



Examining the life cycle

When looking at the life cycle impact of pharmaceuticals there are three key areas for consideration:

- Life cycle impact of primary manufacturing - the synthesis of the active pharmaceutical ingredient (API);
- Life cycle impact of secondary manufacturing – formulation, packaging, excipients etc.;
- End-of-life impacts – this relates to what happens to the API molecule post-patient and its effects in the environment, which can be subdivided into:
 - Potential issues with contamination of human drinking water with APIs and their residues;
 - The effects on organisms other than humans exposed to the APIs and their residues in water courses.

Learning Objectives

By the end of this module you should:

- Understand how each of the different stages in the lifecycle of a pharmaceutical product contribute to the overall environmental impact;
- Be aware of strategies for reducing environmental impact at each of these stages;
- Be aware of 'hot-spots' or areas of high environmental impact.

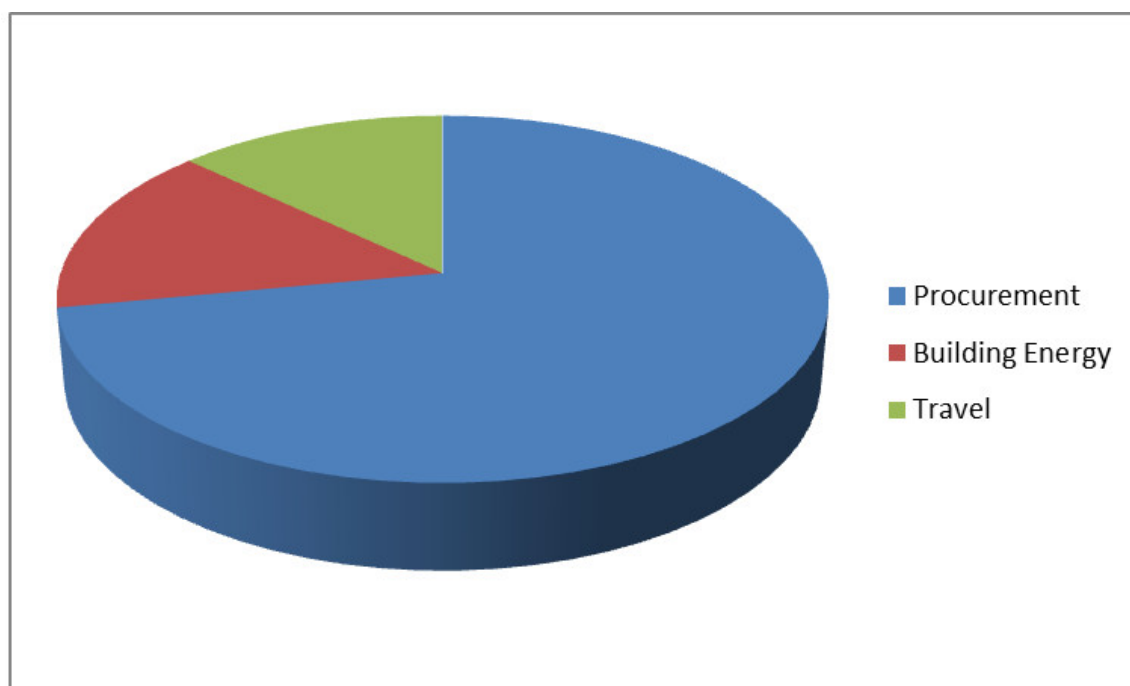
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Drivers towards whole-process thinking

When considering the sustainability impact of pharmaceuticals, LCA (Life Cycle Assessment) discussions are often dominated by the impact of chemical synthesis. However, the customers and stakeholders of the pharmaceutical industry – e.g. the UK National Health Service (NHS), Swedish Medicinal Products Agency – are keen to focus not only on the environmental impact of the synthesis of the API, but on the whole product process all the way to the finished product delivered to the patient. For example, **Figure 1** shows the carbon footprint breakdown of the NHS, where the greatest contributing division is procurement – the goods and services brought in. A more detailed breakdown indicated that pharmaceuticals are the major contributing factor (**Figure 1**).



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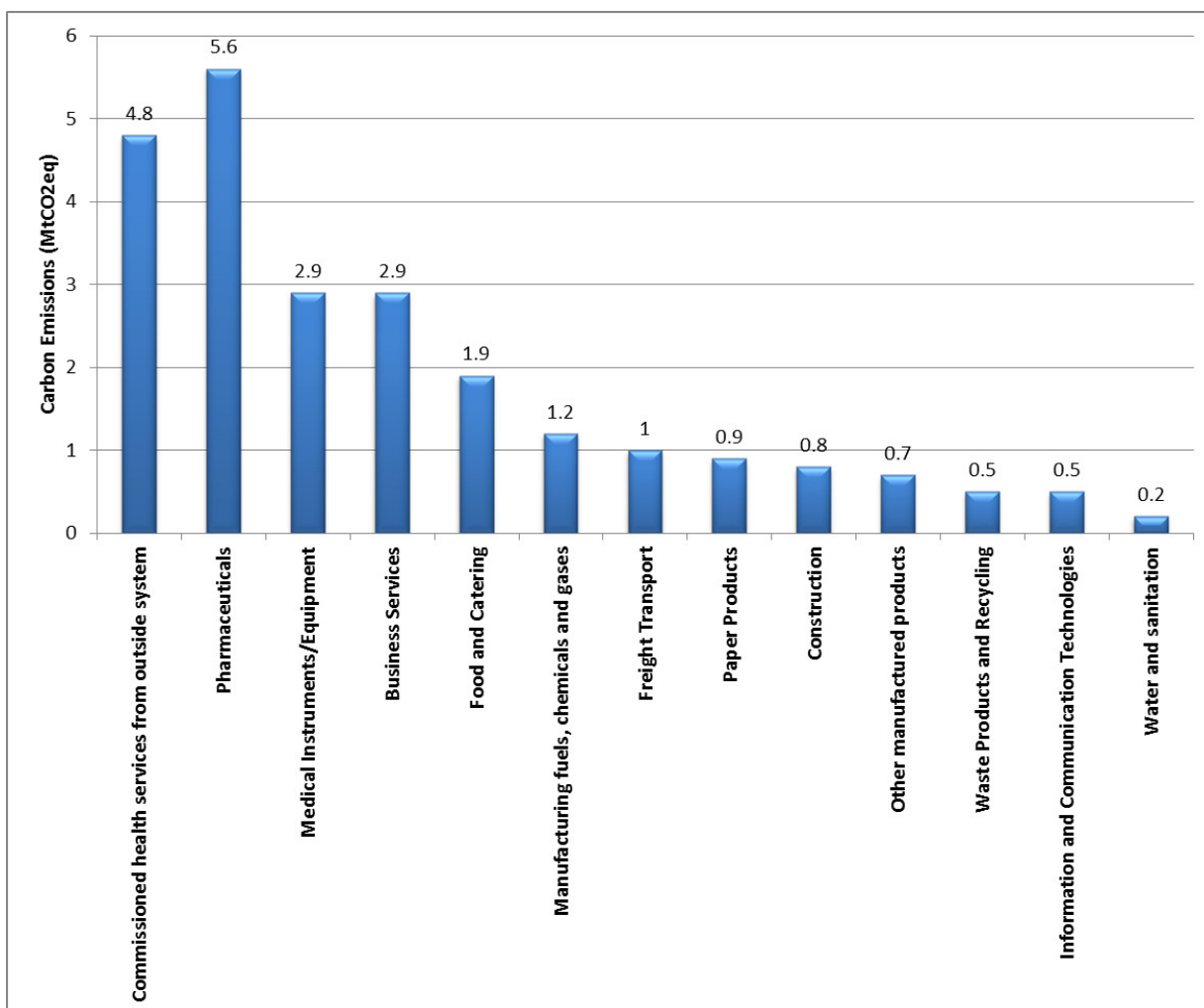


Figure 1: Breakdown of the NHS Carbon footprint by sector for 2012 (above) with Procurement broken down in more detail (below) [1]

The carbon footprint figures for the NHS in 2004 are shown in **Figure 2**. By comparing the figures of 2012 to those of 2004, the data suggests that over this time, the carbon contribution of pharmaceuticals has increased by ~20%. This is not as a result of less sustainable manufacturing but is due to the changes in population demographics. The increasing population and an increasing aged population results in a greater demand for services of such organisations. This poses a real dilemma in reducing total carbon footprint in the face of increasing patient numbers and demand.

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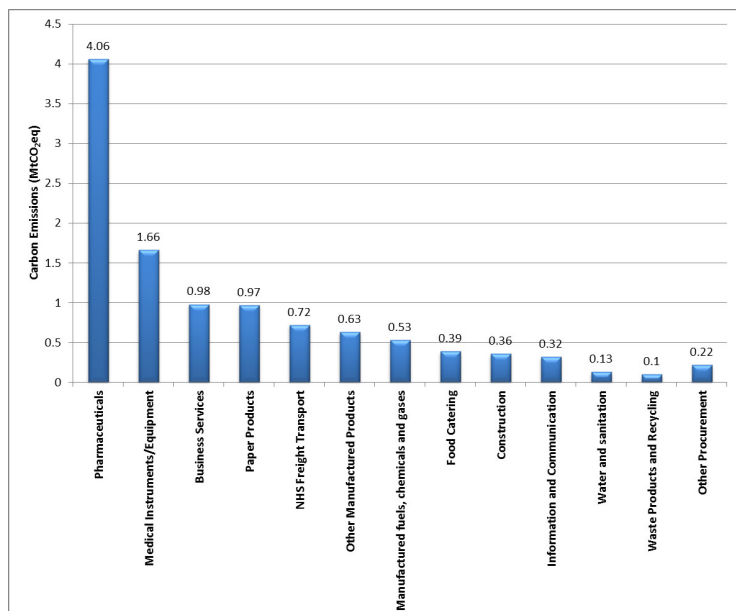


Figure 2: Breakdown of the NHS Carbon footprint by sector for 2004 [1]

1. [NHS carbon footprint reports](#) (Last accessed: March, 2016).

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Challenges in effecting change

One way to reduce carbon footprint is to ask suppliers of products and services to understand, measure and reduce the carbon footprint of the products and services they provide. However, conducting footprinting research and implementing improvements can be costly. Budget limitations and increase in demand are forcing governments and healthcare providers to look to reduce or limit costs. These budget constraints are not only present for high volume generic medicines but also new innovative medicines. Despite a new medicine being given a marketing license by the relevant authority (which considers patient safety and efficacy), costs can be deemed too high in relation to the clinical benefits the patient will receive. As a result, cost has had a significant influence on prescribing policy in recent years.

When submitted for marketing authorisation, all medicines need to have an environmental risk assessment (ERA – covered in more detail [here](#)). Currently the ERA focusses on the end-of-life fate of the API in the environment – the route of manufacture is not considered.

For many years, focus has been placed on environmental fate of pharmaceuticals. However, consideration of carbon footprint and concerns surrounding poor manufacturing practices of non-EU suppliers is promoting the development of various ways to encourage and reward greener pharmaceutical manufacturing. There have also been efforts to lobby the EU to formalise the consideration of fate and manufacturing practice when considering a license for new pharmaceutical products.^[1] Whilst the outputs of LCA might not impact on new/novel therapies, especially best in class (highest current performance level in an industry) or first in class (used as a standard or benchmark to be equalled or exceeded), it is being proposed as a measure by which products containing the same API (generic drugs, such as ibuprofen or paracetamol) can be differentiated (**Figure 1**).

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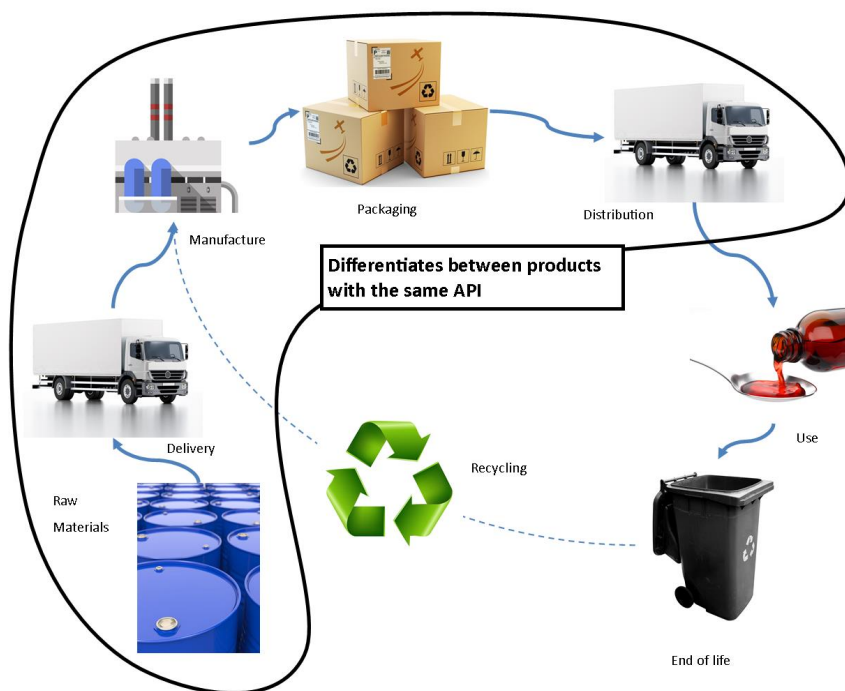


Figure 1: The life cycle of a pharmaceutical product, including end of life and potential recycling[2]

1. B. Annonsbyrå, *National Pharmaceutical Strategy Action Plan 2014*, Ministry of Health and Social Affairs Sweden, 2014.
2. W. De Soete, L. Boone, F. Willemse, E. De Meyer, B. Heirman, H. Van Langenhove and J. Dewulf, *Environmental resource footprinting of drug manufacturing: Effects of scale-up and tablet dosage*, *Resources, Conservation and Recycling*, 2014, **91**, 82-88.

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LCA examples

By examining API LCAs we can understand where carbon footprints and other 'hotspots' are. The first example is an anti-inflammatory API. The carbon footprint breakdown of the product formulated as tablets in a simple blister pack is given in Figure 1 (Tools and assumptions available in [Appendix](#)). As can be seen, the API synthesis contribution dominates the carbon footprint. This is fairly atypical for an average pharmaceutical product, and reflects the current niche therapeutic area in which the API is used as well as the small production run of 20 tonnes per annum. The manufacturing route is dated and inefficient having been established over thirty years ago. The carbon impact of 354 gCO₂ per tablet is very high compared to the average pharmaceutical product. Novartis analysis of cradle-to-grave LCA/supply chain carbon footprint reported an average of 10 kgCO₂e for the annual patient dose of a typical pharmaceutical product.^[1] To contextualise, this figure of 10 kgCO₂e per annual patient dose would equate to driving 77 miles in an average car.^[2]

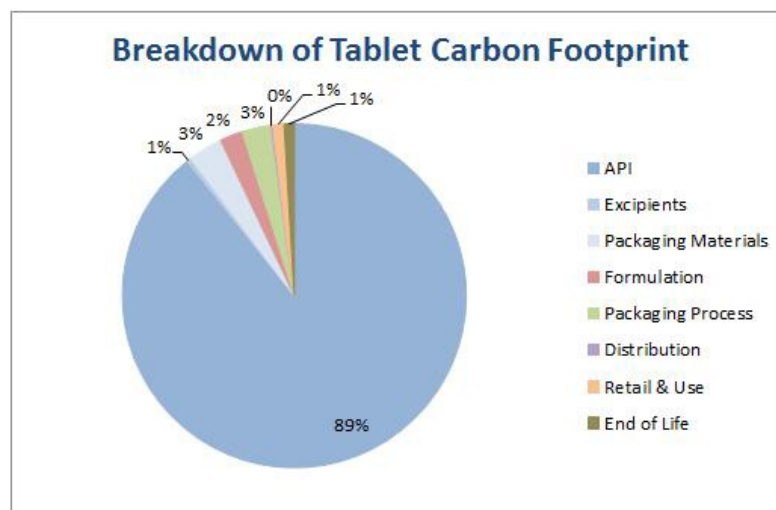


Figure 1: Anti-inflammatory API carbon footprint – original route of manufacture

Redesigning to a more efficient synthetic route to the API gives the carbon footprint shown in Figure 2. This reduces the effective carbon contribution of the API to the tablet from 89% to 77%, but also reduces the carbon footprint per tablet from 354 gCO₂ to 166 gCO₂, thus the benefits of changing the synthetic route are significant with respect to the carbon footprint as a whole. Looking at the contribution of the rest of the secondary manufacturing process, the API still dominates due to the low total annual production. Typically economies of scale work in both primary (synthesis of main product) and

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secondary (formulation and packaging) manufacturing, but are more pronounced with API manufacture.[3]

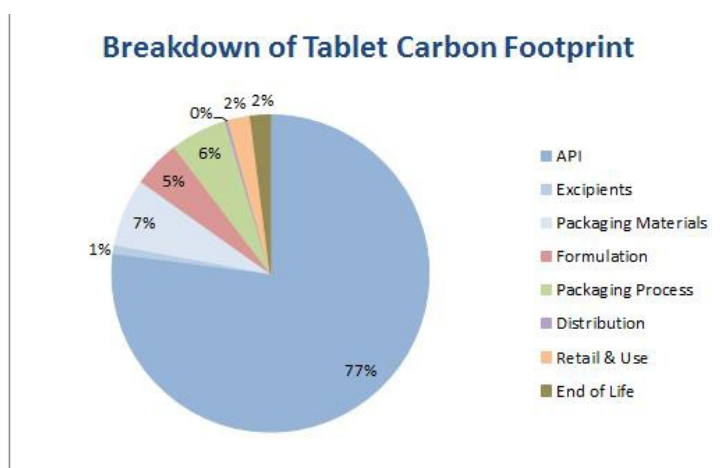


Figure 2: Anti-inflammatory API carbon footprint - new route of manufacture

Modelling the process to a production scale of 200 tonnes per annum gives a picture that is more representative of pharmaceuticals produced in higher volumes, with only 48% of the carbon intensity being due to the API synthesis; the contributions of the other inputs in secondary manufacturing are now clearer and can be seen in Figure 3.

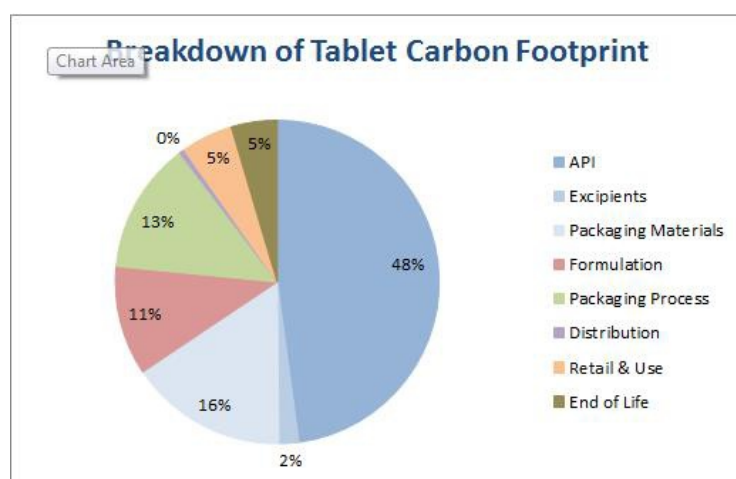


Figure 3: Anti-inflammatory API carbon footprint modelled to 200 tonnes per annum of API

The second example is a selective β_1 -blocker, prescribed for hypertension and other

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cardiovascular conditions. In 2011, this medicine was the 19th most commonly prescribed generic medicine, so is a large volume product. The output of an LCA study focusing on secondary manufacturing is presented in **Figure 4** and gives a more representative example of the carbon footprint of most bulk pharmaceutical products.

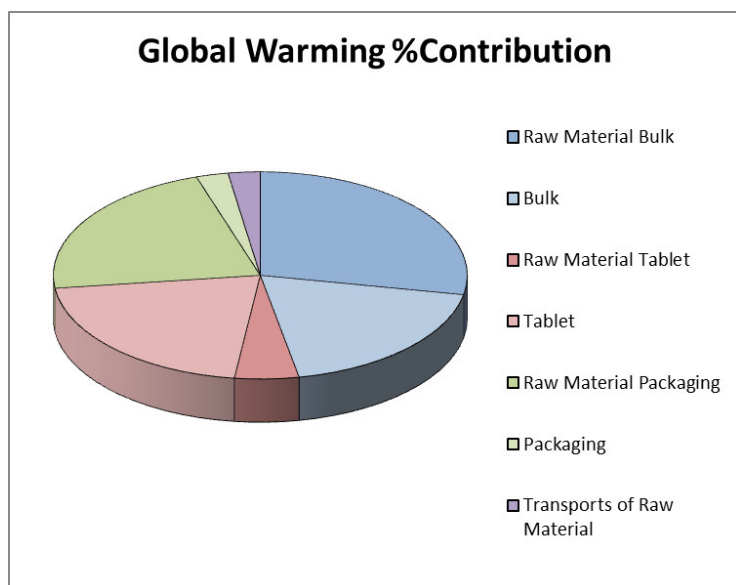


Figure 4: LCA analysis of a β_1 beta-blocker production downstream from API

Note: The information for both of the case studies above has been compiled as part of the CHEM21 project from confidential partner data.

1. [Environmental Sustainability at Novartis](#) (Last accessed: April, 2016).
2. [Regulation \(EC\) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles](#) (Text, 2009).
3. W. De Soete, L. Boone, F. Willemse, E. De Meyer, B. Heirman, H. Van Langenhove and J. Dewulf, [Environmental resource footprinting of drug manufacturing: Effects of scale-up and tablet dosage](#), *Resources, Conservation and Recycling*, 2014, **91**, 82-88.

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Primary manufacturing

Page coming soon

Recommended reading:

D. Ott, D. Kralisch, I. Denčić, V. Hessel, Y. Laribi, P. D. Perrichon, C. Berguerand, L. Kiwi-Minsker and P. Loeb, [Life Cycle Analysis within Pharmaceutical Process Optimization and Intensification: Case Study of Active Pharmaceutical Ingredient Production](#), *ChemSusChem*, 2014, **7**, 3521-3533.

W. De Soete, S. Debaveye, S. De Meester, G. Van der Vorst, W. Aelterman, B. Heirman, P. Cappuyns and J. Dewulf, [Environmental Sustainability Assessments of Pharmaceuticals: An Emerging Need for Simplification in Life Cycle Assessments](#), *Environmental Science & Technology*, 2014, **48**, 12247-12255.

C. Jimenez-Gonzalez and M. R. Overcash, [The evolution of life cycle assessment in pharmaceutical and chemical applications - a perspective](#), *Green Chemistry*, 2014, **16**, 3392-3400.

G. Wernet, S. Conradt, H. Peter Isenring, C. Jimenez-Gonzalez and K. Hungerbühler, [Life cycle assessment of fine chemical production: a case study of pharmaceutical synthesis](#), *The International Journal of Life Cycle Assessment*, 2010, **15**, 294-303.

D. Ott, S. Borukhova and V. Hessel, [Life cycle assessment of multi-step rufinamide synthesis - from isolated reactions in batch to continuous microreactor networks](#), *Green Chemistry*, 2016, **18**, 1096-1116.

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Secondary manufacturing

The manufacture of APIs and its raw materials contribute ~50% of the carbon footprint of a pharmaceutical. API manufacture also contributes to around half of a pharmaceutical's environmental impact when considering acidification, photo-oxidant formation and eutrophication. There are therefore many opportunities both in API synthesis and secondary production to lower the overall life cycle impact of pharmaceutical products at point of use.

In secondary manufacturing, a range of technologies can be employed to reduce environmental impact including: predictive science; new formulations; new packaging; new analytical methodology; more robust processes and flexible batch/continuous processing, all of which can provide the following environmental benefits:

- Reduced waste;
- Reduced energy consumption;
- Reduced emissions during development or production/from patient use
- Improved recycling;
- Sustainability;
- Lower solvent usage.

Note: The information on a pharmaceutical's impact on acidification, photo-oxidant formation and eutrophication has been compiled as part of the CHEM21 project from confidential partner data.

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Packaging

Reduction in volume of materials used and a move to more sustainable packaging materials could greatly improve the environmental credentials of pharmaceutical products. Reducing the size of a tablet, reducing the space between pills in a blister pack and reconsidering the materials used for packaging can have dramatic effects on both environmental and economic costs. As an example, below are the savings achieved with packaging improvements across 20 projects within Novartis between 2008 and 2012:[1]

- **Cost** – USD 2.7 million;
- **Materials** – 572 tonnes of carton/plastic/metals;
- **GHG emissions** – more than 133 tonnes CO₂e;
- **Other** – 30% weight reduction, reduced storage space requirements, shorter lead time, lower work load, less waste.

1. [Environmental Sustainability at Novartis](#) (Last accessed: April, 2016).

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Impact of PIE

Over the past 30 years analytical instrumentation and methodology have advanced to a point where we are able to detect very low levels of contaminants in the environment. Increases in detection limits and sensitivity have been driven principally by the development of hyphenated techniques, for example LC-MS-MS and extractive concentration methodology such as solid phase extraction, which has enabled detection and quantitation down to nanograms per litre (ng L^{-1}) levels and lower.

With around 3000 pharmaceutical products in use worldwide (as well as veterinary products and illicit drugs), a large number of pharmaceutical residues have now been detected in a wide range of environmental matrices.^{[1] [2] [3]} These residues, mainly unchanged APIs but also sometimes degradation products, are principally being detected in water and sludge, but have also been found to be present in organisms like fish and plants. ^{[1] [2] [3]}

The ability to detect and quantify levels of pharmaceuticals in the environment (PIE) has led to an explosion of interest and scrutiny, as evidenced by the marked increase in the number of publications in this area from 1980 to the present day as shown in **Figure 1**. Whilst a number of these publications will be on topics like the manufacture and sustainability of pharmaceuticals, the vast majority are focused on the subject of PIE.

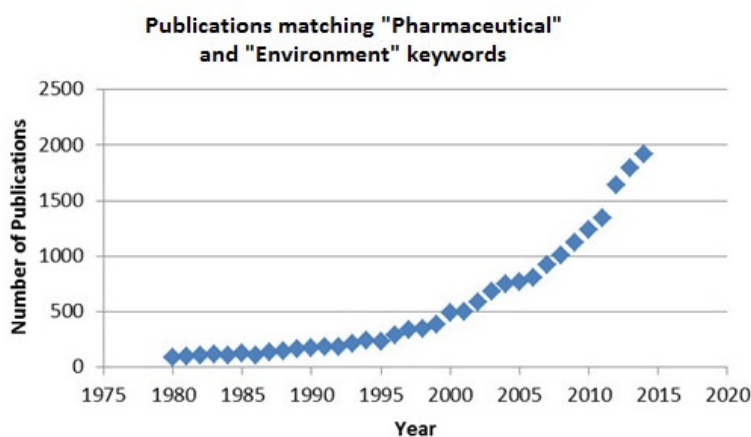


Figure 1: Scifinder™ search for "pharmaceutical" and "environmental" keywords (November 2014)

PIE have also attracted the attention of a large cross-section of the stakeholders in the

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pharmaceutical industry ranging from producers, regulators, academics, non-governmental organisations (NGOs), pressure groups and healthcare providers. Whilst bearing in mind objectivity and scientific balance, it is important to be aware of how these issues can be perceived in the public sphere as this can impact upon the reputation of a company, causing knock-on effects.

Recommended reading:

Several examples of PIE appearing in both the scientific literature and public media are given below for further reading.

M. Wu and S. Janssen, [Dosed Without Prescription: A Framework for Preventing Pharmaceutical Contamination of Our Nation's Drinking Water](#), *Environmental Science & Technology*, 2011, **45**, 366-367.

C. Ort, M. G. Lawrence, J. Rieckermann and A. Joss, [Sampling for Pharmaceuticals and Personal Care Products \(PPCPs\) and Illicit Drugs in Wastewater Systems: Are Your Conclusions Valid? A Critical Review](#), *Environmental Science & Technology*, 2010, **44**, 6024-6035.

G. M. Bruce, R. C. Pleus and S. A. Snyder, [Toxicological Relevance of Pharmaceuticals in Drinking Water](#), *Environmental Science & Technology*, 2010, **44**, 5619-5626.

[This New Study Found More Drugs in Our Drinking Water Than Anybody Knew](#) (Last accessed: 2016).

[Drinking water contaminated by excreted drugs a growing concern](#) (Last accessed: 2016).

[7 Scary Facts About Pharmaceutical Pollution of Drinking Water](#) (Last accessed: 2016).

W. Health Organisation, [Global Health Risks: Mortality and burden of disease attributable to selected major risks](#), 2009.

[Planet's Tougher Problems Persist, UN Report Warns](#) (Last accessed: 2016).

1. D. W. Kolpin, E. T. Furlong, M. T. Meyer, M. E. Thurman, S. D. Zaugg, L. B. Barber and H. T. Buxton, [Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999–2000: A National Reconnaissance](#), *Environmental Science & Technology*, 2002, **36**, 1202-1211.
2. H. - R. Buser, M. D. Müller and N. Theobald, [Occurrence of the Pharmaceutical Drug Clofibric Acid and the Herbicide Mecoprop in Various Swiss Lakes and in the North Sea](#), *Environmental Science & Technology*, 1998, **32**, 188-192.

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3. D. Taylor and V. T. Coombe, **Environmental and Regulatory Aspects**, in *Green Chemistry in the Pharmaceutical Industry*, Wiley-VCH Verlag GmbH & Co. KGaA, 2010, pp. 83-100.

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Appendix: carbon footprinting assumptions

The carbon footprinting for the anti-inflammatory API was done with the [ABPI tool](#). The assumptions taken from the ABPI tool can be found [here](#).

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Multiple choice questions

1. Apart from the API itself, what will comprise a final, commercialised pharmaceutical product once it reaches the consumer?
 1. Catalysts
 2. Packaging
 3. Data on efficacy
 4. Excipients
 5. Transport fuel
 6. Medicines information leaflet
2. Which of the following directly contribute to the carbon footprint of the manufacture of a single pharmaceutical product?
 1. Construction of manufacturing labs and operational infrastructure
 2. Packaging the product
 3. Synthesis of the API
 4. Transportation of the product to market
 5. Use of equipment during drug discovery
 6. Use of equipment for manufacturing and quality control testing purposes
3. Which of the following contribute to the overall carbon footprint of a healthcare building (e.g. hospital, surgery, pharmacist)?
 1. Construction
 2. Electricity, water and gas
 3. Catering
 4. Purchasing of pharmaceuticals
 5. Purchasing equipment
 6. Waste disposal

Answers on [last page](#)

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Summary and further reading

We have seen in this module the need to take a holistic approach to improving sustainability within the pharmaceutical industry and examine the product as a whole, throughout its entire lifecycle and not solely focusing on the API.

Recommended reading:

http://www.janusinfo.se/Global/Miljo_och_lakemedel/Miljobroschyr_2014_engelsk_webb.pdf

http://www.nature.com/nbt/journal/v31/n2/box/nbt0213-95_BX1.html

W. De Soete, L. Boone, F. Willemse, E. De Meyer, B. Heirman, H. Van Langenhove and J. Dewulf, [Environmental resource footprinting of drug manufacturing: Effects of scale-up and tablet dosage](#), *Resources, Conservation and Recycling*, 2014, **91**, 82-88.

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