. The original process used a box the size of a small table, each containing 15kg of packaging that had to be thrown away after delivery with recipients being responsible for its disposal. AstraZeneca decided to work with its distribution partner to develop a new approach involving a returns process and make it workable. Some simple ideas like using the brightest coloured paper for returns instructions – a pink envelope gets more attention than just a white sheet of paper. After a pilot, the initiative was rolled-out across 35 countries.**The results: 98% return rate and reduced packaging waste equivalent to the weight of a 747-jumbo jets.**

d. Dosage

The appropriate dosage to cure patients and treat symptoms whilst not over-prescribing and creating wastage is determined throughout the extensive drug development process. The research continues beyond the initial product launch to look for opportunities to optimize dosage and improve patient experience. An example in immunology is the treatment for plaque psoriasis and psoriatic arthritis where the number of administrations per patient per year has been reduced, and where the stability of the API allows for pre-filled syringe dosing forms instead of lyophilized powders (requiring reconstitution at hospital pharmacies), leading to drastic reductions in material uses per patient per year. Another example in neuroscience is the generation of long-acting injectables in the treatment of schizophrenia, where the dosing frequency is reduced from 26 times per patient per year down to 4 times per patient per year. Consequently, the number of materials per patient per year is drastically reduced.

e. Product Lifetime

Stability of the product is key to ensure that patients receive the optimum dose to support their recovery. The pharma industry has performed extensive research into packaging, to extend the shelf life of a product and minimize waste generation. In general, extending the lifetime of products will lower the environmental impact by reduction in product loss but this must be evidenced for example by the Life Cycle Analysis (LCA).

BOEHRINGER INGELHEIM

Eco-design - Switch from single use to re-usable inhaler

Respimat® re-usable is the result of patient feedback, providing an inhaler with enhancements such as simplified handling and an easy-to-read dose indicator, and significantly reduced impact on the environment.

It reduces waste and product carbon footprint (PCF) can be used with up to six medication cartridges before needing replacement. Respimat® is also propellant-free, meaning its CO2 emissions are 20 times lower than those of commonly used pressurized metered-dose inhalers. **By 2025, it is expected that 776 tons of plastic waste and 14,300 tons of CO_2 emissions will be prevented as a result.** 776 tons of plastic waste equals more than 77.6 million 0.5-liter PET bottles.

SANOFI

Eco-design – Plastic-free packaging for Vaxigrip® vaccine

The new Vaxigrip® packaging has been designed to be plastic-free, thanks to a complete cardboard packaging.

This new packaging halves the size of the box, which optimizes its storage and reduce its environmental footprint:

- 30% reduction of the number of transportations needed (air, sea and road)
- 50% reduction of CO_2 per box
- 25 to 50% reduction of environmental impacts according to the indicator

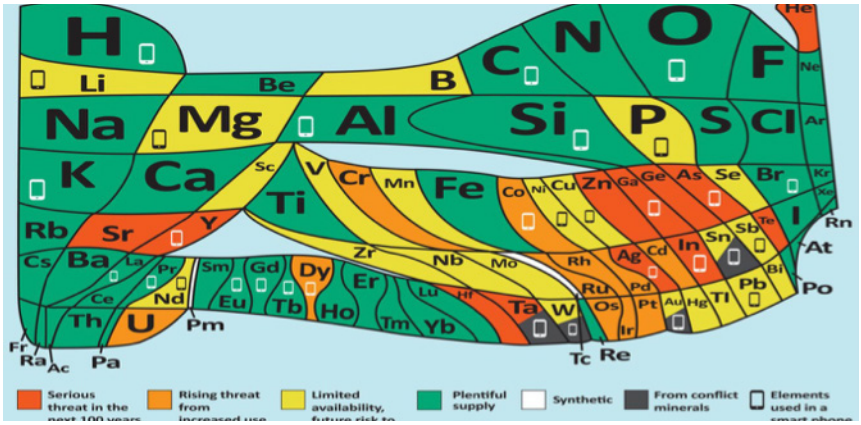
f. Life Cycle Assessment (LCA)

LCA is an existing, well used, tool that can help identify where the pharmaceutical industry should invest and innovate to improve the environmental performance of medicines. It prevents a narrow view of sustainability and allows the opportunity for product principles like the 4Rs (reduction, reuse, recycling and recovery), green chemistry and eco design to be applied to assess and understand the environmental impacts of new products at all the stages of their product lifecycles.

g. Use or provide secondary or renewable raw materials

Certain elements that are critical in the manufacture of medicines (e.g. PGMs – the platin group metals) are being consumed at such a fast rate that there is a tangible risk to future supply. These elements are not destroyed but they become widely dispersed and therefore difficult to harvest in meaningful volumes. The pharma industry recognizes that the growing demand for critical elements represents a material risk for the future supply of medicines and that recycling, and reuse is fundamental to expand the lifetime of raw materials in the value chain.

The periodic table below is comprised of 90 elements that make everything on Earth. The areas correspond to the number of atoms (on a logarithmic scale) of each element in the earth's crust and atmosphere. The area for some of the elements has been exaggerated otherwise they would not be visible.



The re-use of materials directly back into pharmaceutical manufacture is very complex due to the rigorous rules related to patient safety. However, recovery and reuse (which are key principles of green chemistry) of solvents, reactants, intermediates and API is considered acceptable, provided that approved procedures exist for the recovery, and the recovered materials meet specifications suitable for their intended use. When choosing raw materials and chemicals it is also relevant to explore if renewable (e.g. bio based or recycled) materials can be used.

JANSSEN

Plant-on-a-Truck in association with the on-site wastewater treatment partner, Inopsys

Plant-on-a-Truck is an innovative concept in which water layers that cannot be sent to the water treatment works, are treated onsite in a mobile system, which fits in perfectly with the circular economy. That enables reuse of valuable materials, destruction of toxic ingredients or purification of water. By treatment of process water in this system it has been possible to recover zinc for recirculation to production.

Recycled and recovered materials from the pharmaceutical industry which do not comply with pharmaceutical quality requirements might be used for new purposes by other industrial sectors facilitated by strong circular economy partnerships. The pharmaceutical industry segregates waste materials at source to enable recycling. Where possible toll recycling can be utilized.

The pharmaceutical industry actively collaborates across sectors with external partners to open new opportunities and foster innovation. An example is the reuse of waste clay for green walls (Ipsen), the story of the Kalundborg Symbiosis where the waste streams from one industry are used as resource in another and the inhaler recycling scheme of GSK.

IPSEN

Process by-products

At Ipsen's Isle-sur-la-Sorgue site at South France clay is the starting raw material used in the manufacture of a range of products. The clay is washed and graded and different by-products are produced that range from gravel, sand and sludge. In the past the by-products were classified as waste and Ipsen was required to waste them. However, a reclassification of the by-products has allowed them to become commodities with value that can be repurposed for other uses. For example, a neighbouring golf course next to the manufacturing site has found that sand by-product useful because it has some clay mixed with it. The 1,500 tonnes of sand by-products is dispersed over the golf course grass with the beneficial result of reducing the water consumption due to the clay contained in it. One hundred and ten tonnes of grinding residue and gravel is repurposed to make underlaying material for construction.

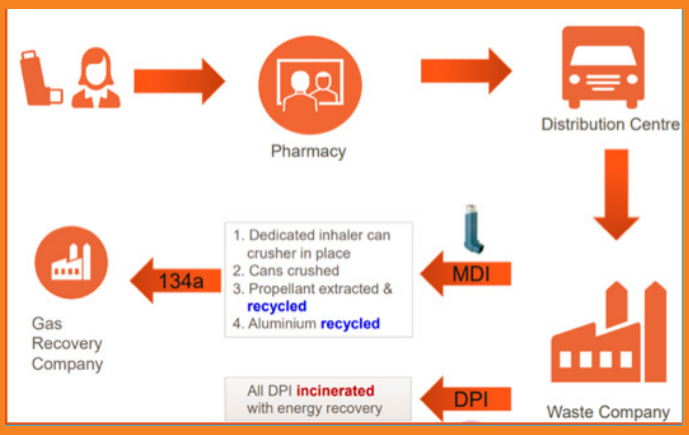
Every year 1,000 tonnes of sludge is reused to make compost and 100 tonnes of waste clay powder is reused by a goat farm for drying litter and by a company to make green walks.

GSK

Complete the Cycle

73 million respiratory inhalers are prescribed every year in the UK and not disposing of them correctly can be harmful to our environment. GSK created an inhaler recycling scheme, Complete the Cycle, which was the first of its kind for respiratory inhalers in the UK. 2 million inhalers had been collected by 2019 and the scheme led to a wider discussion on how a national inhaler return scheme could be created in conjunction with the wider health care system.

By working together with patients, pharmacies and healthcare professionals, we can all help to reduce waste and greenhouse gases, moving towards a more environmentally sustainable treatment of respiratory disease.



**MDI – Metered Dose Inhaler DPI – Dry Powder Inhaler*

LUNDBECK

Cyclic planning

At the pharmaceutical production in Denmark, during 2019, cyclic planning was introduced, which is a planning setup that ensures a more stable and predictable execution of production. This reduces the use of materials and the amount of waste generated in produc¬tion.

In their liquid product production, they reduced packaging waste by 83% compared to 2018. This is equivalent to 1.4 million pieces less waste in the form of cartons, labels or leaflets. In 2020, preparations will be made for implementing the new planning concept for our solid products where the reduction potential is even greater.

Cyclic 8-week production plan.

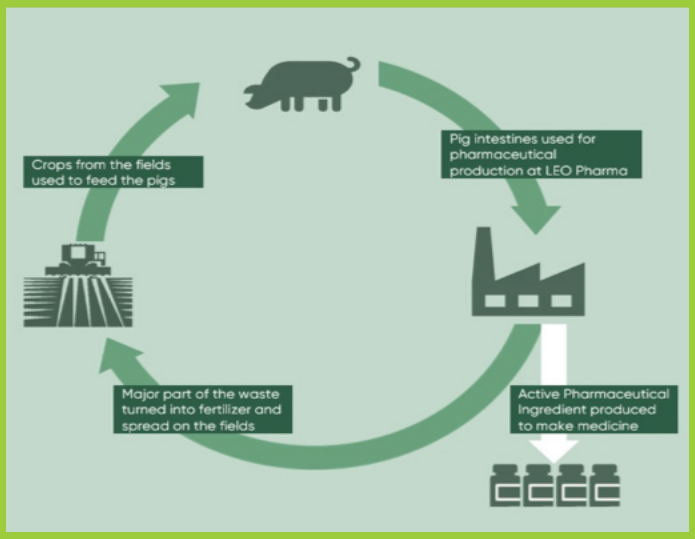
The letters A, B, C and D represents the different product types which are produced in a cycle. The emergency slot is planned if a production batch cannot be produced at the allocated production slot.

LEO PHARMA

Transforming waste into fertilizer

At LEO Pharma in Esbjerg, Denmark an active pharmaceutical ingredient (API) is produced from pig intestines (mucosa). However, only 1% of the pig mucosa contains the core ingredient needed to make the API so a huge amount of waste is generated when more than 70,000 tons of mucosa are handled per year. To reduce our waste, they developed a way to dispose of processed pig mucosa that brings value to the community around the Esbjerg facility. Since 2011, they work with an external company specialized in making good use of organic materials for agricultural purposes, to turn mucosa waste into a high potency organic fertilizer. With this product, 95% of mucosa waste is reused for a product that brings organic material and nutrients to the fields of about 300 farmers.

Read more: www.leo-pharma.com annual report 2018

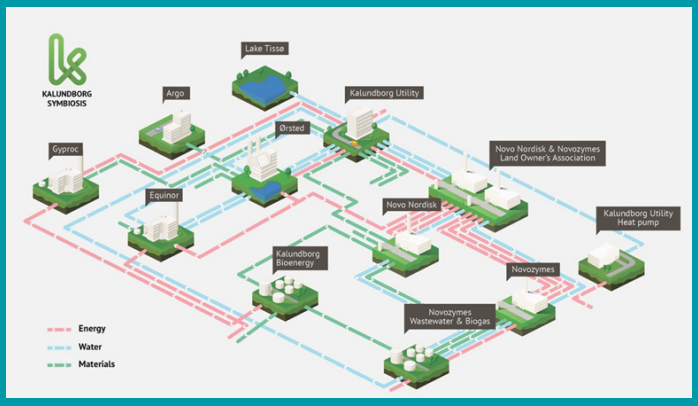


NOVO NORDISK

The Kalundborg Symbiosis

Novo Nordisk is a part of The Kalundborg Symbiosis, a partnership between nine public and private companies in Kalundborg, Denmark. Since 1972 the partnership has developed one of the World's first industrial symbiosis with a circular approach to production. The main principle is, that a residue from one company becomes a resource at another, benefiting both the environment and the economy. The Symbiosis creates growth in the local area and supports the companies' CSR and the climate change mitigation.

Read more here: http://www.symbiosis.dk/en/



ANNEX 1

Need to know more?

Climate change

With respect to circularity as regards CO_2 emissions and climate changes the approach of EFPIA can be accessed here.

Chemicals

Likewise, the view of the pharma industry on chemicals, especially hazardous substances in the manufacturing process, can be seen here.

Pharmaceuticals in the Environment

Controlling and eliminating pollution of pharmaceutical active ingredients in the environment has been discussed and analyzed thoroughly within the pharmaceutical industry and its stakeholders in recent years. The approach of EFPIA on residues of pharmaceutical products in the environment in general and on antimicrobials specifically can be found here.

Take back of unused medicine

In continuation of the discussion on pharmaceuticals in the environment, take-back of medicine is likewise an important issue. Through many years the pharmaceutical industry has participated in unused medicines take-back programs to ensure safety during disposal of unused drugs.

To boost the return of unused medicines, collaboration between medical professionals, pharmaceutical companies and patients is needed to drive behavior change.

Read more about disposal of unused drugs here: http://www.medsdisposal.eu/

Disclaimer: This document has been developed under the leadership of the EFPIA Environment, Health and Safety group. The examples included are a non-exhaustive selection which do not represent the full level of activities on circular economy being undertaken across our industry.

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