Inspiration document

Towards a sustainable pharmaceutical value chain









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Editorial data

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FOREWORD

Medicines provide a valuable contribution to society and are vital to the dayto-day lives of many people. In the Netherlands around 420 million medicine packages are dispensedvevery year, which means that people do not die, heal, live longer, have less or no pain, or are protected from disease.

We believe it is important that people have confidence in their medicines and that they are used in a responsible manner. On the one hand, this concerns providing as much customised treatment as possible by improving screening, diagnostics, and gathering patient characteristics. This not only improves the medicine's effectiveness but also reduces wastage. On the other hand, we must be aware of the impact of medicines on the environment and take this into account in relation to development, production, use and waste processing. This could include the use of raw materials, the consumption of energy and waste streams during production, CO_2 emissions, packaging waste, and the effect of medicine leftover on aquatic life and water quality.

Throughout the chain, we are all responsible for raising levels of sustainability within the pharmacy sector and can only realise this aim if we work together. An overall approach is therefore required, which incorporates the patient's health and safety, costs, delivery certainty, and the environment. The basic principle herein is the fact that medicines must remain accessible to everyone who needs them. General support is required from all partners, including businesses, chemists, doctors, patients, ministries, care-providers, hospitals, wholesalers and drug stores. We are all facing a significant challenge!

With this inspirational guide: 'Towards a sustainable pharmaceutical value chain' aims to provide inspiration and motivation for the sector by outlining current developments in this context and providing practical examples of focus areas. It is a dynamic document that will be regular updated with new insights and examples from the real world.

The area is constantly developing and we don't have an overview of every aspect. There are already various initiatives from the sector, e.g. with respect to circular working methods, CO_2 reduction, and avoiding waste, which are broadly applicable.

Need for speed

The focus on increasing sustainability and climate change is steadily increasing. There is also greater awareness within society regarding the effects of medicines on the environment and the levels of wastage. Legislation and regulations are also increasing with respect to the environment, particularly in relation to medicines. International Sustainable Development Goals offer guidance and the EU has a sustainability agenda.

Corona crisis

The corona crisis has clearly revealed just how vulnerable the chain in this vital sector and the global production and distribution system really is. As a result of pricing issues and efficiency efforts, we have become partially dependent on production in countries such as China and India and, as a result, the availability of medicines has come under pressure. This can sometimes be at odds with CSR and environmental objectives. Simultaneously, the situation offers opportunities to critically assess the current system and examine how 'external issues' such as the impact of products on the environment, employment conditions and human rights, can be incorporated.

Sustainable Pharmacy Coalition

In order to realise this across the chain, the sector organisation Bogin (Biosimilars and generic medicines industry Netherlands), Vereniging Innovative Geneesmiddelen (Association Innovative Medicines), Neprofarm (manufacturers and importers of self-care medicines) and KNMP (Royal Dutch Society for promoting the pharmacy sector) set up the Sustainable Pharmacy Coalition in 2019.

The coalition's mission is:

'To fulfil a prominent role in increasing sustainability in the medication chain so that medicines remain available to all in the future, with the lowest possible impact on the environment and our health.'

Collectively, these branch associations represent a large segment of the pharmacy chain, from producers to chemists.

In signing the Green Deal for Sustainable Care, the coalition is committed to improving sustainability with the following three cornerstones: encouraging circular working methods, combating medicine residues in water, and reducing CO_2 emissions.

Now is the time to use this perspective to make the pharmacy chain futureproof, while incorporating environmental and social values. Sustainability offers opportunities!

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1. INTRODUCTION

A sustainable pharmacy chain will only be successfully realised by means of extensive collaboration between the parties that form the chain itself, from the development and acceptance of medicines, through distribution, prescription and use, to waste processing and water purification.

The medicines sector is a highly regulated market. Initiatives that could expand the sustainability of the sector require research into what can be achieved within the current frameworks and, in some cases, new ones.

Because the medicines sector is inherently international, different elements of the chain such as research, development and production take place across the world. Acceptance of medicines primarily takes place on a European level. Although the direct influence of Dutch players is sometimes limited in this context, the national branches of international companies can ensure that the sustainability of the pharmacy chain is high on the agenda at foreign head offices.

In signing the Green Deal for Sustainable Care, the Sustainable Pharmacy Coalition is committed to improving sustainability and is focussing on the following three cornerstones: encouraging circular working methods, clean water/combating medicine residues in water, and reducing CO₂ emissions. See the summary of underlying goals.

Overzicht programma





Since the beginning of the Sustainable Pharmacy Coalition in January 2019, several concrete activities have been completed and products supplied.

Cornerstone 1A: Avoiding wastage and increasing packaging sustainability

- Branch plan for Sustainable Packaging with goals to be achieved before 2022.
- <u>Sustainable Packaging Guide</u> for the pharmaceutical sector, sustainable packaging for buyers and manufacturers.

Cornerstone 1B: Sustainable production chain and sustainable purchasing

 <u>Research into the production chain for the Dutch pharmaceutical sector</u>, existing IMVO policies, IMVO risks and processing perspectives.

Cornerstone 1B: Sustainable production chain and Cornerstone 2: Medicine residues in water

 <u>Consortium for the Reduction of Antibiotics in water</u>; In order to provide an active contribution towards one of the biggest threats to public health (WHO), i.e. antibiotic resistance, we have created a consortium focussing on reducing antibiotics in water.

Cornerstone 2: Medicine residues in water

• <u>Pilot report for collection week</u>, as preparation for a national awareness campaign.

Cornerstone 3: Sharing expertise and general sustainability

- We have organised five expertise workshops on the subjects of reducing medicine wastage, the Green Deal for sustainable care, medicine residues in water, and risks for man and the environment in the international production chain.
- We have set up an operational team of businesses which share expertise amongst themselves and conduct collective projects. Participants so far have included: Takeda, Teva, Pfizer, Roche, Boehringer Ingelheim, Amgen, Janssen, Chiesi and GSK. In addition, we have a permanent collaboration with chain partners Alliance Healthcare, Institute for Responsible Medication Use and MediSchoon.

In this inspiration document, which we deliver in the context of cornerstone 3, we discuss the environmental impact of medicines, including development, production, use and waste-processing, in terms of what we already know. We also cover several current developments and offer a few inspiring practical examples for each phase.







TOWARDS A SUSTAINABLE PHARMACEUTICAL VALUE CHAIN

PKNMP

Neprofarm



Infographic by Partners for Innovation | (1) Gupta Strategists, 2019. (2) Brancheplan Duurzaam Verpakken - Farmacie en zelfzorggeneesmiddelen, 2019. (3) Estimate of several pharmaceutical companies. (4) C.L. Bekker, 2018. (5) Effecten van een pilot inzamelweek, 2020. (6) Moermond et al., 2016.

2. DEVELOPMENT

The development of a new medicine is a long and complex process. The finalisation of all phases, from scientific research to (pre) clinical trails and the ultimate registration of the medicine takes around 12 years. Pharmacists first have to test the many thousands of substances. Only once safety in humans has been comprehensively tested, according to strict GCP (good clinical practice) rules, will a medicine become available to patients.

A medicine may only be released onto the market once it has been registered. This registration occurs on a central European level by EMA, and then in the Member States, such as in the Netherlands by the 'College ter Beoordeling van Geneesmiddelen' (Medicines Evaluation Board/CBG). The CBG assesses effectiveness and safety for patients.

There are also strict rules governing the production and distribution of medicines, such as GMP (Good Manufacturing Practices) and GDP (Good Distribution Practices). All this is to ensure that medicines are safe and effective when used by patients. For a clear overview of developments in medicines and the pharmaceutical sector, the website <u>'zo werkt de geneesmiddelenzorg'</u> (how the medicinal care sector works), offers a handy reference.

In order to prevent damage to the environment as much as possible, it is important, at an early stage of development, to consider the environmental impact of the further life cycle of a new medicine. In this chapter, we will zoom in on developments which enable these considerations and discuss a few practical examples.



Developments and practical examples

In order to take account of possible environmental effects in an early phase of development, pharmaceutical companies that are proposing a new medicine have been required to carry out an Environmental Risk Assessment (ERA) since 2006 (European Medicines Agency).

Environmental Risk Assessment

An ERA contains information about the risks for the environment due to exposure to (residues of) a medicine. When a higher environmental burden is expected, e.g. if the patient population expands or the maximum recommended dose increases, companies must adapt this ERA (European Medicines Agency, 2016) accordingly. This information is important for water management companies in order to interpret their measurement data. Water companies are consequently kept up-to-date with the types of medicine residues that they can monitor and the corresponding risks.

Strategic Approach to Pharmaceuticals in the Environment

The European Commission has formulated several <u>campaigns</u> targeting the reduction of the environmental impact of the pharmaceutical chain. These concentrate, among other things, on raising awareness and using medicines properly, improving risk analyses, monitoring the environmental impact, preventing medicine wastage, and improving the collection and waste management of leftover medicines.

In line with the European Commission's strategy, the six-year <u>PREMIER</u> <u>research project</u> began recently. This research is being conducted by pharmaceutical companies and public partners and includes three aims: prioritising environmental research into the 200 substances that have already been introduced to the market, creating an environmental database, and including environmental issues in an early stage of medicine development.

In the European context, the umbrella organisations for pharmaceutical companies, the <u>EFPIA</u>, <u>Medicines for Europe</u> and <u>AESGP</u> are working on the Ecopharma co-stewardship (<u>EPS</u>) initiative. This is a collective effort regarding environmental risk assessment and management. The EPS also covers transparency regarding environmental risks.

Publishing ERA end-points

The European Medicines Agency has a <u>guideline</u> for conducting Environmental Risk Assessments (ERA's). The end-points from these risk studies (e.g. solubility in water or the No Observed Effect Concentration for fish) will not be treated as confidential information because they cannot be used by competitors for commercial gain (HMA/EMA Working Group on Transparency, 2012). This information is therefore made public. Examples of pharmaceutical companies who share this data about their products on websites include AstraZeneca and Roche.

Biodegradability of medicines in water

The development of medicines that decompose more effectively in water could be an opportunity to reduce the damaging effects of medicine residues in the ecosystem. The RIVM (National Institute for Public Health and Environment) points out, however, that making medicines decompose more effectively in water could have a detrimental impact on the medicines' effectiveness, its shelf-life, and the accuracy of dosing (Moermond & Venhuis, 2019).

Innovative therapies

The development of innovative therapies, such as *personalised medicine* and *targeted drug delivery*, contributes towards the effective provision of medicines and thus, indirectly, towards reducing the impact on the environment (Moermond & Venhuis, 2019). The necessary quantities of chemotherapy for breast cancer, for example, can be considerably reduced for some therapies if a genetic test is carried out on the tumour in advance (Vereniging Innovatieve Geneesmiddelen, Association of Innovative Medicines).

In the field of immunology, oncology and rare diseases, there are increasing numbers of biological medicines, comprising proteins. Approx. 40% of the medicines in the pipeline are so-called 'biologicals'. These are created in (living) cells or yeasts. Sugar, heat and water are required instead of harsh chemicals. Biologicals include insulin, and also new medicines which help the natural immune system to recognise and destroy cancer cells.

Chain Approach to Medicine residues in Water

In the <u>Chain Approach to Medicine residues in Water</u>, the national government is collaborating with the parties that have a role to play in this chain. The water boards, drinking water companies, and parties from the pharmaceutical/care sectors are working together to reduce medicine residues in surface and groundwater. It is only a collective approach, with measures close to the source and right up to water purification, which will reduce levels effectively. The basic principle herein is the fact that medicines must remain accessible to everyone who needs them. The various parties have agreed to work pragmatically. This means not waiting, but taking action where possible.

See the interactive chain on: medicijnresten.org



MEDICIJNRESTEN UIT WATER

Pharmacogenetic testing (Alliance Healthcare)

The effectiveness of many medicines depends on the prescribed dose and the extent to which the patient's liver can convert the substance so that it is absorbed into the bloodstream. Because each patient is unique, a DNA analysis is required to establish the liver's capacity to fulfil this process. Pharmacogenetic testing can ensure that every patient receives the optimum dose and, in turn, prevent wastage, e.g. when antidepressants or antipsychotic medication is used. See: https://www.alphega-aapotheek.nl/farmacogenetische-test

https://www.boots.eu/zorg-en-diensten/farmacogenetische-test

Sustainable packaging

When developing a new medicine, it is useful to consider optimising the sustainability of the packaging and the pack sizes. By considering these issues at an early stage, surplus medicine and packaging waste can be prevented in the rest of the chain. The Sustainable Pharmacy Coalition has supported this by developing a <u>Branch plan for Sustainable Packaging</u>. One of the corresponding action points is creating a manual for sustainable packaging for medication. This English language manual is to be published at the beginning of 2020.

Recycling blister packs

Another focus area is the ability to recycle blister packs. According to Wageningen Food & Biobased Research, it is possible to separate the aluminium and plastic (mainly PVC) from one another, but this rarely happens in practice. This is due to the fact that the necessary logistics and technical processes are not yet economically viable.

PVC is often used for blister packs as it offers an effective moisture and oxygen barrier and this benefits the shelf life of the medicines. It is also easy to process using thermoforming technology. Possible alternatives to PVC are PP and PET, for which there are better recycling infrastructures. PP offers a good moisture barrier but is not as effective when it comes to oxygen. When using PP, it is therefore necessary to add an extra layer of barrier material (e.g. EVOH). PET, by contrast, offers a great oxygen barrier but only a moderate moisture barrier. When using PET it is often necessary to use a PET-PET dual-layer thermoforming film.

It is clear that neither of these alternatives therefore offers an easily recyclable option. PP-EVOH can probably be recycled but no public information is currently available. PET-PE is the same as the material that is used for meat trays. This is not recyclable at the moment but various parties are seeking a solution to this issue.



Inhalers and the environment (Boehringer-Ingelheim)

Boehringer Ingelheim has been working on modifying a commonly used inhaler and introduced the resulting item in April 2019. The modifications mean that the inhaler can be refilled for up to six months and does not have to be disposed of each month. This is a difference of 10 inhalers per patient per year and provides an enormous material saving across the world. The <u>CO₂-footprint</u> is 57% and 71% lower for 3 and 6 months respectively, than when the inhalers are thrown away.

The original properties have also been retained; the product is free of propellants and lactose and daily use for the patient has not changed. Research has shown that modification of the inhalers will save an estimated 776 tons of plastic and 14,300 tons of CO_2 -emissions, from the moment of introduction to 2025. For comparison: 776 tons of plastic is the same as over 77.6 million 0.5 PET bottles. Boehringer Ingelheim won the Pharmapack Eco-Design Award 2020 with this design.



3. PRODUCTION

Many medicines that are intended for the Dutch market are produced elsewhere. The biggest pharmaceutical countries are China, mainly for the production of 'active pharmaceutical ingredients' (APIs) and India, both formulation and API productions (Fransen, Sluis, Gosman, & Soederhuizen, 2019).

The production of (classic) medicines comprises a number of basic steps. Firstly, the active pharmaceutical ingredients are formed by means of chemical reactions. These ingredients are then formulated to create the end product.

This chapter will focus on the environmental impact of the production phase, development areas, and will offer a few examples of current developments.



Environmental impact in the production phase

CO₂ emissions

The Dutch healthcare sector is responsible for CO_2 emissions of 11 Mton per year. This equates to 7% of the overall emissions in the country. Around one fifth of these emissions (2 Mton) are caused by the production, processing and transport of medicines. Of these 2 Mton, a small share (13%) can be directly attributed to pharmaceutical companies but the majority (87%) is linked to earlier in the production chain. (Gupta Strategists, 2019). This clearly shows that collaboration within the production chain is vital in order to realise a reduction in CO_2 .

Water and soil pollution

At locations where the active pharmaceutical ingredients are produced, there is a risk of soil and water pollution. This can lead to various consequences for the environment, such as damage to local biodiversity, soil fertility issues, and the availability of clean drinking water. Light and noise pollution can also disrupt the environment around production facilities and, in turn, damage biodiversity (Fransen et al., 2019).

Exceeding safe concentrations of antibiotic emissions

Recent research has shown that the safe concentrations of antibiotic emissions are exceeded at many locations, including rivers in Asia and Africa. Ciprofloxacine, for example, presents a potential risk of antimicrobial resistance in 7 of the 31 countries researched (Wilkinson & Boxall, 2019). Antibiotics were detected in 65% of the 711 tested river locations in 72 countries.

The causes, alongside (excessive) use of antibiotics by people, include the use of antibiotics in animals and agriculture (to encourage growth and good hygiene, and leaks of antibiotic residues from production locations, primarily in India and China.



CO₂ neutral production (AstraZeneca)

AstraZeneca's <u>Ambition Zero Carbon Program</u> aims to produce in a CO_2 neutral manner by 2025 by transitioning to renewable energy and electric transport methods. Together with its chain partners, the pharmaceutical producer is working on solutions for capturing more CO_2 than is produced to ensure that the whole chain is operating in a CO_2 -negative manner by 2030. Antimicrobial Resistance (AMR) with antibiotic resistance as the primary cause, represents a serious threat to healthcare. Antimicrobial resistance leads to treatments, which are now common, becoming less effective or even completely useless. At the moment, around 700,000 people die due to AMR each year (<u>OECD, 2019</u>) If no action is taken in this regard, it is estimated that this will rise to 10 million victims in 2050. According to the WHO, AMR is one of the three biggest problems facing public health.

Plant on a Truck (Janssen)

<u>Plant on a Truck</u> is a mobile water purification plant which treats process water on location. Zinc originating from a diabetes medicine, for example, can be captured and then reused.

Each year, this innovation prevents 500 tons of CO_2 -emissions and recycles 100 tons of chemicals.



Developments and practical examples

There are various developments in Europe, such as the European Green Deal, the climate act and developments within the sphere of due diligence obligations in the supply chain. Within EFPIA (The European Federation of Pharmaceutical Industries and Associations), work is focussing on a white paper in relation to climate change, the circular economy, water quality and chemicals. Within Europe, returning production to Europe is now also high on the agenda (even more so due to the corona crisis) to avoid being so dependent on countries such as China and India.

Pharmaceutical Supply Chain Initiative

Around forty businesses have signed up to the <u>Pharmaceutical Supply Chain</u> <u>Initiative</u> (PSCI). This initiative was founded by large, international pharmaceutical companies who are working towards improved social, environmental and economic circumstances at production locations. The <u>Pharmaceutical Industry Principles for Responsible Supply Chain</u> <u>Management</u> encompass five core themes: ethics, employment conditions, safety, health, and the environment.

AMR Industry Alliance

The <u>AMR Industry Alliance</u> is a coalition of pharmaceutical companies and private parties which concentrates on tackling antimicrobial resistance. The focus lies on research and production as well as the responsible use of and accessibility to antibiotics. The alliance has also published standards which are applied to waste water from production locations.

Digital information leaflet

The digital alternatives to the paper information leaflets which accompany medicines are improving all the time. As well as the benefits in patient safety, having the most up-to-date information at all times and replacing the paper equivalent would be very beneficial for the environment too. Legislative changes, however, are required on a European level for this change to be implemented.

The 'College ter Beoordeling van Geneesmiddelen' (Medicines Evaluation Board/CBG) is working with the KNMP and pharmaceutical companies on research examining whether the source information about a prescribed medicine (including the information leaflet) can be made digitally accessible, e.g. by scanning the pack via <u>www.apotheek.nl</u>. The information could also be clarified further using animated films.

Healthcare insurance companies have made the <u>kijksluiter.nl</u> (a website which explains details about medicines in easy to understand language) mandatory in their (plus) contracts. In order to expand the use of kijksluiter, Alliance Healthcare has added a QR code to all information leaflets, with a reference to the data on the website. This is in preparation for the complete replacement of the paper information leaflet.



Pharmi, digital chemist

<u>Pharmi</u> contains validated, reliable, digital information (text, animations and videos) that enables patients to find out more about their medicines during the first few weeks of using them. The patients are then able to understand their medicines better and avoid mistakes. The basic principle is digital care where possible and human care where necessary.



Pilot project - digital information leaflets

The results of a pilot in hospitals in Belgium and Luxembourg, started in August 2018, have shown that the removal of the paper information leaflet is found to be a positive experience. Over 90% of the participating hospital pharmacies say that paper leaflets are not missed by healthcare personnel as the digital information is easily accessible. As a result of this success, the pilot has been extended for 2 years and more medicines will be added to the test.

This year, PharmaPartners made the new Digital Prescription (Digitaal Recept) available to all pharmacies in the Netherlands. Prescriptions no longer need to be printed; all of the instructions are provided in one, clear screen.

4. DISTRIBUTION

The majority of medicines that we use in the Netherlands are imported from abroad. Wholesalers supply these to pharmacies, hospitals, care institutions and retailers. Despite the optimisations in the stock systems, medicines are wasted during the distribution process before the patients even get hold of them. In this chapter, we will take a deeper look at the possible solutions.

One of the most important causes of wastage in the distribution phase is the minimum shelf life that is applied to the supply of medicines. Medicines that have a shelf-life of under a year can sometimes no longer be sold on and must therefore be disposed of (VIG, Bogin, Neprofarm, 2019). This wastage is also undesirable if there are simultaneous shortages of certain medicines.

Medicine shortages

The number of medicines linked to a (temporary) shortage, doubled within a year from 769 varieties in 2018, to 1,492 in 2019 (KNMP). Medicine shortages may be temporary (e.g. due to production problems, increased demands, or supply problems due to limited stocks) or permanent. In the latter case, a medicine may be removed from the market for economic reasons (KNMP). The corona crisis has flagged up just how vulnerable the supply system is. A partial solution to reducing medicine shortages is to hold more stock but this can, in turn, lead to wastage.



Environmental impact in the distribution phase

Medicine wastage

According to an estimate based on working figures, at least 4,500 boxes of generic medicines with a shelf-life of at least one year, are destroyed on a daily basis within the distribution phase. On an annual basis, this equates to over 1.6 million products. As a result of the low cost of these products (an average of EUR 2.20 per pack), and a focus on price, medicines are quickly disposed of rather than finding other sustainable solutions in the chain.

Exchanging medicines between pharmacies (PharmaSwap)

PharmaSwap is an initiative that is currently being piloted and involves (hospital) pharmacies exchanging medicines with one another via a digital platform in order to avoid wastage in the distribution phase. At the moment, however, the initiative does not fit into current legislation and regulations. In order to use the platform, the requesting pharmacist needs a prescription. Two hundred pharmacies are taking part and the system has led to a saving of 119 packs, with a total value of EUR 150,000. The initiative has now won two prizes; the prize for the Most Sustainable Care professional and the KNMP Innovation Prize. There must now be an investigation into whether this initiative can be accommodated within the law and regulations.

Packing waste

Although the majority of the medicines produced abroad are sold on the Dutch market in their original packaging, around 10% are repacked locally. This process creates packaging waste. Repacking can be justified, however, if it means that medicine wastage in the usage phase can be avoided. As well as the old consumer packaging that is thrown away, waste is also generated by secondary and tertiary waste in the distribution phase. In the pharmaceutical and self-care sector, around 36,000 tons of packaging materials are used each year; this is mainly paper, cardboard and plastic but also includes aluminium, glass and wood.





Every year, **36,000**

tonnes of packaging materials are used, mainly paper, cardboard and plastics. Anually,



packaging units of medication are destroyed in the distribution phase.

Renewable medicine roll-bags (Brocacef)

Brocacef Maatmedicatie, in collaboration with DD Innovations, has developed <u>a biodegradable film</u> which can be used for medicine roll bags. The new, thinner material is made of 90% paper which is made using residual waste from FSC certified wood processing. By the end of 2020, Brocacef would like to use the new film for all its medicine rolls and, in turn, help to support a cleaner medicine chain.



Developments and practical examples

When purchasing products, the price and functional properties, but also the environment, climate and social criteria are taking on an ever more important role. This also applies to pharmaceuticals and packaging materials. In the current situation, the focus tends to lie on costs alone. But avoiding medicine wastage can often provide environmental benefits as well as cost savings when it comes to expensive medicines. With cheaper medicines, disposal is often cheaper than more sustainable solutions.

Online tool for socially responsible purchasing

The Government has issued purchasing criteria for environmentally-friendly, climate-friendly and socially sustainable purchasing for many years. As of 1 November 2018, the national criteria for socially responsible purchasing (MVI) have been accessible via a user-friendly webtool <u>mvicriteria.nl</u>. Earlier this year, the RIVM (National Institute for Public Health and Environment) calculated that MVI alone, with eight product groups, had saved almost 5 megatons of CO_2 over the duration of the contracts.

5. USE

Both the KNMP and the pharmaceutical companies are focussing on developing and implementing care programmes and instruments to encourage the efficient use of medicines. This concerns customisation for patients, by ensuring that the right patient is given the right medicine at the right time but also in the right quantities. As a result, the use of medicines is safe, effective and goal-oriented. The unnecessary use of medicines is prevented and patient confidence in therapies increases. These interventions have a beneficial impact on avoiding wastage and, in turn, the environment.

This chapter further examines the environmental impact of the use phase, current developments and a few practical examples.

Good usage

Good usage of medicines provides health benefits for the patients and can reduce hospital admissions (Ministry of Public Health, Welfare and Sport, 2017).

With the help of 'Medisch Farmaceutische Beslisregels' (Medical Pharmaceutical Decision Rules/MFB's), the prescribed medicines are combined with patient characteristics such as age, gender and a blood test result. The consideration of patient characteristics means that the number of monitoring signals reduces, these signals become more relevant, and medication can be checked at any time, e.g. if there are new blood results.



Benefits that will raise the bar even further in terms of globally respected pharmaceutical monitoring in the Netherlands. The G-Standard now incorporates 6,000 MFBs which are developed and maintained using an advanced application. Suppliers of information systems for healthcare providers are currently focussing on integrating the MFB structure.

'Mijn Geneesmiddel in Beeld' (An Overview of my Medication/Teva)

An example of a medication overview that pharmacies can offer to patients in the context of the effective use of medicines is called 'Mijn Geneesmiddel in Beeld'. It is a summary of all the medications, images, intake moments, instructions and warnings. For more information go to: www.MijnGiB.nl



Promoting confidence in therapies

There are various successful interventions for promoting confidence in therapies. These have not yet found their way into regular healthcare. ZonMw is therefore focussing on the implementation of these interventions in outpatient care. To this end, <u>4-8 trials have been financed</u>. A consortium of experts is supervising these living labs, developing a set of instruments, evaluating the trials and supporting the further dissemination of the experiences gained. The Make-It consortium comprises researchers/carers who have collaborated on promoting confidence in therapies for many years.

Good use of diclofenac gel (GSK)

Manufacturers play a significant role in minimising potential environmental risks by encouraging the responsible use of medicines and explaining the appropriate methods for disposing thereof, via packing instructions and educational materials.

In line with this, GlaxoSmithKline has modified the instructions in the information leaflet for diclofenac. Users are now instructed to wipe any excess product from their hands with absorbent paper, and to throw this in the bin before washing their hands. Users are also told to wait until the gel has dried before they take a bath or shower.

Environmental impact in the use phase

Overall medicine usage in the Netherlands is estimated to be 3.5 million kilograms per year, excluding the use of x-ray contrast agents (Bogin in Moermond et al., 2016).

Medicine wastage

Every year in the Netherlands, we issue medicines worth around EUR 5 billion. Of this, medicines worth around EUR 100 million are thrown away every year (Charlotte Bekker, UMC Utrecht, 14 November, 2018). According to this research, approximately 40% of unused medicines are needlessly thrown into the bin. There are many reasons for medicines being wasted in the use phase: too much medicine is prescribed or for a longer period than is necessary, there could be confusion about changing packs, the therapy itself is changed, or there is a lack of patient confidence in the therapy itself. Medicines are also often left at home when a patient is admitted to hospital or dies.

Packaging waste

As well as wastage of medicines, packaging waste is also an issue in the use phase. In the Netherlands, this equates to around 417 million packs each year. Prescribed medicines make up around 260 million items and self-care products account for the remaining 157 million (VIG, Bogin, Neprofarm & KNMP, 2019). The blister pack is the most common primary packaging. But it is not easy to recycle (see chapter 2). Medicine packaging that cannot be recycled easily is generally incinerated. Cardboard boxes and transport packaging can be recycled easily.



Farmabuddy

In the Farmabuddy project, patients in the palliative and terminal phase and their carers are given fixed contacts in the pharmacy; i.e. two pharmacy assistants, as pharmacy 'buddies'. The intensive pharmaceutical patient care that is vital for both patient and carer is thus better structured and more focussed on the patient. This has the beneficial side-effect that wastage is reduced because people use the highest levels of medication in the final phase of life.

Using medicines from home, in hospital

A pilot in 2017, which focussed on using medicines from home after a hospital admission, offered promising results. The pilot was conducted with eight nursing departments at seven Dutch hospitals. When patients do not have to change medication but can continue to use their tried-and-tested medicines, it can avoid wastage, save time for hospital personnel, and increase patient satisfaction. The total economic value of wasted medication during the pilot reduced by 39.5%, from EUR 3,983 to EUR 2,411 per 100 patient days.

FTO module for medicines and the environment (IVM)

In order to raise awareness and expertise about pharmaceuticals in the environment among doctors and pharmacists, the 'Instituut Verantwoord Medicijngebruik' (Institute of Responsible Medicine usage) has developed an <u>FTO module</u> on this topic. The IVM has also investigated how care institutions that offer long term care cope with medicine waste, the most significant problem areas, and what efforts can be made to tackle these. https://www.medicijngebruik.nl/projecten/duurzaam-medicijngebruik

Developments and practical examples

Lifestyle changes

De-prescribing is the process of halting or reducing the dose of medication, under the supervision of a care provider, when the advantages for the patient no longer outweigh the disadvantages. In 2020, expert documents were published for ten medicine groups (including blood sugar reducers) which focus on responsible reduction and stopping.

Reissue

The practical and financial feasibility of reissuing expensive medicines was examined in pilot studies. This concerns medicines that have been issued to patients and which have a shelf life which meets the corresponding requirements but, for various reasons, have not been used. Instead of being thrown away, they could be reissued.

Researchers from the Radboudumc and the University of Utrecht are investigating whether unused oral anti-cancer medicines can be reissued to other patients. The project has received a subsidy of EUR 500,000 from ZonMw. Of all the patients who use new oral cancer medication, around 30% stop their therapy prematurely. Half of these patients have leftover, expensive medicines. An important condition is that the quality of the returned medicines must be guaranteed, e.g. that the medicines have been stored at the right temperature and under the right (light/moisture) conditions (Radboudumc, 2020).

De-prescribing for type 2 diabetes

When long term diabetes is combined with a higher age range, the effectiveness of reducing blood sugar in relation to decreasing (micro) vascular complications lessens considerably. And, simultaneously, there may be a risk of side-effects such as hypoglycaemia in relation to the reduced liver function. In the Netherlands, 20-40% of older patients have more severe glucose levels than are recommended according to guidelines regarding age, medication and diabetes duration. The intensity of treatment could be reduced in these cases. Dutch research has shown that doctors treating around half of the possibly over-treated patients could successfully reduce the treatments designed to reduce blood sugar but that this is a complex and time-consuming process.

To combat counterfeit medicines, the FMD (Falsified Medicines Directive) came into force in February 2019. Medicines that are provided in Europe must be equipped with a 2D code and a unique number to verify their authenticity. When issued, each product must be signed-out via a database.

The FMD complicates reissue projects because returned medicines cannot be re-entered into the database and can therefore not be verified when issued to any subsequent patients (Bekker, Gardarsdottir, Egberts, Bouvy, & van den Bemt, 2017, p. 203).

Alloga also had to destroy a large consignment of quality medicines recently because it was unable to provide adequate proof that checks complied with FMD regulations.



Miljoenen aan (onnodige) verspilling



6. WASTE PROCESSING

In this chapter, we will focus on how medicine residues are processed in the waste phase, which risks they form to the environment and how pollution can be prevented. The majority of pharmaceutical residues in surface water (90-95%) arrive there via the human body and the sewerage system. The majority of all emissions from medicine residues (90%) come from patients' homes; the other 10% is released from hospitals or care institutions (Ministry of Infrastructure and the Environment).

Unused liquid products that are flushed down sinks and toilets also go directly into the sewers. Once there, depending on the type of product, they only partially decompose. Non-decomposed residues then flow along this route into surface water.

Unused medicines that are handed back to a pharmacy or refuse centre will be processed in a responsible manner in incinerators (incinerated at 1000-1300 degrees) for chemical waste. The hazardous gases that are released as a result are purified. If medicines are thrown away with household waste, they end up in the regular waste processing system (incinerated at 850-1050 degrees) where they could be hazardous to the environment.



What do patients do with unused medicines?

The IVM, 'Medischoon' and the Sustainable Pharmacy Coalition are all focussing on improving the collection of unused medicine residues. The involvement of citizens is vital, in this context. This is also clear from the pilot 'Effects of pilot collection week for unused medication' which we conducted at pharmacies in Zoetermeer and Noord Holland on behalf of the Ministry of Health, Welfare and Sport in November 2019. When it comes to medicine residues that are thrown away at home, around 25% are disposed of by flushing down sinks or toilets. Of the 700 citizens interviewed in public pharmacies, 17% did not know that this was wrong.

The research also revealed that three-quarters of all patients (n=700) retain leftover medicines. Around half of them take these back to the pharmacies and around 6% take them to the refuse centre. It is worth noting that of the patients who do not hand back their medicines, only a small group is *not* aware of the fact that this would be the right thing to do. Almost 36% say that they know but find that it's too much trouble or can't see the point. There is also confusion about the way in which medicines can be returned. This further underscores the need for awareness campaigns among the public regarding the environmental risks associated with medicine residues.

According to this pilot, a collection week for unused medicine residues is a great way to raise awareness among citizens about correctly disposing of medicines. That is why a 'return unused medicines to the pharmacy' tool kit template was developed during the pilot. This tool kit should be used by pharmacies at a regional level and may be linked into a nationally coordinated collection week. The tool kit will be ready in July 2020.









Teva Returns box (Teva)

The <u>Teva Returns box</u> has been developed for collecting leftover medication and empty blister packs. The box will be available in pharmacies and makes it easy for patients to hand in unused medicines and empty blister packs. The collected medicine waste will then be processed in a responsible manner and the packaging will be collected separately, improving the potential for recycling. Blister packs must be empty though and that remains a challenge. The project is a collaboration between Teva Nederland, Thio Pharma pharmacies, recycling company Renewi and the Intstituut Verantwoord Medicijngebruik (Institute of Responsible Medicine Usage).



MediSchoon

The '<u>MediSchoon</u>' programme encourages the collection of unused medicines. MediSchoon works on a regional level and improves the collection options for unused medicines with pharmacies so that they do not have to bear the corresponding costs. Clear agreements are made about the collections of unused medicines between pharmacies and the municipality.

MediSchoon also raises awareness about the issue of medicine residues in water among residents. This helps ensure effective medicine usage, the correct waste processing techniques, but also supports water awareness. MediSchoon works with water boards, sector organisations, drinking water companies, municipalities, provinces, and hospitals on this issue.

The **Strategic Approach to Pharmaceuticals in the Environment** suggests researching whether the last use-by date (or shelf-life date) can be safely extended so that fewer medicines, which can still be used, are thrown away.

Environmental impact in the waste processing phase

Medicine residues in water

Every year, in the Netherlands, around 140 tons of medicine residues (excluding metabolites) and 30 tons of contrast agents are drained into surface water via the sewers. Some of these medicine residues (approx. 5-10%, OECD, 2019) could have a damaging impact on water organisms, at certain concentrations. They could, for example, lead to tissue damage (due to analgesics) and changes in sex (due to contraceptives) in fish and behavioural changes (due to antidepressants) in fish, lobster and crayfish (Moermond et al., 2016). These negative effects are a growing concern.

Although medicine residues can also be found in drinking water, they tend to be such low concentrations that they are not damaging to humans. Antibiotic residues are also a growing problem and when they accumulate in surface water it increases the risk of antibiotic resistance.

X-ray contrast agents are a particular challenge as they are given in high doses, do not decompose effectively, are extremely mobile, and can pass through the sewerage system almost unhindered. These substances, in high concentrations, form a hazard for organisms but, because they do not decompose effectively, there is also a risk that they will accumulate in the environment (Ministry of Infrastructure and the Environment). These substances are also undesirable for drinking water as they have a negative impact on the purification process.

Urine bags for x-ray contrast agents

Within the Chain Approach to Medicine residues in Water, there is a working group focussing on x-ray contrast agents with all of the relevant parties. This working group concentrates on reducing the use of these agents, the drainage situations in hospitals, and the patients at home. The average quantities of contrast agent per patient can be reduced by making adjustments based on the weight of the particular patient and their specific requirements. In hospitals, the patient's urine can be collected and treated. When it is processed, some elements can even be recuperated. At home, for the first 24-hours after x-ray agents have been administered, the urine bags can be used to prevent the agents ending up in the environment. Several hospitals were willing to cooperate with scaling up a pilot that has already taken place in a Deventer hospital.

140 tonnes

of medication residues (excl. 30 ton contrast agents) are discharged into the surface water every year.



Medication residues can cause tissue damage, sex- and behaviour change in water organisms. Antibiotics residues increase the risk of antimicrobial resistance.

Developments and practical examples

Sewerage purification - 'implementing lessons'

A lot of the medicine residues end up in surface water via sewerage water purification installations (RWZI) because it is impossible to remove all of the substances from the water. How well medicine residues and micro-pollutants can be removed varies per substance (Medicine residues in water). In the context of the Chain Approach to Medicine residues in Water, various projects have begun to further develop the purification capabilities of these installations by learning lessons from abroad, among other things. In this context, STOWA, the expertise centre for water boards, conducted a hot-spot analysis to evaluate the sewerage water purification installations (RWZIs) with the biggest impact on water quality. A community of practice for 14 water boards is designing the best system for comprehensive purification of medicine residues. STOWA is also continuing to develop practical purification techniques within the micro-pollutant innovation programme. ILOW, the cooperative partnership for water quality management laboratories, is working on a uniform method for sampling and analysing medicine residues in water so that research results are easy to compare (Ministry of Infrastructure and Water Management, 2019).

Focussed combination of targeting the source and purifying medicine residues

Aa and Maas Water is explicitly focussing on tackling the source (preventing medicine residues from ending up in waste water) and then purifying the waste water to reduce the emission of medicine residues into surface water. On the one hand, because purification cannot remove everything (at least, not for a reasonable cost) and, on the other, because water boards are tasked with ensuring that surface water does not become excessively polluted (duty of care). This provides different processing perspectives for each group of substances.

Circular plant cultivation (Weleda)

Weleda Benelux in Zoetermeer is the market leader in 100% natural care products and anthroposophic remedies. 80% of the necessary raw materials for the anthroposophic remedies come from the garden. After harvesting, the plants (or a certain plant part) are processed to create a tincture. The residues of the plants are then put on a compost heap where they break down to create nutrition for the soil where the next generation of plants will grow. It's a great example of circular plant growing.



7. SUSTAINABLE PHARMACY COALITION

The Sustainable Pharmacy Coalition is a cooperative partnership of the organisations below.

Vereniging Innovatieve Geneesmiddelen (Association Innovative Medicines)

The Association Innovative Medicines is is the industry association for the Dutch branches of innovative pharmaceutical companies which focus on the research and development of new medication. The Association has 44 members which are largely multinationals The biopharmaceutical sector in the Netherlands offers direct and indirect employment opportunities to 65,000 people.

The Association Innovative Medicines works on the fields of economics of health care, pharmaceutical affairs, innovation, biotechnology, medicalscientific issues, legal affairs and communication. The pharmaceutical sector is enterprising and innovative. The Association also aims to promote the availability of new medicines for patients, create a favourable research climate, and support the value of innovative pharmaceuticals.

Bogin

The Biosimilars and generic pharmaceutical industry Netherlands (Bogin) is the representative organisation for generic medicine manufacturers. Bogin was founded in 1987, functions as a 'spokesperson' for eight members (manufacturers) and represents its members in platforms and networks (discussions with ministries, professional organisations, governing bodies). Bogin stimulates quality systems and codes of conduct and focuses on promoting the market positions of its members. It also focuses on stimulating market processes and influencing national and European legislation. The market for generic medicines in the Netherlands comprises 7-8 wideranging suppliers and around 40 smaller providers. The total gross turnover figure for extramural care in 2018 was EUR 730 million (pharmacy purchasing prices). The share of Bogin members within the market for generic medicines in the Netherlands amounts to 87% (both in turnover and volume). The employment opportunities within the overall, generic sector in the Netherlands equates to around 1,700 people.

Neprofarm

Neprofarm is the Dutch association representing manufacturers and importers of branded OTC medicines, including non-prescription medicines, food supplements and medical devices. Neprofarm represents the collective interests of the affiliated companies in many areas and supports an optimum social and political climate for self-care. The range of members includes Abrand self-care medicines (also homoeopathic, phytotherapeutic, and anthroposophic), as well as nutritional supplements, herbal preparations, and medical devices.

Neprofarm has 24 members: 15 Dutch branches of multinationals with a head office outside the Netherlands, 5 companies that operate in multiple countries with a head office in the Netherlands, and 4 distributors of product from other countries (much of it originating abroad). Just 3 of the above companies produce (some of) their products in the Netherlands. The majority share of the products which Neprofarm bring onto the market in the Netherlands are produced by main branches/sister-companies outside the Netherlands or by third parties (contract manufacturing services).

The self-care market had grown significantly over the past few years, from EUR 520 million in 2003 to EUR 730 million in 2017 but this growth has stagnated somewhat over the last couple of years. The collective turnover for Neprofarm members is around EUR 500 million (consumer price levels) per year. This equates to 70% of the overall self-care market.

KNMP

The Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Society for Promoting Pharmacy) is the professional and sector organisation for pharmacists and pharmacies. As an umbrella organisation for pharmacists, the KNMP (1842) represents the interests of both its members and those of the pharmacy sector.

Around 90% of all pharmacies in the Netherlands is a member of the KNMP. Most members work in public pharmacies. Other members work as pharmacists in hospitals, in industry or elsewhere. As of 1 January 2019, there were 2,010 public pharmacies registered in the Netherlands.



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👤 Neprofarm

