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Swedish eHealth Agency

Pharmaceutical substances with potential environmental impact 2000–2024

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Preface

Pharmacies and other vendors that sell pharmaceuticals are legally obligated to report their sales to the Swedish eHealth Agency. The Agency therefore holds data on all pharmaceutical sales in Sweden and is responsible for quality assuring, managing, compiling, and providing national statistics on pharmaceuticals based on this material.

Since 2024, the eHealth Agency has published statistics on sold quantities of pharmaceutical substances with potential environmental impact as open data on its website. These statistics are used for various purposes by regional authorities, government agencies, and researchers. This report deepens the analysis and puts the published statistics in context, with the aim of making the statistics more comprehensible and accessible to a wider audience. For a number of selected substances, the report presents their uses, sales during 2000–2024, and the known potential environmental impacts of the substances.

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The decision to publish this report was taken by head of department Thomas Pettersson Westerberg. Analyst Maria Lidén served as rapporteur. Head of unit Cecilia Enström Öst participated in the final processing.

Summary

Since 2024 the Swedish eHealth Agency has published statistics on sold quantities of pharmaceutical substances with potential environmental impact as open data on its website, covering more than 1,600 different substances.[1]

Pharmaceutical substances enter the environment during manufacture, use and through waste generated after use and disposal. Many are difficult to neutralize or remove in wastewater treatment plants and are therefore released into the environment where they may cause harm even at low concentrations. Some substances persist in the environment for long periods of time.[2]

For most pharmaceutical substances, knowledge of their environmental risks is limited, particularly for substances in older pharmaceuticals. Environmental risk assessments when applying for approval of new pharmaceuticals cannot cover all environmental effects that the substances involved may have in the short and long term.

In Sweden, environmental legislation is regulated in the Environmental Code (1998:808). In practice, other regulations apply for the pharmaceutical sector, so the principles of the Environmental Code do not always have full impact. Important regulations for pharmaceuticals in the environment are the Swedish list of Specific Pollutants (SFÄ), the Urban Wastewater Treatment Directive (UWWTD) and the EU Priority Substances Directive. This report focuses on substances included in those regulations and sold on the Swedish market.[3]

Environmental considerations are currently not part of the benefit–risk assessment when pharmaceuticals for humans are approved for sale, nor taken into account when assessing whether pharmaceuticals for humans may be sold as over the counter (OTC) medicines.

The analysis starts with an overview of the ten most sold pharmaceutical substances in Sweden in 2024. Most of these are not identified as particularly harmful to the environment according to SFÄ, the draft EU Priority Substances Directive or the UWWTD. The report then analyses sales of pharmaceutical substances that are included in SFÄ, the EU Priority Substances Directive or the UWWTD.

[1] Swedish eHealth Agency, Miljöstatistik

[2] Swedish Medical Products Agency, Miljöpåverkan från läkemedel; Swedish Medical Products Agency, Läkemedelsboken

[3] Regulation HVMFS 2019:25; DIRECTIVE (EU) 2024/3019 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; COM/2022/540 final (version available summer 2025)

Azithromycin, ciprofloxacin, erythromycin and clarithromycin are antibiotics that degrade slowly in the environment and are highly toxic to aquatic organisms. These substances have been detected in treated wastewater in Sweden and may contribute to the development of antibiotic-resistant bacteria. Combating antibiotic resistance is a high priority in Sweden. Sweden, like other Nordic countries, has low antibiotic use and a low prevalence of resistance in an international perspective, but more serious forms of resistance are increasing over time.[4]

Citalopram and venlafaxine are antidepressants. Residues in treated wastewater can affect the condition and behavior of fish and other aquatic organisms, making them less sensitive to stress and more prone to high-risk behavior.

Sex hormones such as estradiol and ethinylestradiol are used in commonly prescribed pharmaceuticals and contraceptives. They degrade slowly in the environment and may disrupt sexual development and reproductive capacity in fish, amphibians and other aquatic animals. They bioaccumulate in aquatic organisms over time, increasing the risk of long-term effects on the ecosystem. Topically applied hormone treatments may also affect children, animals and other adults who are in close contact with the treated person or with pharmaceutical waste.

Diclofenac and ibuprofen are nonsteroidal anti-inflammatory drugs (NSAID) used to reduce pain and inflammation. In 2024, OTC sales of diclofenac gels accounted for 67% of total diclofenac sales. Topically applied pharmaceuticals are widely released to the environment via wastewater from showering and washing. Diclofenac is difficult to remove in treatment plants, highly toxic to the environment and degrades slowly. OTC medicines, including environmentally harmful substances such as diclofenac, are often used without a physician’s prescription. Ibuprofen is also toxic to aquatic organisms, but to a much lesser extent than diclofenac.

Imidacloprid is used in veterinary drugs against various parasites and is classified as an insecticide. In the environment, imidacloprid may have harmful effects on bees and other insects.

The UWWTD, which entered into force on 1 January 2025, requires advanced treatment at wastewater treatment plants, financed by producers of pharmaceuticals and cosmetics. Several companies have brought legal actions against the European Parliament and the Council of the European Union seeking removal of provisions on extended producer responsibility from the Directive.[5] The outcome of these legal actions, i.e., how producer

[4] Public Health Agency of Sweden and Swedish Veterinary Agency (SVA) (2025) Swedres-Svarm 2024

[5] EUR-Lex e.g. C/2025/2672 - C/2025/2687; Svenska dagbladet, 2025-07-21

responsibility is to be applied and how fees for pharmaceuticals will be structured, were not settled at the time this report was written.

Pharmaceutical legislation in the EU is currently under review. According to current proposals, companies wishing to put pharmaceuticals on the EU market may be required to provide environmental risk assessments and implement risk reduction measures. The proposals also recommend intensified efforts to combat antibiotic resistance.[6]

Key conclusions:

- For most pharmaceutical substances, knowledge of their environmental effects is limited.
- Antibiotics such as azithromycin, ciprofloxacin, erythromycin and clarithromycin may contribute to the development of antibiotic-resistant bacteria in the environment.
- Antidepressants such as citalopram and venlafaxine may cause fish to exhibit more high-risk behavior.
- Hormones such as estradiol and ethinylestradiol may disrupt sexual development and reproduction in aquatic animals; topically applied medicines may also affect people and animals in close contact with treated individuals or pharmaceutical waste.
- In 2024, 67% of diclofenac sales were OTC gels; diclofenac is released to the environment via wastewater from showering and washing, is difficult to remove in treatment plants, is very toxic to the environment and degrades slowly.
- Imidacloprid, used in veterinary drugs, is an insecticide that negatively affects bees and other insects in the environment.

[6] European Council, Council of the European Union, The pharma package: new EU rules on medicines; Pharmazeutische zeitung 2024-04-10

Content

1 Introduction

Pharmacies and other vendors that sell pharmaceuticals are legally required to report sales to the Swedish eHealth Agency. Thus, the Agency holds data on all pharmaceutical sales in Sweden and is responsible for providing national statistics on pharmaceuticals based on this material.

Since 2024, the eHealth Agency publish statistics on quantities sold of pharmaceutical substances with potential environmental impact as open data on its website, covering more than 1,600 different substances.[7] The statistics are available for free download from the statistical database.[8] They meet important needs for users within regions (regional health authorities), government agencies and science, and the demand is expected to remain high for a long time.

This report deepens the analysis and puts the published statistics in context, making the statistics more comprehensible and accessible to a wider audience. For a number of selected substances, the report presents their uses, sales on the Swedish market during 2000–2024, and the known potential environmental impacts of the substances.

1.1 Scope

This report focuses on substances included in the nationally developed list of Specific Pollutants (SFÄ), listed in the Urban Wastewater Treatment Directive (UWWTD) and/or included in the draft EU Priority Substances Directive that was available in the summer of 2025.[9] See Annex 1 Reported substances and section 2 below. In the eHealth Agency's statistical database these substances are also presented in separate tables with information on geographic region, sales channel and point of sale.

2 Background

2.1 Pharmaceuticals in the environment

Safe and effective pharmaceuticals are essential for the health of both humans and animals. All pharmaceuticals are developed to prevent, alleviate, or cure diseases. The

[7] Swedish eHealth Agency, Miljöstatistik

[8] Swedish eHealth Agency statistical database

[9] Regulation HVMFS 2019:25; DIRECTIVE (EU) 2024/3019 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL; COM/2022/540 final (version summer 2025)

active substances in pharmaceuticals must be stable and must not degrade before they are used or before they reach the part of the body to produce the intended therapeutic effect. The time it takes for a pharmaceutical to break down and leave the body varies between pharmaceuticals. The active substances in a pharmaceutical can be difficult to degrade or remove in wastewater treatment plants, and some substances may remain in the environment for a long time, where they can negatively affect animals and plants. Pharmaceutical substances released into the environment can, even at low concentrations, be toxic and affect other organisms in the same or similar ways as in the humans and animals for whom the pharmaceuticals were intended; see Figure 1.

Figure 1. Perch and other aquatic animals and plants can be affected by pharmaceutical substances released into water.

The substances may also cause effects other than those intended. For example, emission of various types of antibiotics can contribute to the development and spread of antibiotic-resistant bacteria.[10] A simplified description of how pharmaceutical substances spread in the environment is provided in Figure 2. Pharmaceutical substances can reach the environment during manufacturing, during use, and through the waste generated after use, as well as through the disposal of unused pharmaceuticals.

[10] Swedish Medical Products Agency, Miljöpåverkan från läkemedel; Swedish Medical Products Agency, Läkemedelsboken

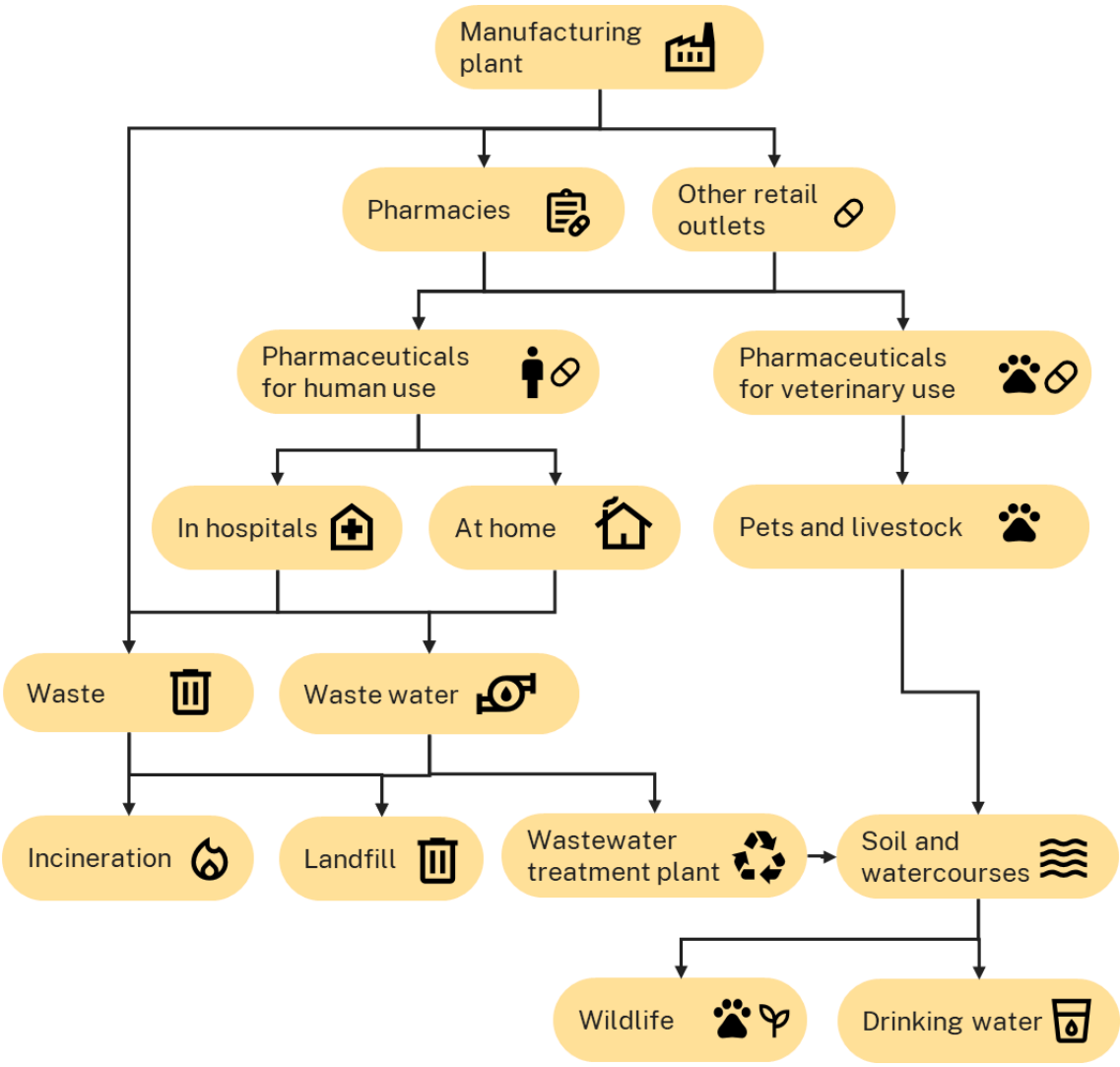

Figure 2. Simplified pathways for the spread of pharmaceutical substances in the environment.

Efficient and safe management of waste and wastewater is essential to minimize the spread of pharmaceutical substances to the environment. Unused pharmaceuticals should always be returned to a pharmacy, where they are sent for destruction by incineration. Residual household waste that is not sorted for composting or material recycling is, in Sweden, typically sent for incineration with energy recovery at a heating plant.[11]

Wastewater must be collected and treated before it can be discharged. This is normally done at a wastewater treatment plant. Pharmaceutical residues can be difficult to remove

[11] Swedish Environmental Protection Agency, Avfallsbehandling i Sverige

in wastewater treatment plants, and many substances pass through into the effluent to a greater extent than desired. Achieving sufficient removal of pharmaceutical substances requires additional treatment technologies that can be applied after existing treatment steps.[12]

Substances in pharmaceuticals administered to animals often end up directly in soil and water where the animals live, rather than in waste that can be incinerated or in wastewater that can be treated. This means that, to minimize the spread of pharmaceutical substances to the environment from veterinary pharmaceuticals, the quantity of pharmaceuticals administered to animals must be minimized, and the substances used must be as gentle to the environment as possible while still providing the therapeutic effect the animal needs.

2.2 Information on environmental impact of pharmaceutical substances

The statistics on sold quantities of pharmaceutical substances with potential environmental impact, presented on the Swedish eHealth Agency's website for the years 2000–2024, include more than 1,600 different pharmaceutical substances.[13] For most of these, knowledge about the environmental risks they may pose is limited.

When companies apply for approval of new pharmaceuticals on the European market, they must submit an environmental risk assessment.[14] However, an environmental risk assessment cannot cover all environmental effects that the substances may have in the short or long term. For older pharmaceuticals, which were already on the market when environmental risk assessment requirements were introduced, knowledge about environmental risks is often limited.

Publicly available information in Swedish on the environmental impact of pharmaceutical substances can be found on the websites described below.

2.2.1 FASS

On Fass.se, companies may, if they choose, publish environmental information for their products under the section on environmental data. The information is often based on the tests carried out for the environmental risk assessment required when registering new products. The information is published per pharmaceutical product, not compiled for each

[12] Swedish Environmental Protection Agency, Avloppsvattnets miljöpåverkan

[13] Swedish eHealth Agency statistical database

[14] Swedish Medical Products Agency, Miljöhänsyn i lagstiftning

active substance. The information may differ for the same active substances in different products, as it is based on different tests and provided by different companies.[15]

2.2.2 The Swedish Agency for Marine and Water Management

The Swedish Agency for Marine and Water Management works to ensure the sustainable management of seas, lakes, and watercourses, which also includes addressing various problems in the aquatic environment. Information on pharmaceuticals in the aquatic environment is available on the agency's website.[16] The Swedish Agency for Marine and Water Management is responsible for the nationally developed list of SFÄ (see section 2.3 below).

2.2.3 Janusinfo

Commercially independent pharmaceutical information is published on Janusinfo.se. In the database "Läkemedel och miljö", environmental information is compiled for each active substance. The knowledge base is derived from environmental information in assessment reports from the European Medicines Agency (EMA), which includes risk assessments from a European perspective; environmental information on Fass.se, where risk assessments are based on the total sales of an active substance in Sweden in a given year; and environmental risk assessments for certain substances based on concentrations measured in the Swedish environment and effect studies conducted from an environmental perspective.[17]

2.2.4 Kloka listan

The website Kloka listan (eng. the Wise List) provides information on pharmaceuticals recommended for the treatment of common diseases. The recommendations are based on scientific evidence regarding efficacy and safety, pharmaceutical expediency, cost-effectiveness, and environmental considerations. When pharmaceuticals have comparable medical efficacy and safety, cost and environmental assessments become important factors in determining what is recommended. The site also provides general information on the environmental effects of pharmaceuticals.[18]

[15] FASS, Miljöinformation i Fass

[16] Swedish Agency for Marine and Water Management, Läkemedel

[17] Region Stockholm, Janusinfo, Läkemedel och miljö

[18] Region Stockholm, Kloka listan

2.2.5 Läkemedelsboken

The website Läkemedelsboken (eng. the pharmaceutical book) provides independent information on pharmaceutical treatment for various medical conditions. It also contains general chapters addressing broader aspects of pharmaceutical use, including a chapter on the environmental impact of pharmaceuticals.[19]

2.2.6 Läkemedelsfakta

The Swedish Medical Products Agency provides a service containing information on all authorised and registered pharmaceuticals and substances for humans and animals in Sweden. It is possible to search for either a specific pharmaceutical or for a specific substance.[20]

2.2.7 The Swedish Environmental Protection Agency

The Swedish Environmental Protection Agency is responsible for ensuring that Swedish and European environmental legislation is applied in an appropriate and correct manner, for example by ensuring that wastewater treatment plants use the best available techniques. The agency is also responsible for monitoring the state of the environment, including measuring the presence and concentrations of various environmental pollutants, among them pharmaceutical substances. Information on pharmaceuticals in the environment is available on the Swedish Environmental Protection Agency's website.[21]

2.3 Legislation and Other Regulations

In Sweden, environmental legislation is consolidated in the Environmental Code (1998:808).[22] General rules of consideration are set out in Chapter 2 of the Environmental Code. Several of these rules are internationally established and have been made legally binding in Sweden through the Environmental Code. The following are particularly relevant for environmental effects related to pharmaceuticals:[23]

[19] Swedish Medical Products Agency, Läkemedelsboken

[20] Swedish Medical Products Agency, Sök läkemedelsfakta

[21] Swedish Environmental Protection Agency, Läkemedel i miljön

[22] Environmental Code (1998:808)

[23] Swedish Environmental Protection Agency, Hänsynsreglerna – 2 kap. miljöbalken

Section 2 – The Knowledge Requirement: Knowledge must precede action, as knowledge is a fundamental prerequisite for all environmental protection efforts. The requirements that may be imposed vary depending on the nature and scope of the activity.

Section 3 – The Precautionary Principle: When certain knowledge is lacking, the precautionary principle shall be applied to prevent possible harm and inconvenience. The principle is internationally recognized and appears in several international conventions.

Section 4 – The Product Choice Principle: Products that may be assumed to pose environmental risks shall be replaced with products that can be assumed to be less harmful.

Section 8 – Responsibility for Environmental Damage: This provision expresses the principle that the polluter pays. When environmental damage occurs, it is the polluter who must bear the cost of the measures required to remedy the damage.

In theory, the general rules of consideration in Chapter 2 of the Environmental Code apply to all activities. In practice, however, other regulatory frameworks govern the pharmaceutical sector, which means that the principles of the Environmental Code are not always fully complied with. According to the Swedish Medical Products Agency[24], there are several examples of how pharmaceutical legislation deviates from the rules of consideration in the Environmental Code:

- An environmental risk assessment (ERA) is required when approving new pharmaceuticals. For medicinal products for human use, the environmental risk assessment does not affect the approval decision. For veterinary pharmaceuticals, environmental risk may lead to rejection.
- Manufacturing authorization under the Pharmaceuticals Act is separate from environmental permits under the Environmental Code.
- Producer responsibility for pharmaceutical waste is regulated in a specific ordinance[25], not directly in the Environmental Code.

The interim target “Pharmaceuticals in the Environment” within the Swedish environmental objectives system aims to minimize pharmaceutical residues in the environment. Regulations and other measures that reduce the negative environmental

[24] Swedish Medical Products Agency, Miljöhänsyn i lagstiftning

[25] Ordinance (2009:1031) on Producer Responsibility for Pharmaceuticals

effects of pharmaceuticals must be in place in Sweden, in the EU and/or internationally by 2030.[26]

Regulations that support the interim target on Pharmaceuticals in the Environment include SFÄ, the UWWTD, and the European Commission's proposal for an updated Priority Substances Directive. The pharmaceutical substances covered by these regulations and present on the Swedish market are presented in this report.

The SFÄ list includes substances that either appear on the EU watch list for surface waters or that Sweden assesses are discharged in quantities that could prevent the achievement of ecological status objectives—that is, how well surface waters function as ecosystems compared with a natural, undisturbed state.[27] Five of the listed substances are active ingredients in pharmaceuticals sold in Sweden.

The UWWTD entered into force on 1 January 2025. Efforts to incorporate its provisions into Swedish law are ongoing and must be completed by 31 July 2027. The directive is part of the EU's Zero Pollution Action Plan for air, water and soil, and includes mandatory requirements for advanced treatment of nitrogen and micropollutants at wastewater treatment plants. The removal of micropollutants is to be financed through producer responsibility for pharmaceutical and cosmetics manufacturers. The directive specifies that emissions of a number of substances from wastewater treatment plants must be monitored. Substances listed in Category 1 are those that can be treated very easily in wastewater treatment plants. These substances are broken down biologically or chemically during treatment and no longer pose a risk when the water is discharged. Substances listed in Category 2 are those that can be easily removed. [28] These substances are separated from the wastewater and collected in sludge or filtered out using advanced techniques such as membrane filtration or activated carbon. The substance must then be managed further—often as hazardous waste or through specialized sludge handling.

A number of pharmaceutical substances are included in the European Commission's proposal for an updated Priority Substances Directive.[29] The proposal aims to update EU water legislation by revising the lists of priority substances that pose risks to the aquatic environment. It entails new and existing pollutants—including several pharmaceutical substances—and establishes stricter environmental quality standards for surface water and groundwater in order to strengthen the protection of human health and ecosystems.

[26] Sveriges miljömål, Läkemedel i miljön

[27] Regulation HVMFS 2019:25

[28] DIRECTIVE (EU) 2024/3019 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[29] COM/2022/540 final (version available summer of 2025)

Amendments may be made to the directive, meaning that some substances may be removed and others added.

2.4 Environmental bonus

The Swedish eHealth Agency, the Dental and Pharmaceutical Benefits Agency (TLV), and the Swedish Medical Products Agency have, on behalf of the Government, developed a proposal for a pilot scheme introducing an environmental bonus within the pharmaceutical benefits system. The environmental bonus is intended to function so that pharmaceutical companies may voluntarily apply for the bonus, and if the pharmaceutical meets the established environmental criteria, the company receives an additional reimbursement per package sold. The aim is to create incentives for environmentally sustainable pharmaceutical production. The pilot scheme covers three groups of pharmaceuticals: antibiotics, sex hormones, and nonsteroidal anti-inflammatory drugs (NSAIDs).[30]

2.5 Pharmacist-Only Category

The Swedish Medical Products Agency has, on assignment from the Government, investigated the introduction of a new category of pharmaceuticals in Sweden, a pharmacist-only category. This refers to non-prescription pharmaceuticals that may only be sold following counselling by a pharmacist. According to the Agency's proposal, a pharmaceutical should be eligible for classification in the pharmacist-only category based on three criteria relating to patient safety, public and animal health, and the environment.[31]

Environmental considerations are currently not included in the benefit–risk assessment when medicinal products for human use are approved for sale. Environmental aspects are also not taken into account when assessing whether a pharmaceutical for human use may be sold without a prescription. Introducing a pharmacist-only category, in which the pharmacist provides information and counselling before a potential purchase, would make it easier for pharmacy customers to make informed choices with regard to the criteria above.

[30] Swedish Medical Products Agency (2022); Swedish eHealth Agency (2022) Försöksverksamhet för en miljöpremie; Dental and Pharmaceutical Benefits Agency (2022); Swedish Medical Products Agency, Föreslår krav för att minska miljörisker vid läkemedelstillverkning

[31] Swedish Medical Products Agency (2024)

3 Method

The report is based on statistics produced from the sales data submitted to the Swedish eHealth Agency by pharmacies and other points of sale authorized to sell pharmaceuticals. The sales data are combined with information on the active substances in the relevant pharmaceutical products from the national product and article register (VARA)[32]. This makes it possible to calculate quantities of different pharmaceutical substances. The method is described in more detail in Annex 3 .

4 Results

To provide an overview, the ten most sold active pharmaceutical substances in 2024 are presented in section 4.1.

Section 4.2 presents, in alphabetical order, the active substances sold in Sweden since 2000 that are the main focus of this report. These are included in the SFÄ list, in the proposed Priority Substances Directive, and/or in the UWWTD.

4.1 Most Sold Active Pharmaceutical Substances in Sweden in 2024

The quantities sold of the ten most sold active pharmaceutical substances in 2024 are shown in Table 1 and Figure 3. Of these ten substances, ibuprofen is included in the proposed Priority Substances Directive; see section 4.2.12 for further details. The remaining substances are not included in the SFÄ list, the Priority Substances Directive, or the UWWTD.

[32] Swedish eHealth Agency, VARA – Produkt- och artikelregister

Table 1. Ten most sold active pharmaceutical substances in 2024, tonnes

Substance	CAS No.	Quantity sold 2024 (tonnes)
paracetamol	103-90-2	649
metformin hydrochloride	1115-70-4	204
cefuroxime sodium	56238-63-2	184
ibuprofen (base substance)	15687-27-1, 57469-82-6, 57469-76-8, 79261-49-7, 527688-20-6	141
acetylsalicylic acid	50-78-2	81
iohexol	66108-95-0	58
propylene glycol	57-55-6	40
mesalazine	89-57-6	38
gabapentin	60142-96-3	36
naproxen	22204-53-1	25

Below is a description of what these substances are used for.[33]

Paracetamol has been the most sold active pharmaceutical substance every year since 2009. In 2024, 649 tonnes of paracetamol were sold. Paracetamol is an analgesic and antipyretic that may also be sold outside pharmacies.

Metformin hydrochloride is primarily used to treat type 2 diabetes and was the second most sold active pharmaceutical substance in 2024, with a total of 204 tonnes. Sales have increased every year since 2000.

Cefuroxime sodium is an antibiotic used to treat various types of infections and was the most sold active pharmaceutical substance up until 2008. Between 2000 and 2005, 1,150–1,190 tonnes were sold annually. Sales then decreased sharply until 2014 and have since stabilized at around 180 tonnes annually. In 2024, 184 tonnes of cefuroxime sodium were sold.

Acetylsalicylic acid, iohexol, propylene glycol, mesalazine, gabapentin, and naproxen each had sales below 100 tonnes in 2024.

Acetylsalicylic acid is used to treat various types of pain and also has an antipyretic effect. It is one of the pharmaceuticals that may be sold outside pharmacies. The substance is also used as a blood-thinning agent by reducing the risk of blood clot formation. The dosage of the substance depends on the intended use.

[33] FASS

Iohexol is a substance used in contrast media for radiological examinations. It is administered before an examination to make the X-ray image clearer.

Propylene glycol is a humectant with mild antimicrobial properties. It is used in various products, such as creams, to treat dry skin.

Mesalazine is used to treat inflammatory bowel disease, such as ulcerative colitis. It is used both for treating flare-ups and as maintenance therapy. Pharmaceuticals containing mesalazine reduce inflammation in the intestine and alleviate painful symptoms.

Gabapentin is used to treat epilepsy and also to treat peripheral neuropathic pain, which is long-term pain caused by nerve damage.

Naproxen has anti-inflammatory, analgesic, and antipyretic effects and is used for various types of pain and inflammation. Naproxen is also used in acute cases of migraine.

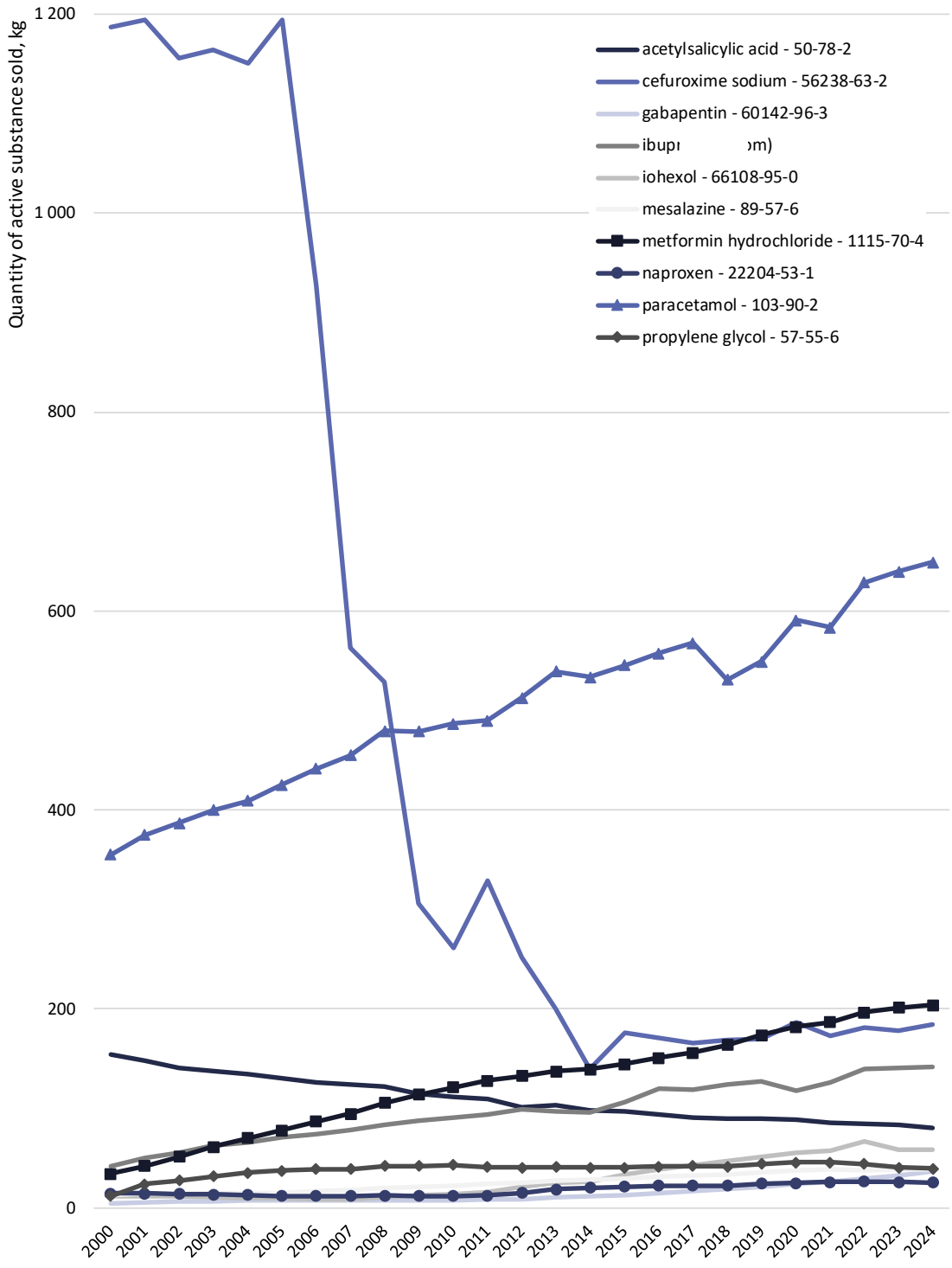

Figure 3. Quantities Sold 2000–2024 for the Ten Most Sold Active Pharmaceutical Substances in 2024.

4.2 Pharmaceutical Substances Included in the List of Specific Pollutants, the Priority Substances Directive, or the Urban Wastewater Treatment Directive

This section presents, in alphabetical order, the active pharmaceutical substances sold in Sweden since 2000 that are included in the SFÄ list, in the proposed Priority Substances Directive, and/or in the UWWTD. For each active pharmaceutical substance, the type of substance, its use, sales by sales channel and dosage form, and the most important known environmental effects when released into the environment are described.

4.2.1 Azithromycin

Azithromycin is an antibiotic belonging to the macrolide group (protein synthesis inhibitors). It is used to treat various bacterial infections, such as pneumonia, otitis media, skin infections, and certain sexually transmitted diseases.[34]

In 2024, 144 kg of the substance were sold (see Figure 4). Since 2000, sales have increased by 318 percent. In 2024, 89 percent of sales consisted of prescribed oral solid-form pharmaceuticals.

Azithromycin degrades slowly in the environment and is highly toxic to aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. The substance has been detected in Swedish wastewater treatment plants at concentrations that may contribute to antibiotic resistance.[35] Azithromycin can interact with other macrolide antibiotics in the environment, potentially amplifying its negative effects. It has previously been monitored under EU water legislation and is included in the proposal for an updated Priority Substances Directive.

[34] FASS

[35] Region Stockholm, Janusinfo, Läkemedel och miljö

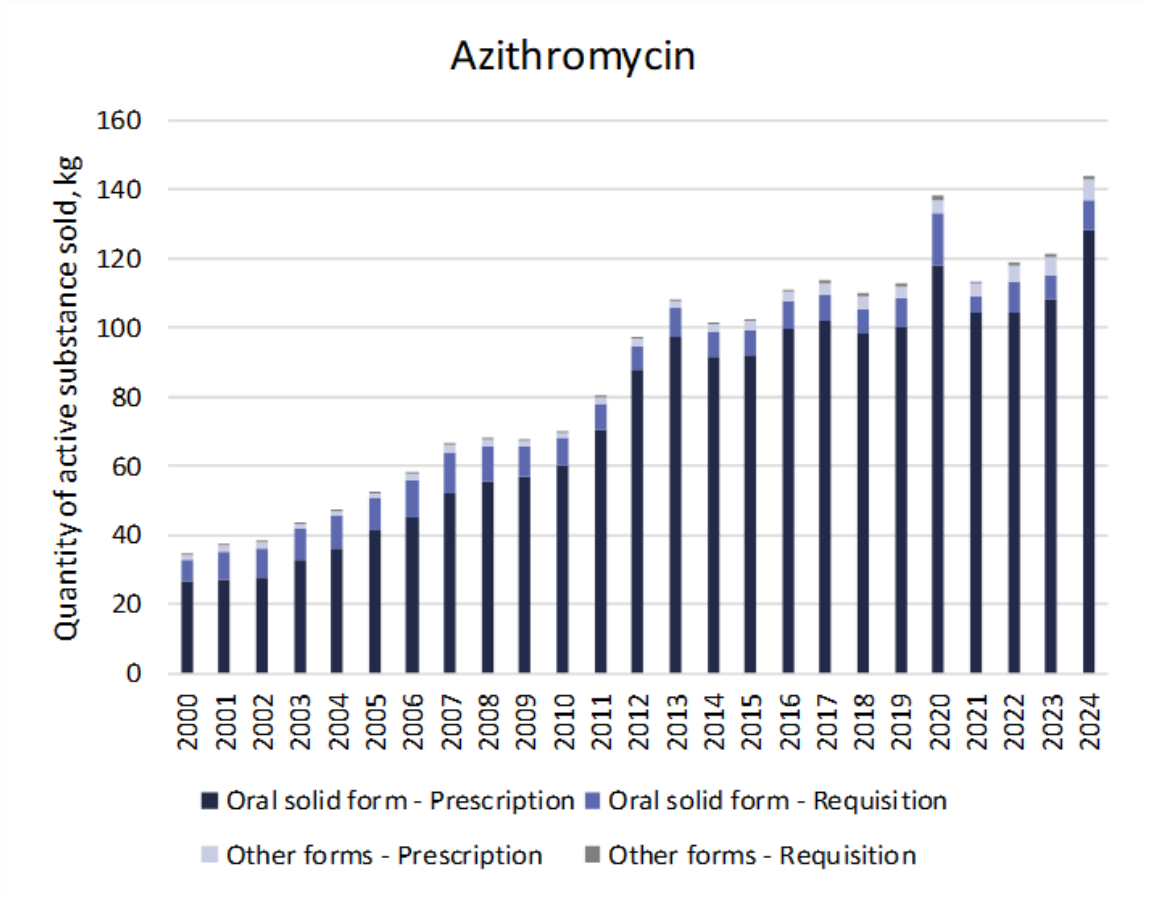

Figure 4. Quantity of azithromycin sold 2000–2024 by dosage form and sales channel.

4.2.2 Candesartan

Candesartan is an angiotensin II receptor blocker (ARB) used to treat high blood pressure (hypertension) and heart failure. It is used both as monotherapy and in combination with other antihypertensive pharmaceuticals. It is particularly useful for patients who do not tolerate antihypertensive medicines of the ACE inhibitor type.[36]

In 2024, 2,060 kg of the substance were sold (see Figure 5). Since 2000, sales have increased by 3,100 percent. Virtually all sales consist of prescribed oral pharmaceuticals in solid form.

[36] FASS

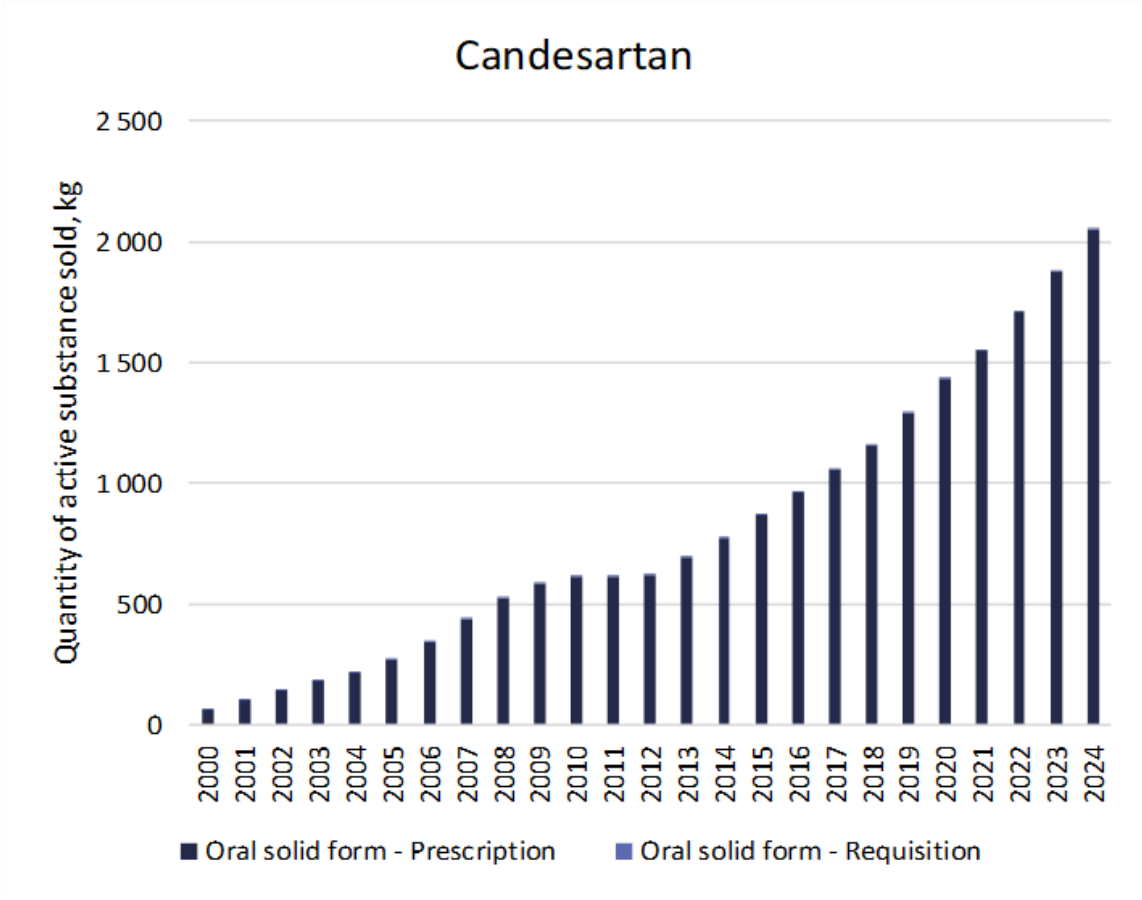

Figure 5 Quantity of candesartan sold 2000–2024 by dosage form and sales channel.

Candesartan is persistent, meaning that it degrades very slowly in the environment. It has moderate chronic toxicity, particularly for aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time.[37]

The presence of the substance must be monitored at wastewater treatment plants in accordance with the UWWTD.

4.2.3 Carbamazepine

Carbamazepine is an antiepileptic medicine. It is used to treat various forms of epilepsy, but also trigeminal neuralgia — a type of severe facial pain — as well as alcohol withdrawal to prevent seizures.[38]

[37] Region Stockholm, Janusinfo, Läkemedel och miljö

[38] FASS

In 2024, 3,784 kg of the substance were sold (see Figure 6). Since 2000, sales have decreased by 52 percent. In 2024, 97 percent of sales consisted of prescribed oral pharmaceuticals in solid form.

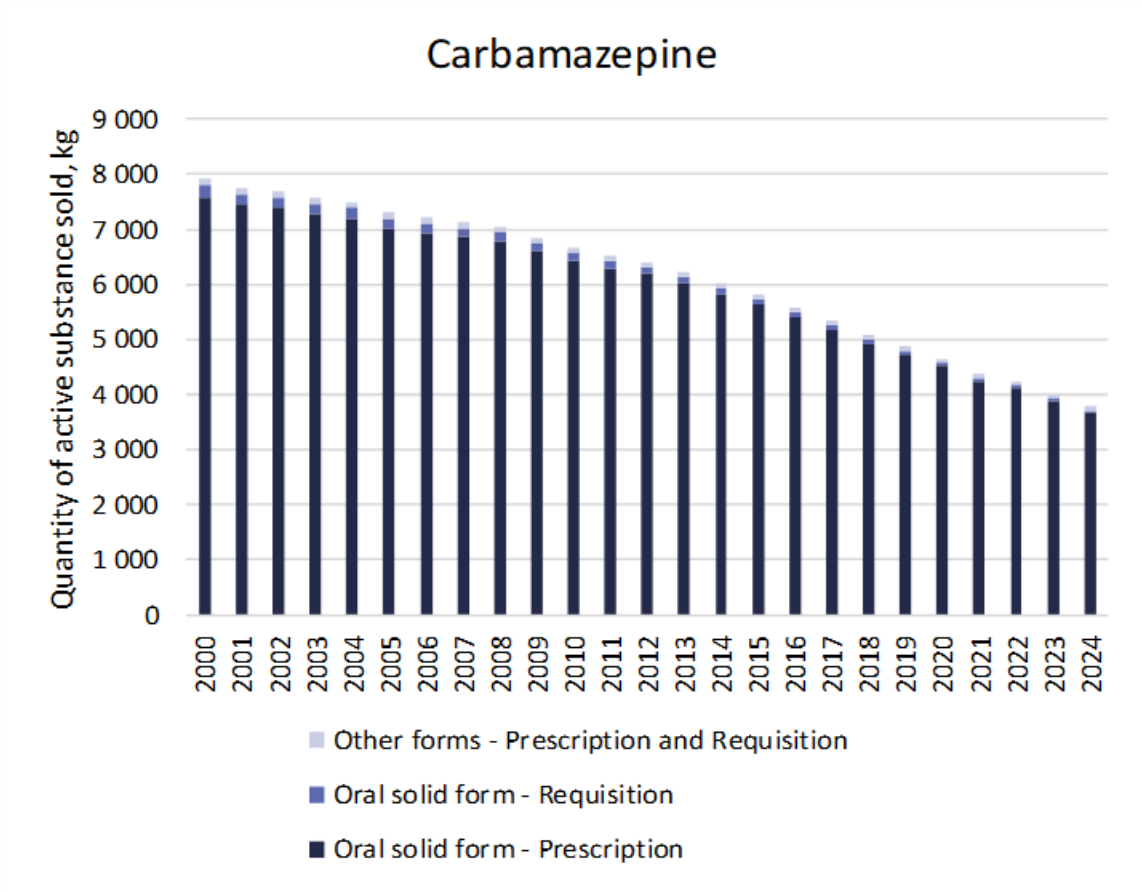

Figure 6 Quantity of carbamazepine sold 2000–2024 by dosage form and sales channel.

Carbamazepine is persistent, meaning that it degrades very slowly in the environment. It is also highly toxic to aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. The substance has been detected in treated wastewater, surface waters and drinking water in Sweden.[39]

The presence of the substance must be monitored at wastewater treatment plants in accordance with the UWWTD. It is also included in the proposal for an updated Priority Substances Directive.

[39] Region Stockholm, Janusinfo, Läkemedel och miljö

4.2.4 Ciprofloxacin

Ciprofloxacin is a broad-spectrum antibiotic in the quinolone group, used for urinary tract infections, respiratory tract infections, and gastrointestinal infections, among others. Broad-spectrum antibiotics should be used with caution due to the risk of resistance and side effects.[40]

In 2024, 2,268 kg of the substance were sold (see Figure 7). Since 2000, sales have increased by 32 percent. In 2024, 80 percent of sales consisted of prescribed oral solid-form pharmaceuticals.

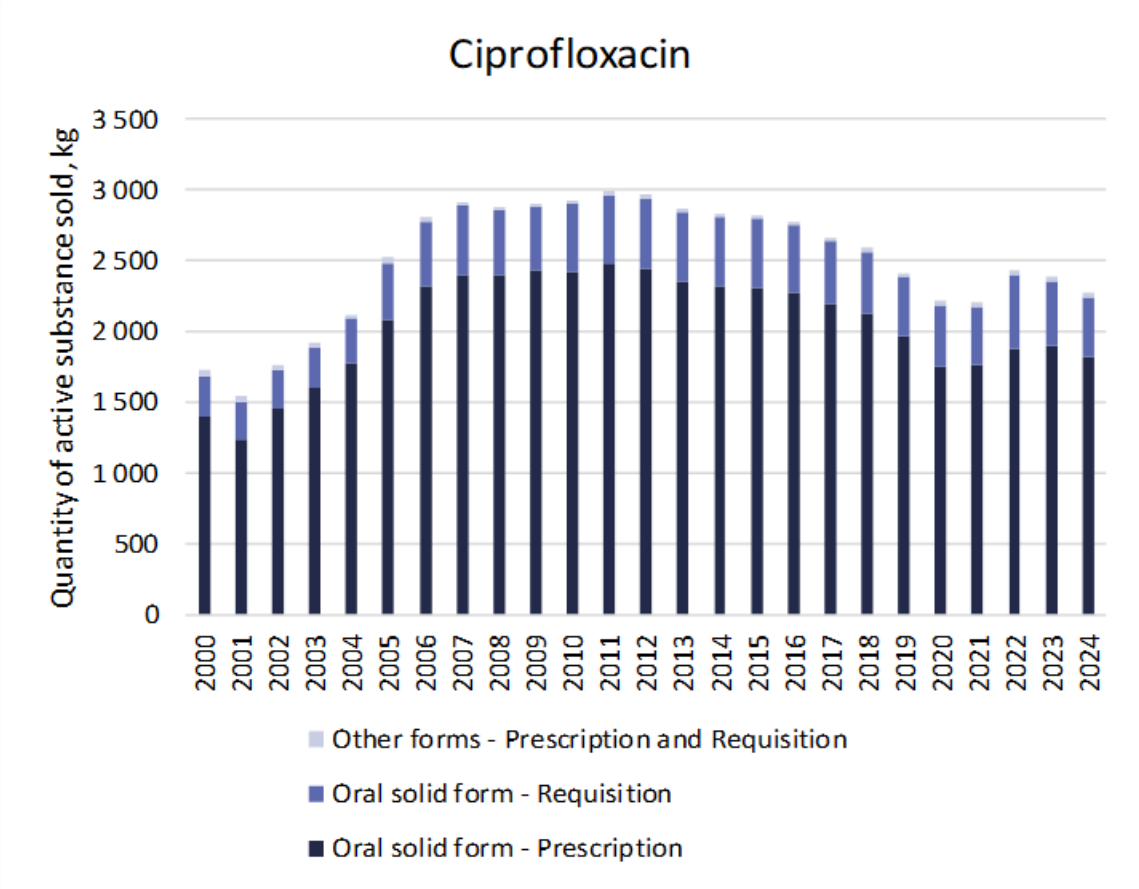

Figure 7 Quantity of ciprofloxacin sold 2000–2024 by dosage form and sales channel.

Ciprofloxacin degrades slowly in the environment and has very high chronic toxicity, particularly for aquatic organisms. It accumulates only to a limited extent in the body or

[40] FASS; The Swedish Medical Products Agency, Läkemedelsboken, Antibiotikaresistens, ABR; Läkemedelsvärlden 2023-05-15

in living organisms over time. Ciprofloxacin is found in Swedish wastewater treatment plants at concentrations that pose a risk for the development of resistant bacteria. The substance has also been detected in treated wastewater.[41]

Ciprofloxacin has been monitored under EU water legislation and is included in the nationally developed SFÄ list.

4.2.5 Citalopram

Citalopram is an antidepressant belonging to the group of selective serotonin reuptake inhibitors (SSRIs). It is used primarily for the treatment of depression, but also for panic disorder and obsessive-compulsive disorder.[42]

In 2024, 706 kg of the substance were sold (see Figure 8). Since 2000, sales have decreased by 42 percent. In 2024, 80 percent of sales consisted of prescribed oral solid-form pharmaceuticals.

[41] Region Stockholm, Janusinfo, Läkemedel och miljö

[42] FASS; Region Stockholm, Kloka listan

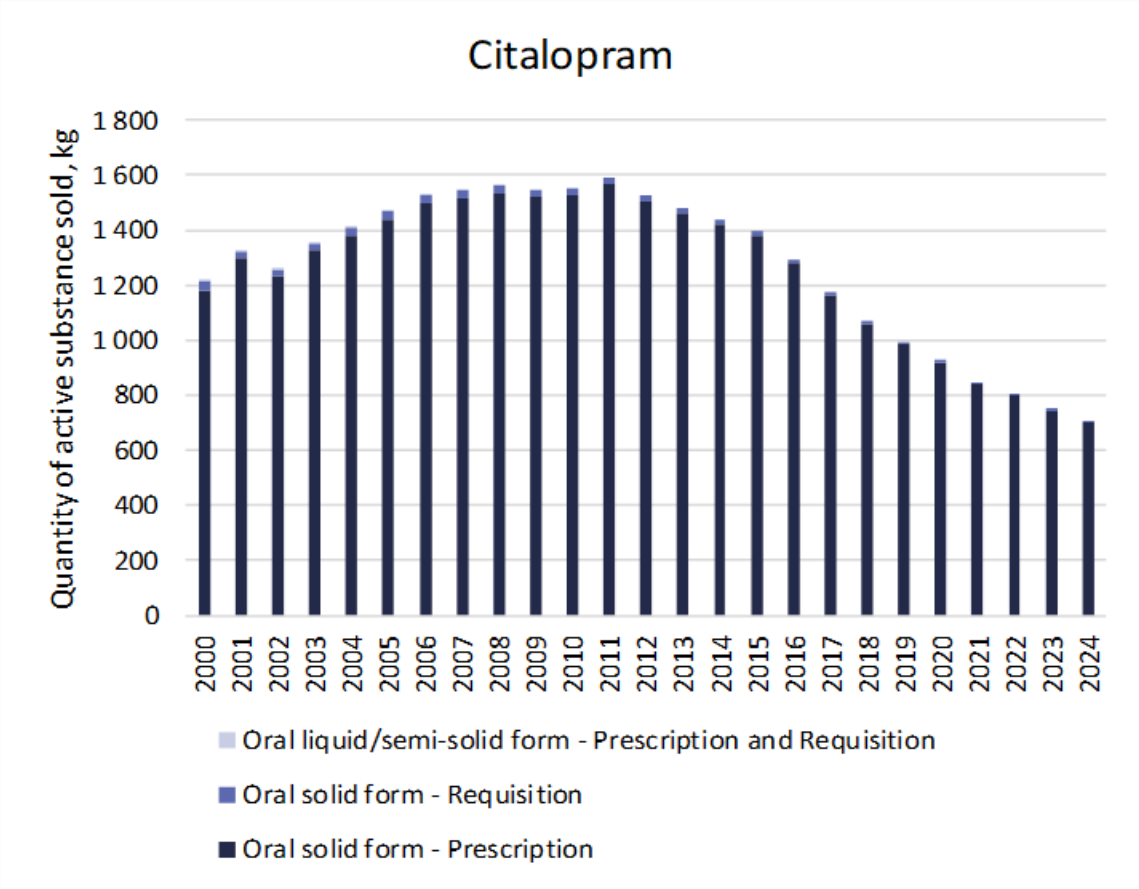

Figure 8. Quantity of citalopram sold 2000–2024 by dosage form and sales channel.

It cannot be ruled out that citalopram is persistent—that is, that it degrades very slowly and remains in the environment for a long time—due to a lack of data. Citalopram is highly toxic, particularly to aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. Citalopram has been detected in treated wastewater and surface waters in Sweden. In fish exposed to treated wastewater, concentrations of citalopram corresponding to therapeutic levels in humans have been measured.[43] Fish exposed to SSRI substances may become less sensitive to stress, which can lead to high-risk behavior. The presence of the substance must be monitored at wastewater treatment plants in accordance with the UWWTD.

[43] Region Stockholm, Janusinfo, Läkemedel och miljö

4.2.6 Clarithromycin

Clarithromycin is an antibiotic belonging to the macrolide group (protein synthesis inhibitors). It is used to treat various bacterial infections, such as respiratory tract infections, sinusitis, tonsillitis, and skin and soft-tissue infections. The substance is also used in combination with other medicines to treat helicobacter pylori infection in peptic ulcer disease.[44]

In 2024, 245 kg of the substance were sold (see Figure 9). Since 2000, sales have increased by 38 percent. In 2024, 91 percent of sales consisted of prescribed oral pharmaceuticals in solid form.

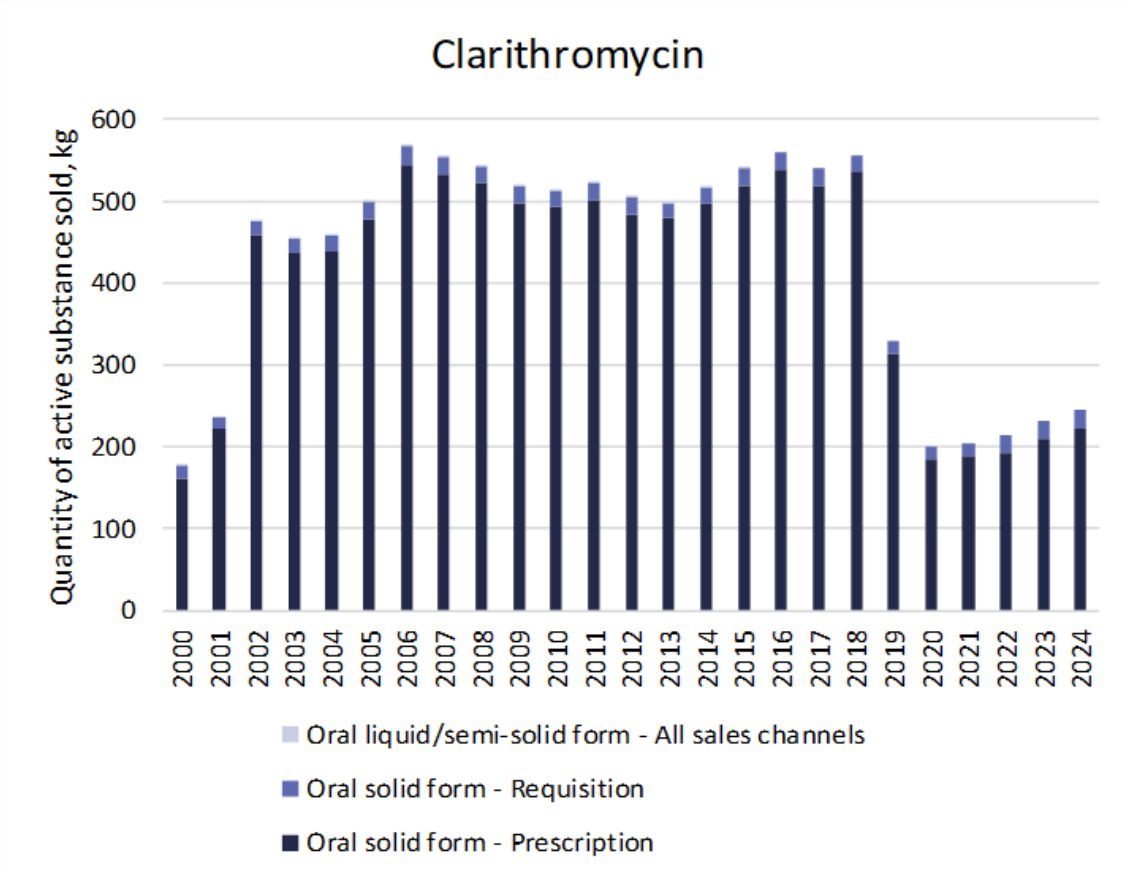

Figure 9 Quantity of clarithromycin sold 2000–2024 by dosage form and sales channel.

Clarithromycin degrades very slowly in the environment. It is highly toxic to aquatic organisms but accumulates only to a limited extent in the body or in living organisms

[44] FASS; The Swedish Medical Products Agency, Läkemedelsboken, Helicobacter pyroli-infektion

over time. The substance has been detected in treated wastewater in Sweden. Even low concentrations of antibiotics in the environment can contribute to the development of antibiotic resistance.[45]

Clarithromycin is included on the EU list of substances whose concentrations in groundwater are considered important to monitor. The presence of the substance must be measured at wastewater treatment plants in accordance with the UWWTD. It is also included in the proposal for an updated Priority Substances Directive.

4.2.7 Diclofenac

Diclofenac belongs to the group of NSAIDs and has analgesic and anti-inflammatory properties. It is used to treat various types of pain and inflammation.[46]

Some pharmaceuticals containing diclofenac require a prescription or requisition to be sold. There are also non-prescription diclofenac products in gel form that are sold as self-care pharmaceuticals in pharmacies and through other points of sale such as grocery stores and kiosks.

In 2024, 2,003 kg of the substance were sold (see Figure 10). Since 2000, sales have decreased by 28 percent. OTC sales of diclofenac were permitted from 2005 and increased until 2016, after which they stabilized. In 2024, 67 percent of sales consisted of self-care sales.

Diclofenac degrades slowly in the environment and is highly toxic to aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. The substance is difficult to remove in wastewater treatment plants, which means it remains in effluent water at levels high enough to potentially affect the environment.[47] Diclofenac is included in the SFÄ list as well as in the proposal for an updated Priority Substances Directive. The presence of diclofenac must be measured in effluent water at wastewater treatment plants in accordance with the UWWTD.

[45] Region Stockholm, Janusinfo, Läkemedel och miljö

[46] FASS

[47] Region Stockholm, Janusinfo, Läkemedel och miljö

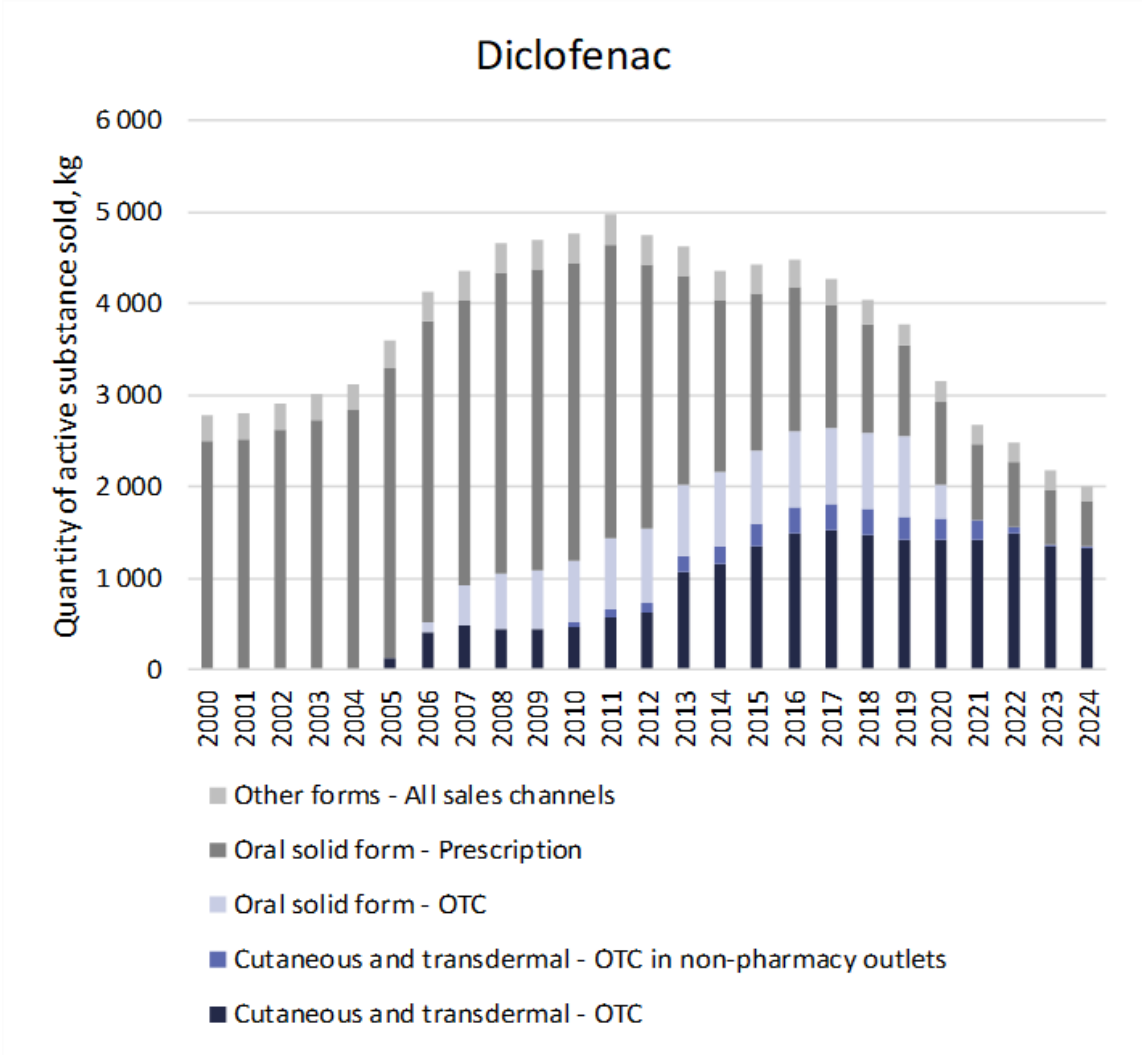

Figure 10 Quantity of diclofenac sold 2000–2024 by dosage form and sales channel.

A pharmaceutical taken orally is partially metabolized in the body. A substance applied to the skin, however, is not broken down in the body to the same extent. A larger proportion is released unchanged into the environment, often via wastewater when an individual showers or washes textiles that have been in direct contact with diclofenac-containing gel. The diclofenac gels sold OTC do not have the same side-effect profile as oral preparations such as tablets, but they can cause serious environmental problems in the way described above. Because a physician's prescription is often not involved for OTC medicines, it cannot be guaranteed that all use of diclofenac gels is medically justified.

4.2.8 Erythromycin

Erythromycin is a broad-spectrum antibiotic belonging to the macrolide group (protein synthesis inhibitors) and is used to treat various bacterial infections. It can be used to treat infections of the respiratory tract, skin, ears, eyes, stomach and intestines, as well as certain sexually transmitted infections.[48] Erythromycin interacts with several other medicinal products, which is important to consider during treatment.

In 2024, 213 kg of the substance were sold (see Figure 11). Since 2000, sales have decreased by 89 percent. In 2024, 62 percent of sales consisted of prescribed oral pharmaceuticals in liquid or semi-solid form.

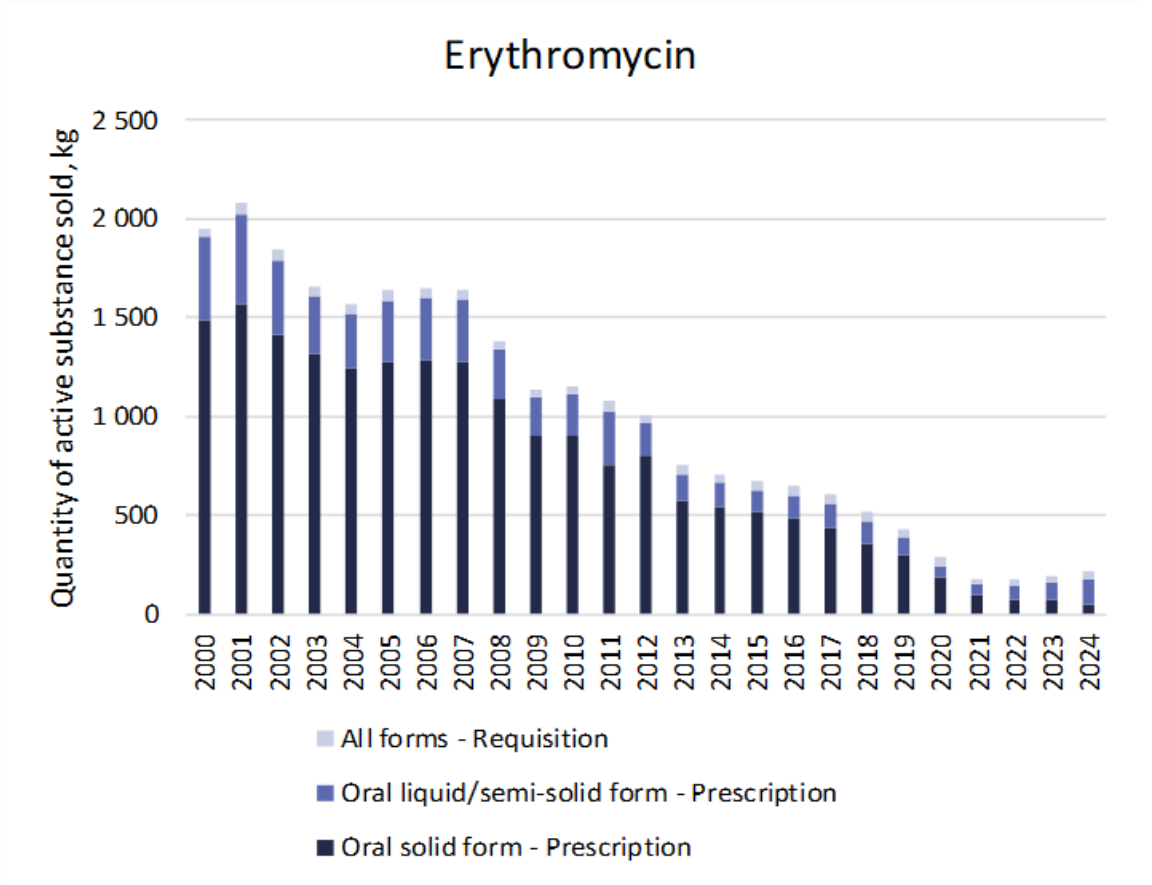

Figure 11 Quantity of erythromycin sold 2000–2024 by dosage form and sales channel.

Erythromycin is potentially persistent, meaning that it degrades slowly in the environment. It is highly toxic, particularly to aquatic organisms. It accumulates only to a

[48] FASS

limited extent in the body or in living organisms over time. The substance has been detected in treated wastewater and sewage sludge in Sweden. Even low concentrations of antibiotics in the environment can contribute to the development of antibiotic resistance, and therefore as little as possible should be released into the environment. Erythromycin has previously been monitored under EU water legislation.[49] The substance is included in the proposal for an updated Priority Substances Directive.

4.2.9 Estradiol

Estradiol is a naturally occurring estrogen. The substance is used primarily in hormone replacement therapy (HRT) to relieve menopausal symptoms. It is also used, among other things, to prevent osteoporosis in postmenopausal women.[50]

In 2024, 75 kg of the substance were sold (see Figure 12). Since 2000, sales have decreased by 51 percent. In 2024, 46 percent of sales consisted of patches, gels or sprays, with sprays dominating. The proportion of pharmaceuticals applied via the skin has increased every year since 2019.

Estradiol degrades slowly in the environment and has very high chronic toxicity, meaning it is highly toxic under long-term exposure. It accumulates only to a limited extent in the body or in living organisms over time. When estradiol is released into the environment, there is a risk of disrupted sexual development and impaired reproductive capacity in fish, amphibians and other aquatic organisms.[51]

[49] Region Stockholm, Janusinfo, Läkemedel och miljö

[50] FASS

[51] Region Stockholm, Janusinfo, Läkemedel och miljö

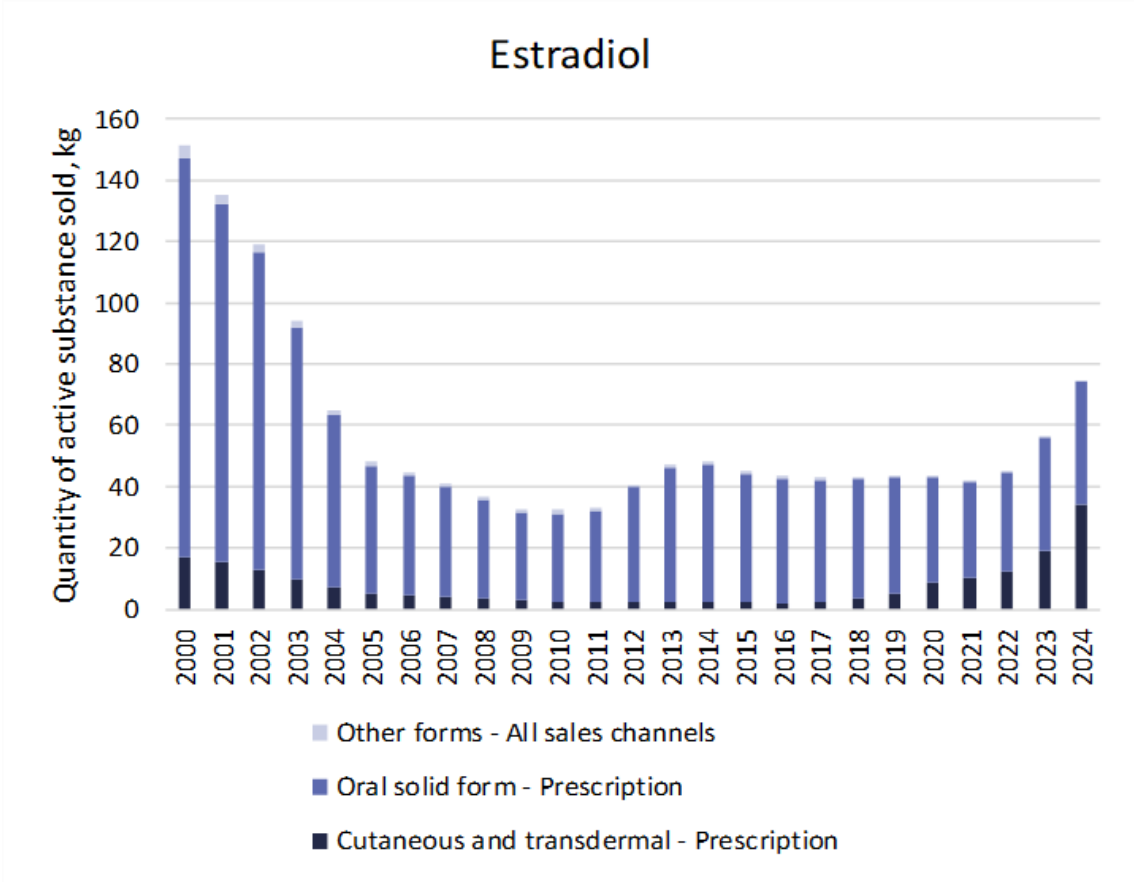

Figure 12 Quantity of estradiol sold 2000–2024 by dosage form and sales channel.

A pharmaceutical taken orally is partially metabolized in the body. A substance in a pharmaceutical applied to the skin, however, is not broken down in the body to the same extent; instead, a large proportion is released unchanged into the environment, often via wastewater when an individual has showered or washed clothing that has been in contact with the gel. Topical formulations containing estradiol pose a higher risk of environmental impact than oral estradiol pharmaceuticals. Hormone treatment applied to the skin may also affect children, animals and other adults who come into close contact with the treated individual or with waste such as used patches (Figure 13).[52]

The substance is included in the SFÄ list as well as in the proposal for an updated Priority Substances Directive.

[52] Dagens Nyheter 2024-11-29

Figure 13. Pets can be affected by hormonal pharmaceuticals applied to human skin.

4.2.10 Ethinylestradiol

Ethinylestradiol is a synthetic estrogen used in many combined hormonal contraceptives, such as oral contraceptive pills, transdermal patches and vaginal rings. In addition to contraceptives, ethinylestradiol is also used in various other pharmaceuticals.[53]

In 2024, 3 kg of the substance were sold (see Figure 14). Since 2000, sales have decreased by 45 percent. In 2024, 86 percent of sales consisted of prescribed oral pharmaceuticals, and 11 percent consisted of prescribed vaginal pharmaceuticals.

[53] FASS

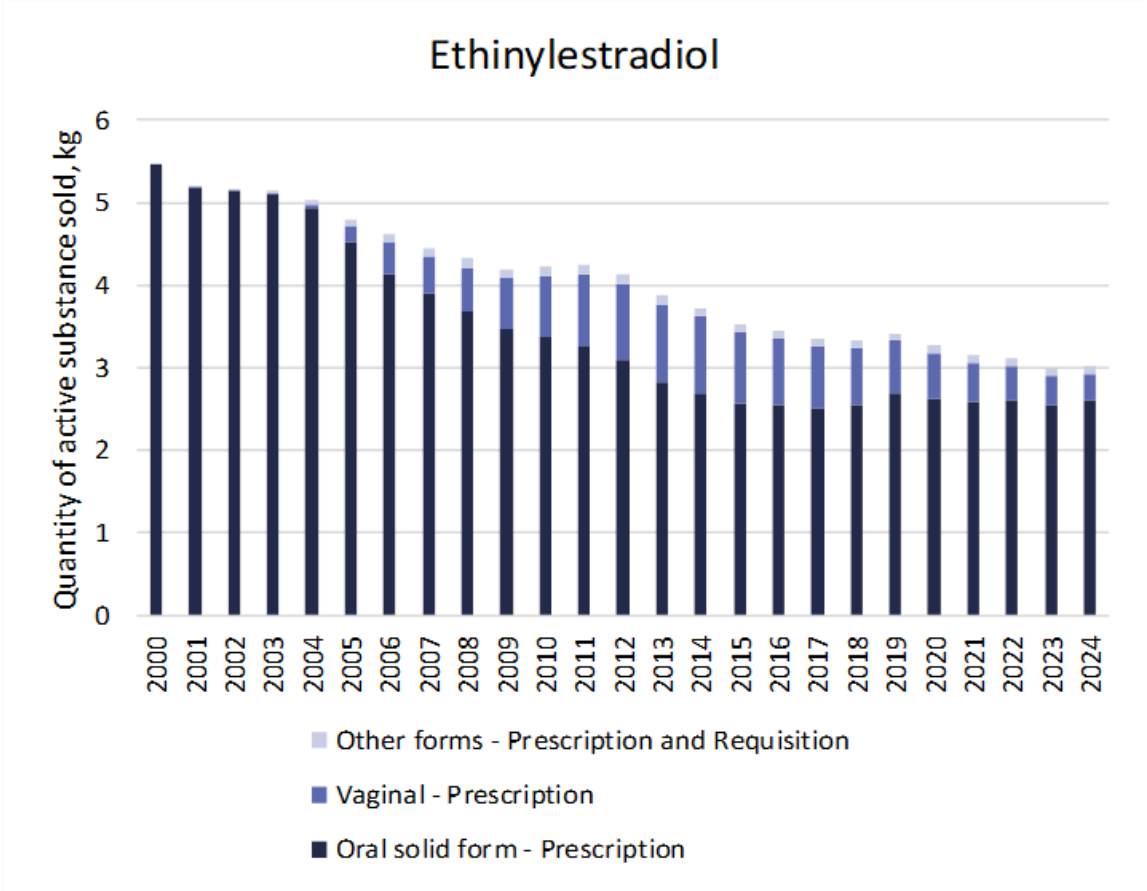

Figure 14 Quantity of ethinylestradiol sold 2000–2024 by dosage form and sales channel.

Ethinylestradiol is difficult for the body to break down, and a large proportion of the substance that is ingested leaves the body unchanged and enters the wastewater system. The substance degrades slowly in the environment, which means it can persist for a long time. When ethinylestradiol is released into the environment, there is a risk that it may cause disrupted sexual development and impaired reproductive capacity in fish, amphibians and other aquatic organisms. It has high chronic toxicity and accumulates readily in aquatic organisms over time, increasing the risk of long-term impacts on ecosystems. Estimated concentrations in Swedish watercourses have shown levels of ethinylestradiol that in some cases are high enough to affect reproduction and sexual development in fish.[54] The substance is included in the SFÄ list as well as in the proposal for an updated Priority Substances Directive.

[54] Region Stockholm, Janusinfo, Läkemedel och miljö

4.2.11 Hydrochlorothiazide

Hydrochlorothiazide is a diuretic (a fluid-reducing pharmaceutical) belonging to the group of thiazide diuretics. It is used primarily to treat high blood pressure (hypertension) and oedema, which is fluid retention in the body that may occur in heart failure, kidney disease or liver disease. Hydrochlorothiazide is often used in combination with other antihypertensive pharmaceuticals.[55]

In 2024, 2,406 kg of the substance were sold (see Figure 15). Between 2000 and 2024, sales increased by 61 percent, although the trend has been declining since 2011. Almost all sales consist of prescribed oral pharmaceuticals.

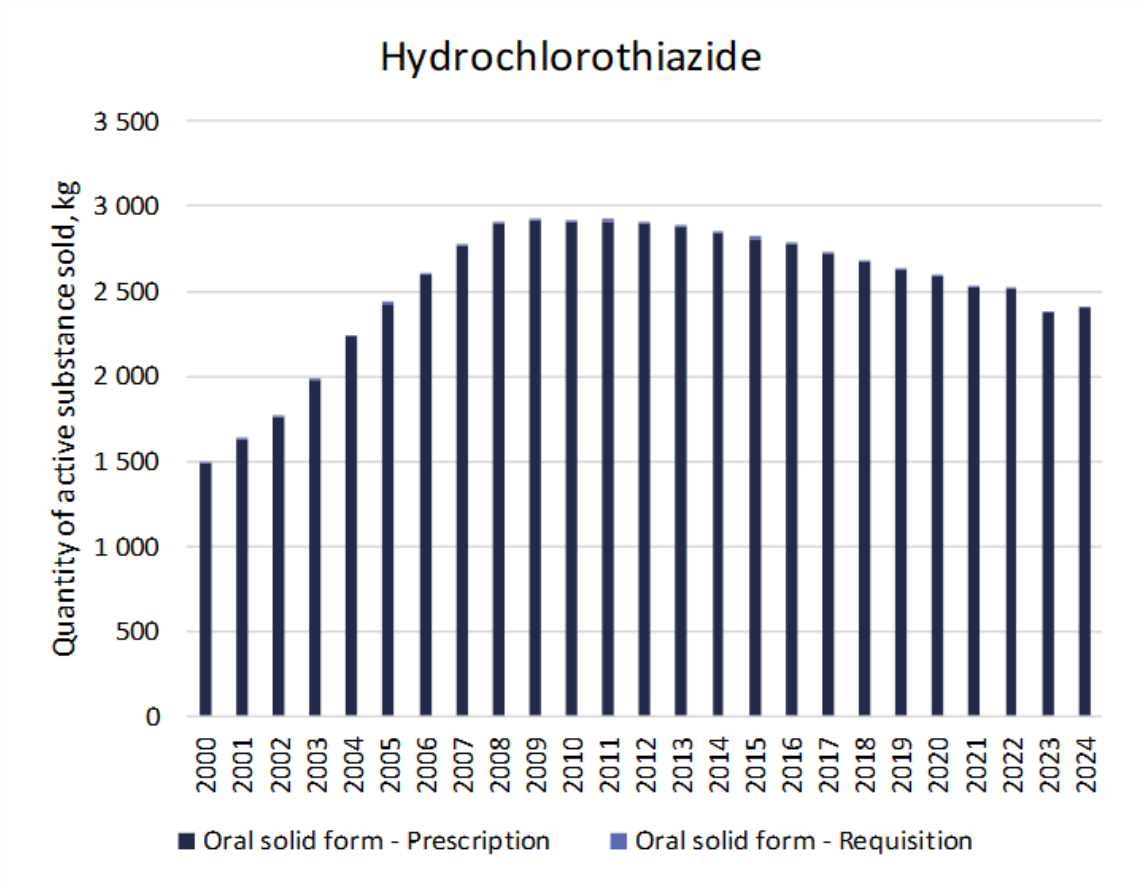

Figure 15 Quantity of hydrochlorothiazide sold 2000–2024 by dosage form and sales channel.

[55] FASS

Hydrochlorothiazide degrades slowly in the environment. It accumulates only to a limited extent in the body or in living organisms over time and has low chronic toxicity, meaning it has limited impact on aquatic organisms. Hydrochlorothiazide has been detected in the aquatic environment in the Stockholm Region.[56] The presence of the substance must be monitored at wastewater treatment plants in accordance with the UWWTD.

4.2.12 Ibuprofen

Ibuprofen is antipyretic, anti-inflammatory and analgesic, and belongs to the NSAID group. It is used for headaches, menstrual pain, toothache, muscle and joint pain, back pain, fever associated with colds, and inflammatory conditions such as osteoarthritis and rheumatism.[57]

In 2024, 141,207 kg of the substance were sold (see Figure 16). Since 2000, sales have increased by 235 percent. The majority of all ibuprofen is sold as self-care pharmaceuticals. In 2024, 61 percent of sales consisted of OTC self-care products sold in pharmacies, and 30 percent consisted of self-care products sold outside pharmacies.

[56] Region Stockholm, Janusinfo, Läkemedel och miljö

[57] FASS

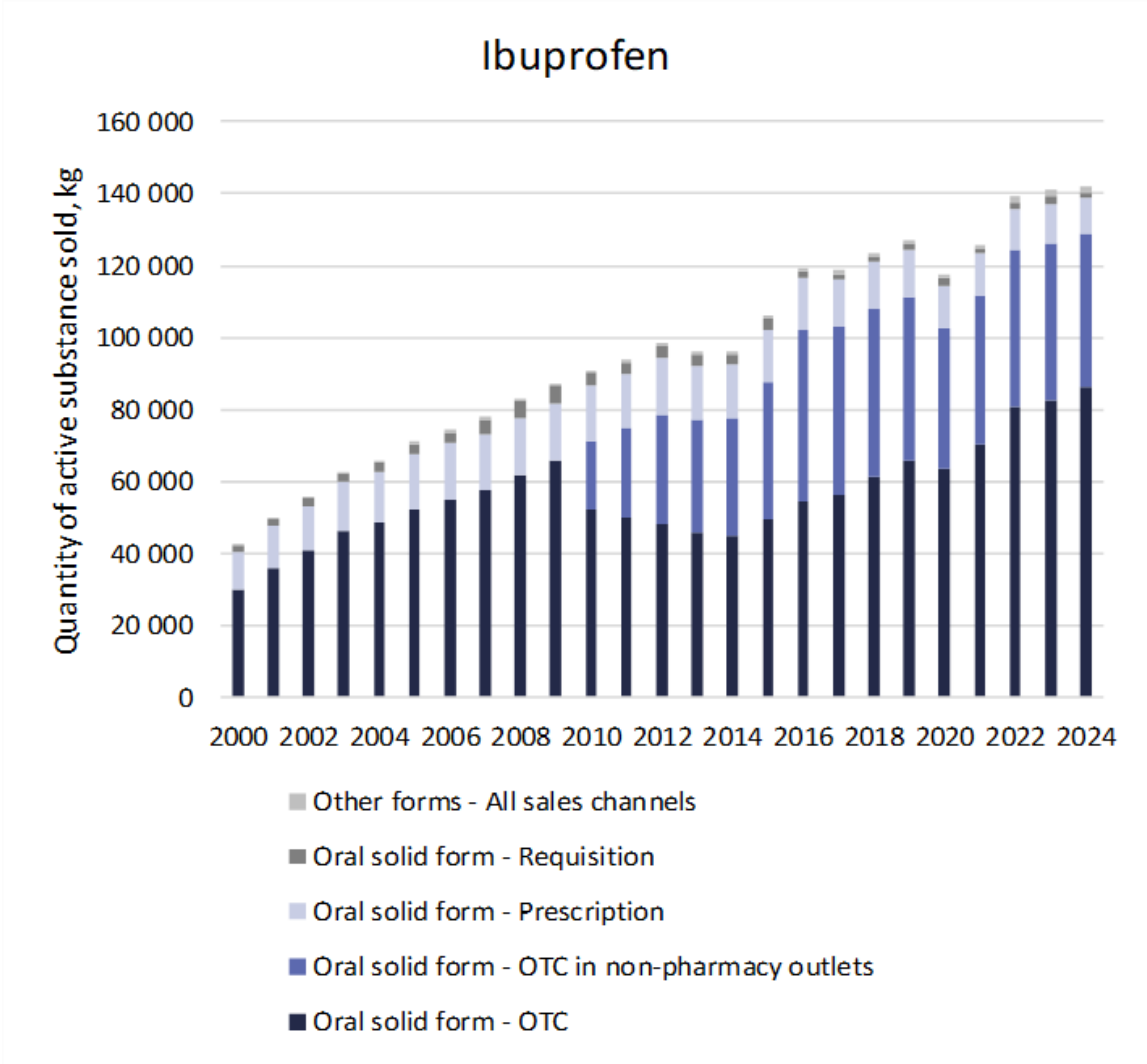

Figure 16 Quantity of ibuprofen sold 2000–2024 by dosage form and sales channel.

Ibuprofen degrades in the environment and has a low potential to accumulate in aquatic organisms. It is toxic to aquatic organisms such as algae and fish, and has been detected in surface water, treated wastewater and fish in Sweden. However, the concentrations found in fish have been low.[58]

Ibuprofen is included on the EU watch list of substances whose concentrations in groundwater are considered important to monitor in Member States for environmental reasons. The substance is also included in the proposal for an updated Priority Substances Directive.

[58] Region Stockholm, Janusinfo, Läkemedel och miljö

4.2.13 Imidacloprid

Imidacloprid is a substance belonging to the group of neonicotinoids. It is used in veterinary pharmaceuticals and is effective against various types of parasites such as fleas, lice and ticks. Pharmaceuticals containing the substance are sold by prescription and requisition, as well as OTC medicines for veterinary use. Previously, the substance was only available as a spot-on solution, but since 2013 collars have also been sold, which have become the most common dosage form.[59]

In 2024, 128 kg of the substance were sold (see Figure 17).

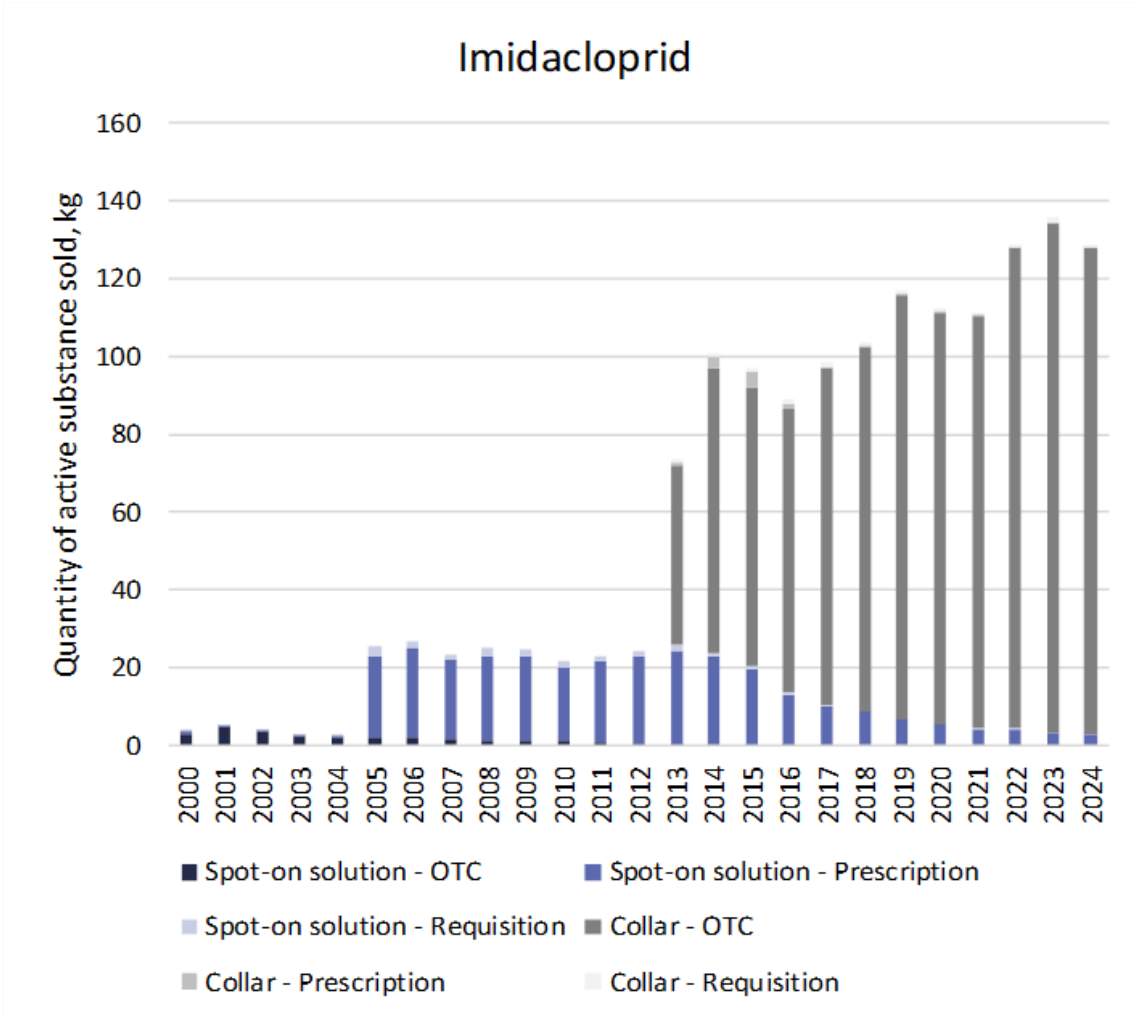

Figure 17 Quantity of imidacloprid sold 2000–2024 by dosage form and sales channel.

[59] FASS

Since 2000, sales have increased by 3,125 percent. In 2024, 97 percent of sales consisted of self-care veterinary pharmaceuticals.

Imidacloprid is classified as an insecticide and has been shown to be highly harmful to bees and other insects. As a result, the European Commission has banned its use as an outdoor plant protection product.[60] It is, however, still permitted for other uses. When used, imidacloprid spreads into the environment wherever the treated animal moves. Improved wastewater treatment is therefore not a solution for preventing the spread of imidacloprid in the environment. When the substance is released into the environment, insects living on land and in water are negatively affected.

A study from the University of Sussex has recently shown that birds are also affected by imidacloprid as they use animal fur to build their nests. The study found that when eggs are exposed through direct contact with insecticides such as imidacloprid in the nest, it can lead to increased mortality among the chicks (Figure 18).[61]

Figure 18. Blue tit eggs may be affected by imidacloprid from animal fur.

Imidacloprid is included in the SFÄ list developed by the Swedish Agency for Marine and Water Management.

[60] COMMISSION IMPLEMENTING REGULATION (EU) 2020/1643; Swedish Chemicals Agency, Neonikotinoider

[61] Tassin de Montaigu, C et al. (2025)

4.2.14 Irbesartan

Irbesartan is an angiotensin II receptor blocker (ARB) used primarily to treat high blood pressure in adults and to protect kidney function in patients with type 2 diabetes and concurrent hypertension. It may also reduce the risk of cardiovascular complications in these patients.[62]

In 2024, 1,175 kg of the substance were sold (see Figure 19). Since 2000, sales have increased by 63 percent, although sales have declined every year since 2009. Virtually all sales consist of prescribed oral pharmaceuticals in solid form.

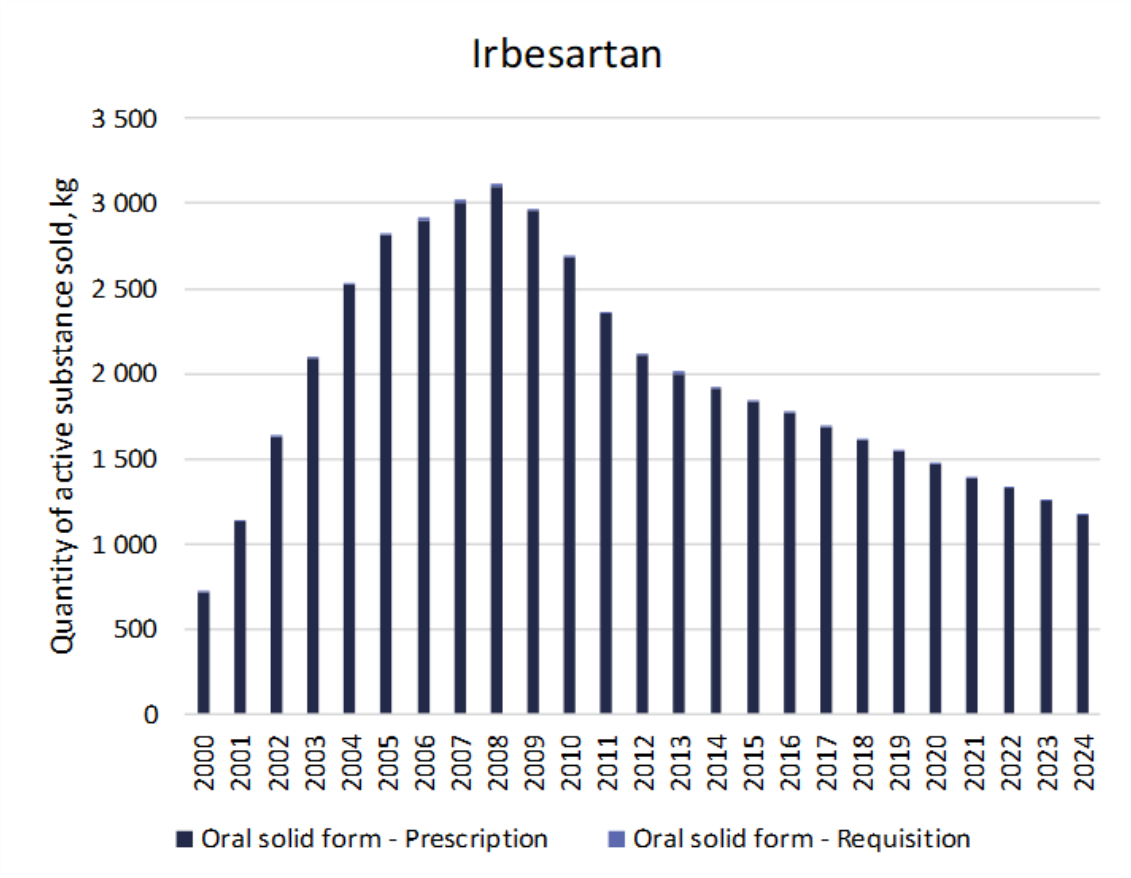

Figure 19 Quantity of irbesartan sold 2000–2024 by dosage form and sales channel.

Irbesartan degrades slowly in the environment and accumulates to a high degree in the body or in living organisms over time. It has low chronic toxicity. The substance has been

[62] FASS; The Swedish Medical Products Agency, Irbesartan Actavis

detected in treated wastewater and surface waters and may occur at concentrations that pose an environmental risk.[63]

The presence of the substance must be monitored at wastewater treatment plants in accordance with the UWWTD.

4.2.15 Metoprolol

Metoprolol is a beta-blocker used to treat several different cardiovascular conditions such as high blood pressure, angina pectoris, heart failure, arrhythmias, and as preventive treatment after myocardial infarction. Metoprolol can also be used to prevent migraine and to treat palpitations.[64]

In 2024, 10,985 kg of the substance were sold (see Figure 20). Since 2000, sales have increased by 60 percent. In 2024, 99 percent of sales consisted of prescribed oral pharmaceuticals in solid form.

[63] Region Stockholm, Janusinfo, Läkemedel och miljö

[64] FASS

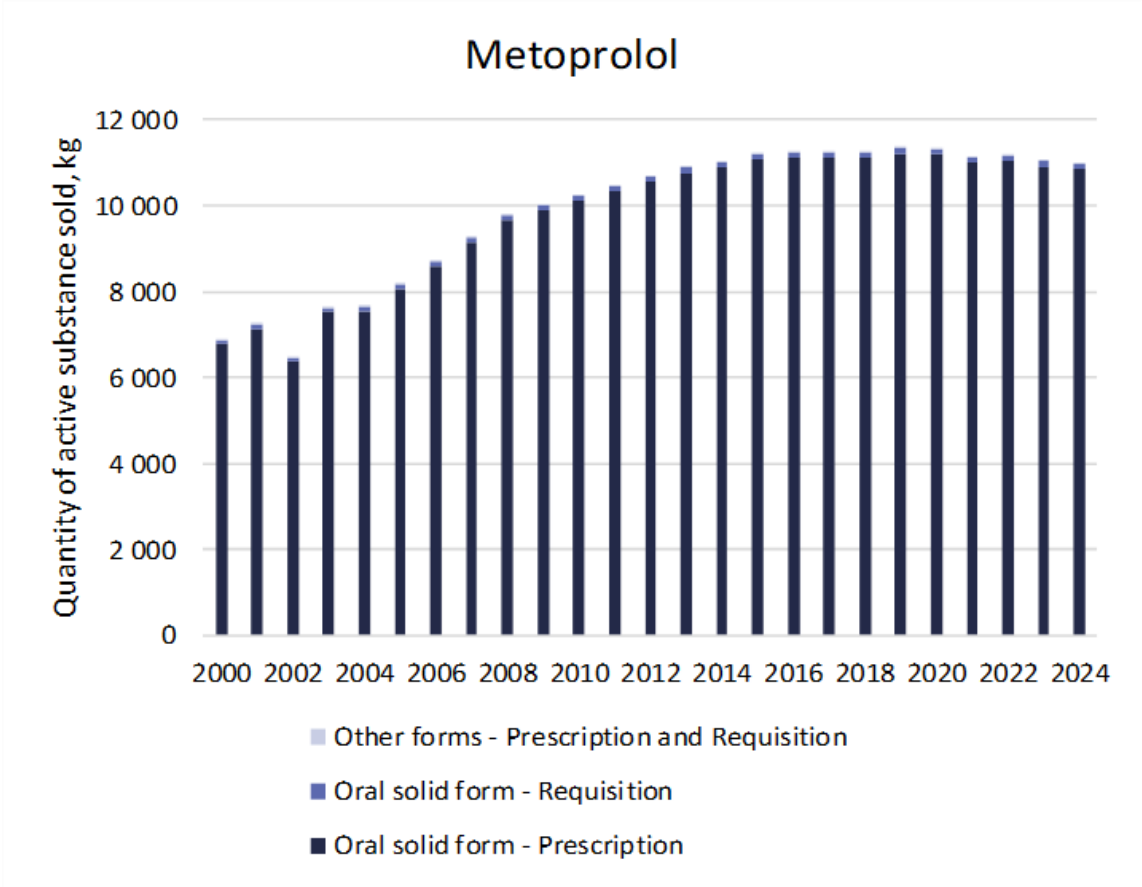

Figure 20 Quantity of metoprolol sold 2000–2024 by dosage form and sales channel.

Metoprolol degrades slowly in the environment. It has moderate acute toxicity, particularly for aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. The substance has been detected in wastewater, surface waters and drinking water in Sweden.[65] The presence of metoprolol must be monitored at wastewater treatment plants in accordance with the UWWTD.

4.2.16 Venlafaxine

Venlafaxine is an antidepressant belonging to the group of serotonin and norepinephrine reuptake inhibitors (SNRIs). It is used primarily to treat depression, generalized anxiety disorder (GAD), social anxiety disorder and panic disorder in adults.[66]

[65] Region Stockholm, Janusinfo, Läkemedel och miljö

[66] FASS

In 2024, 4,013 kg of the substance were sold (see Figure 21). Since 2000, sales have increased by 261 percent. In 2024, 99 percent of sales consisted of prescribed oral pharmaceuticals in solid form.

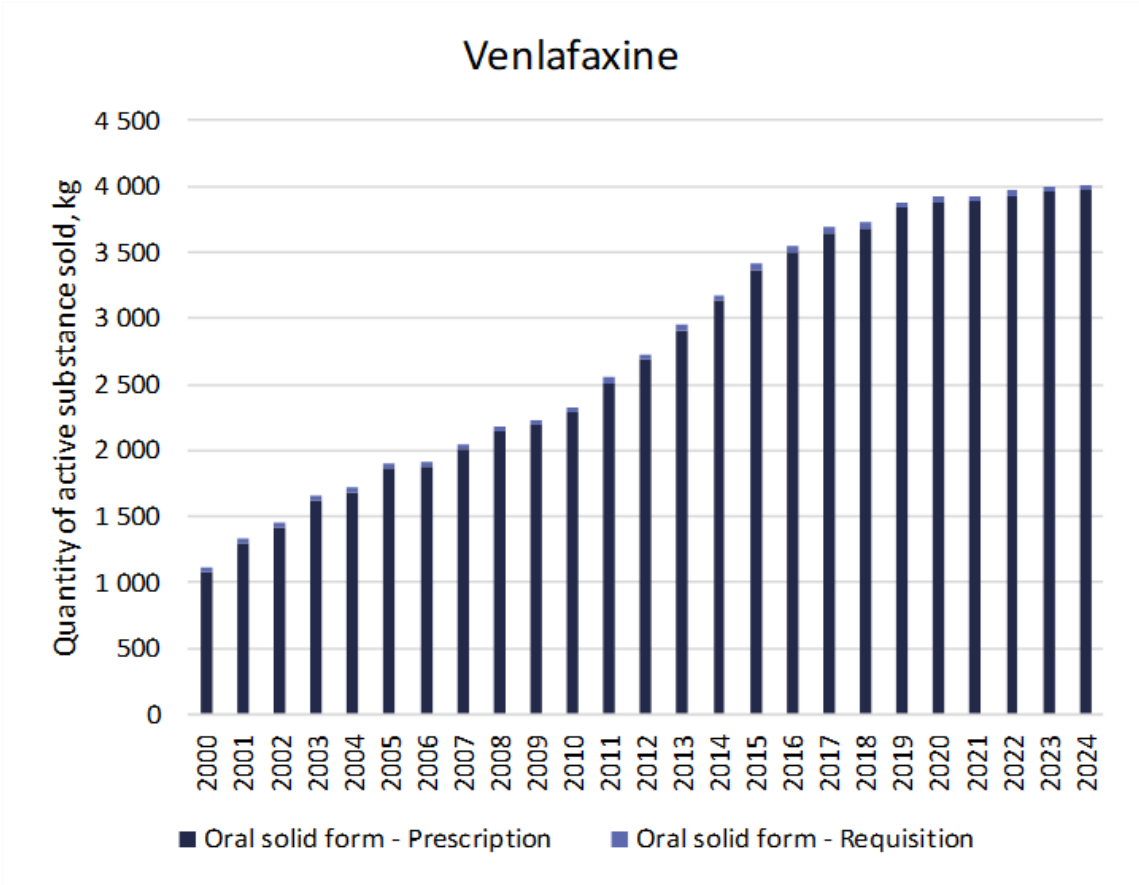

Figure 21 Quantity of venlafaxine sold 2000–2024 by dosage form and sales channel.

Venlafaxine degrades slowly in the environment and has high acute toxicity, particularly for aquatic organisms. It accumulates only to a limited extent in the body or in living organisms over time. The substance has been detected in treated wastewater, surface waters and fish in Sweden, and may affect the behavior and reproduction of aquatic organisms.[67] Venlafaxine is monitored in accordance with EU water legislation, and the presence of the substance must be measured at wastewater treatment plants in accordance with the UWWTD.

[67] Region Stockholm, Janusinfo, Läkemedel och miljö

5 Conclusions

The general consideration rules in Chapter 2 of the Environmental Code theoretically apply to all activities. In practice, however, other regulatory frameworks govern the pharmaceutical sector, which means that the principles of the Environmental Code do not always have full effect.[68] Knowledge about environmental impact is lacking for the vast majority of active pharmaceutical substances, which means that the precautionary principle should be applied in many cases. When possible, pharmaceuticals with known environmental risks should be replaced with pharmaceuticals that can be assumed to be less harmful to the environment.

Diclofenac, estradiol, ibuprofen and imidacloprid are sold as OTC medicines. When decisions are made about whether a pharmaceutical may be sold without a prescription, environmental aspects are currently taken into account for veterinary pharmaceuticals but not for medicinal products for human use.

Since March 2023, there has been an agreement within the pharmacy sector in Sweden to require mandatory counselling when selling non-prescription diclofenac, to ensure that customers receive information on when and how diclofenac should be used and what impact the substance has on nature.[69] However, this report shows that the agreement has not had any noticeable effect on the sales of non-prescription diclofenac during 2023 or 2024 (see Figure 10). Marketing by pharmaceutical manufacturers may provide misleading information about self-care treatment, and advertisements for diclofenac have, for example, been ruled against by the Information Review Board (IGN).[70]

The introduction of a pharmacist-selected assortment for OTC medicines, as proposed by the Medical Products Agency[71], may be one way to help pharmacy customers make informed choices, for example based on which self-care pharmaceuticals have known environmental risks. When prescribing pharmaceuticals via prescription or requisition, tools such as Kloka listan[72] can support environmentally sound choices while maintaining therapeutic benefit for the patient.

Antibiotics must be used rationally — only when needed and in the correct manner.[73] In Sweden, efforts to combat antibiotic resistance are highly prioritized, which is also

[68] Swedish Medical Products Agency, Miljöhänsyn i lagstiftning

[69] Dagens medicin 2023-02-28

[70] Läkemedelsvärlden 2025-06-30; Dagens medicin 2025-07-24

[71] Swedish Medical Products Agency (2024)

[72] Region Stockholm, Kloka listan

[73] Swedish Medical Products Agency, Läkemedelsboken, Antibiotikaresistens, ABR

reflected in the Swedish Strategy against Antimicrobial Resistance 2026–2035.[74] The Public Health Agency of Sweden and the Swedish Board of Agriculture have a joint mandate from the government to lead a national coordination function in the work against antibiotic resistance, in which several authorities (including the eHealth Agency) and organizations collaborate.[75] Sweden, like other Nordic countries, has low antibiotic use and low levels of resistance in an international perspective. At the same time, more serious forms of resistance are slowly but steadily increasing over time, also in Sweden.[76]

Antidepressant pharmaceutical substances of the SSRI/SNRI type, such as citalopram and venlafaxine, increase the levels of neurotransmitters in the brain, which affects the well-being of the individual taking the pharmaceutical. Residues of these pharmaceuticals that remain in treated wastewater can similarly affect the well-being of fish and other aquatic organisms, making them less sensitive to stress, which may lead to more high-risk behavior and an increased likelihood of, for example, being eaten by predatory fish.

The National Board of Health and Welfare has, on behalf of the government, developed national guidelines for menopausal symptoms.[77] These guidelines include recommendations for treatment with hormonal pharmaceuticals such as the oestrogens estradiol and ethinylestradiol. The national guidelines will help ensure that more women with menopausal symptoms receive the care they need, but will likely also lead to increased use of estradiol and ethinylestradiol.

The Environmental Code’s principle that the polluter pays for the measures required to remedy environmental damage is not fully applied in the pharmaceutical sector today. The UWWTD, which entered into force on 1 January 2025, includes mandatory requirements for advanced treatment of micropollutants at wastewater treatment plants. According to the directive, this treatment must be financed through extended producer responsibility for pharmaceutical and cosmetics producers. The directive therefore concludes that the polluter-pays principle will also apply to pharmaceuticals. Several pharmaceutical and cosmetics companies have filed lawsuits against the European Parliament and the Council of the European Union, demanding that all provisions related to extended producer responsibility be removed from Article 9 of the directive.[78] The outcome of these lawsuits, how producer responsibility under the directive will be

[74] Ministry of Health and Social Affairs (2025): Sveriges strategi mot antimikrobiell resistens 2026–2035

[75] Public Health Agency, Nationella samverkansfunktionen mot antibiotikaresistens

[76] Public Health Agency of Sweden and Swedish Veterinary Agency (SVA) (2025) Swedres-Svarm 2024

[77] National Board of Health and Welfare, Nationella riktlinjer 2025: Klimakteriebesvär

[78] EUR-Lex e.g. C/2025/2672 - C/2025/2687; Svenska dagbladet, 2025-07-21

applied, and how fees related to pharmaceuticals will be designed, had not been determined at the time this report was written.

EU pharmaceutical legislation is currently undergoing a revision aimed at better meeting patient needs, maintaining the EU's competitiveness and supporting innovation. It is the first major revision of EU pharmaceutical legislation since 2004. Under the proposed new rules, companies seeking to place pharmaceuticals on the market may be required to conduct environmental risk assessments and implement risk-mitigation measures. The package also includes a recommendation to intensify efforts to combat antibiotic resistance.[79]

Pharmaceuticals are developed to produce an effect. An effect that is positive for the treated individual — and the very reason the pharmaceutical exists — can become a negative effect and a risk in another part of the ecosystem, with far-reaching consequences. Much remains to be done to reduce the environmental impact from the manufacturing and use of pharmaceuticals. Knowledge about environmental effects is lacking for the vast majority of active pharmaceutical substances, which complicates more coordinated and evidence-based development. The Swedish eHealth Agency contributes to knowledge dissemination by producing statistics related to pharmaceutical sales available and by analyzing them. These statistics and analyses will continue to be developed in future reports on pharmaceutical substances with potential environmental impact.

[79] European Council, Council of the European Union, The pharma package: new EU rules on medicines; Pharmazeutische zeitung 2024-04-10

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Annex 1 Reported substances

The report covers substances included in the nationally developed list of SFÄ, listed in the UWWTD and/or included in the proposed updated Priority Substances Directive as of the summer 2025:

Table 2. Pharmaceutical substances included in the nationally developed list of SFÄ, listed in the UWWTD and/or included in the proposed updated Priority Substances Directive.

Base substance	Substance	CAS number	List/Directive
Azithromycin (anhydrous)	azithromycin (dihydrate)	117772-70-0	Priority Substances Directive
	azithromycin (monohydrate)	121470-24-4	
	azithromycin (anhydrous)	83905-01-5	
Candesartan	Candesartan	139481-59-7	UWWTD, category 2
	candesartan cilexetil	145040-37-5	
Carbamazepine	Carbamazepine	298-46-4	Priority Substances Directive, UWWTD category 1
Ciprofloxacin	Ciprofloxacin	85721-33-1	SFÄ
	ciprofloxacin hydrochloride (monohydrate)	86393-32-0	
	ciprofloxacin hydrochloride (anhydrous)	93107-08-5	
	ciprofloxacin lactate	97867-33-9	
	ciprofloxacin hydrogen sulfate	853268-20-9	
Citalopram	Citalopram	59729-33-8	UWWTD, category 1
	citalopram hydrobromide	59729-32-7	
	citalopram hydrochloride	85118-27-0	
Clarithromycin	Clarithromycin	81103-11-9	Priority Substances Directive, UWWTD category 1
Diclofenac	Diclofenac	15307-86-5	SFÄ, Priority Substances Directive, UWWTD category 1
	diclofenac diethylamine	78213-16-8	
	diclofenac epolamine	119623-66-4	
	diclofenac potassium	15307-81-0	
	diclofenac sodium	15307-79-6	
Erythromycin	Erythromycin	114-07-8	Priority Substances Directive
	erythromycin ethylsuccinate	1264-62-6	
	erythromycin lactobionate	3847-29-8	
	erythromycin propionate	134-36-1	
	erythromycin stearate	643-22-1	
Estradiol	Estradiol	50-28-2	SFÄ, Priority Substances Directive
	estradiol acetate	4245-41-4	
	estradiol hemihydrate	35380-71-3	
	estradiol valerate	979-32-8	
	polyestradiol phosphate	28014-46-2	

Base substance	Substance	CAS number	List/Directive
Ethinylestradiol	Ethinylestradiol	57-63-6	SFÄ, Priority Substances Directive
	ethinylestradiol betadex		
Hydrochlorothiazide	Hydrochlorothiazide	58-93-5	UWWTD, category 1
Ibuprofen	Ibuprofen	15687-27-1	Priority Substances Directive
	ibuprofen arginine	57469-82-6	
	ibuprofen-D,L-lysine	57469-76-8	
	ibuprofen potassium	79261-49-7	
	ibuprofen sodium dihydrate	527688-20-6	
Imidacloprid	Imidacloprid	138261-41-3	SFÄ
Irbesartan	Irbesartan	138402-11-6	UWWTD, category 2
	irbesartan hydrochloride (anhydrous)	329055-23-4	
	irbesartan hydrochloride sesquihydrate	874657-02-0	
Metoprolol	Metoprolol	51384-51-1	UWWTD category 1
	metoprolol succinate	98418-47-4	
	metoprolol tartrate	56392-17-7	
Venlafaxine	Venlafaxine	93413-69-5	UWWTD category 1
	venlafaxine hydrochloride	99300-78-4	

Annex 2 Concepts

Active substance: The chemical compound(s) in a pharmaceutical that produce the intended therapeutic effect.

Antibiotic resistance: When bacteria develop resistance to antibiotics. This means that antibiotics can no longer be used to treat infections caused by these bacteria.

ATC: Anatomical Therapeutic Chemical Classification, a system for classifying pharmaceuticals established by the WHO.[80]

Base substance: The fundamental form of an active substance, without salts or similar components.

Bioaccumulation: A substance accumulates in an organism (animal or plant) over time. This occurs when the organism absorbs the substance faster than it can be broken down or excreted, causing the concentration of the substance in the organism to increase.

Chronic toxicity: When adverse health effects occur after long-term or repeated exposure to a substance, often with delayed and potentially irreversible consequences.

Cutaneous and transdermal pharmaceuticals: Cutaneous pharmaceuticals are applied to the skin and act locally, while transdermal pharmaceuticals are absorbed through the skin to act systemically throughout the body.

Geographic region: The geographic classification varies depending on the sales channel:

- **Prescription**: The Region in which the patient who collected the pharmaceutical is registered as a resident.
- **Requisition**: The geographic location of the dispensing point (pharmacy) or the hospital, depending on whether the requisition concerns outpatient or inpatient care.
- **Self-care:** The geographic location of the dispensing point.

Oral pharmaceuticals: Pharmaceuticals administered via the mouth.

Persistent: Resistant to degradation; the substance breaks down very slowly in the environment.

Pharmaceutical formulation: The form in which a pharmaceutical is prepared to be taken or administered to a patient, for example tablet, capsule, or ointment.

[80] WHO, Anatomical Therapeutic Chemical (ATC) Classification

Prescription: Sales of pharmaceuticals to a private individual based on a prescription (e-prescription, dose prescription, or traditional paper prescription). May include both OTC and prescription-only pharmaceuticals.

Requisition: Sales in pharmacies to healthcare providers in outpatient or inpatient care, or to another customer who is not a private individual.

Resistant bacteria: Bacteria that have developed resistance to antibiotics, making infections caused by them more difficult or impossible to treat with commonly used pharmaceuticals/antibiotics. This resistance arises when bacteria are exposed to antibiotics and adapt to survive.

Sales channel: The way in which the pharmaceutical has been sold. Pharmaceuticals may be sold by prescription, by requisition, or as self-care pharmaceuticals.

Self-care: Sales of pharmaceuticals to private individuals in pharmacies or outside pharmacies where no customer information is registered at the time of sale.

SSRI: Selective serotonin reuptake inhibitors, a type of antidepressant pharmaceutical.

Therapeutic levels: A concentration level of a pharmaceutical/active substance corresponding to the dose administered to a patient for the pharmaceutical to have an effect.

Vaginal pharmaceuticals: Pharmaceuticals administered into the vagina.

Annex 3 Method for the compiled statistics

Data collection

The eHealth Agency's sales databases (FOTA, FOTAOTC) have been used as data sources for quantities of pharmaceuticals sold.

All pharmaceutical sales transactions that take place in Sweden are included in the statistical dataset. Pharmacies and other outlets that sell pharmaceuticals are legally obligated to report their sales to the eHealth Agency. Data collection is largely automated, as sales transactions are generated in pharmacy cash register systems and sent directly to the Agency.

Retailers notify the Medical Products Agency when they intend to sell certain OTC pharmaceuticals. They then receive a statutory obligation to report data to the eHealth Agency. For sales outside pharmacies, data collection takes place monthly through manual reporting to the Agency via web form or file.

Requisition sales—pharmaceuticals sold to healthcare providers via pharmacies—must also be reported to the eHealth Agency. In cases where a Region has taken over the management of a pharmaceutical supply, reporting is not required. However, since 2022 requisition sales have been included for all Regions.

Data processing

Total sales for each pharmaceutical are obtained from FOTA for sales in pharmacies and FOTAOTC for sales outside pharmacies.

The quantity of pharmaceutical substance for all pharmaceuticals sold in Sweden is obtained from the national product and article register (VARA) [81]. In VARA, the following component types are registered for each pharmaceutical:

- **Active component**: the active substance in a pharmaceutical, in pure form or conjugated with a respondent (the base substance may need to be linked to a molecule to be practically usable in a pharmaceutical preparation).
- **Adjuvant**: enhances the effect of another pharmaceutical or treatment. Adjuvants occur, for example, in vaccines where they increase the immune system's ability to produce antibodies.

[81] Swedish eHealth Agency, VARA – Produkt- och artikelregister

- **Conjugate to active**: a substance conjugated to an antigen in a vaccine to strengthen the immune response.
- **Excipient**: a substance in a pharmaceutical added, for example, to facilitate absorption in the body and to simplify its practical use, identification, and manufacturing.
- **Equivalent active (respondent)**: base substance for an active substance. For some substances, several different base substances are specified, which makes this variable difficult to use in the statistics.
- **Equivalent adjuvant**: the effective amount of adjuvant that the actually used chemical compound corresponds to.

The component type Active component is included in the statistics.

The total quantity of substance is calculated for each substance, substance role, and pharmaceutical as:

Total quantity of substance =
[quantity of substance per unit according to VARA] ×
[number of units sold according to FOTA/FOTAOTC]

This is included in the statistics

Active components from the following types of pharmaceuticals are included in the reported statistics:

- Pharmaceuticals sold in pharmacies through the sales channels self-care, prescription, and requisition for outpatient/inpatient care.
- Pharmaceuticals sold outside pharmacies (OTC).
- Pharmaceuticals for humans and animals.
- Pharmaceuticals where the active substance can be reported in kilograms.

This is not included in the statistics

The following types of components are not included:

- Adjuvant and conjugate to active (occurs only in biological medicines)
- Excipient
- Equivalent active (respondent) and equivalent adjuvant are not included, to avoid double counting.

Active components from the following types of pharmaceuticals are not included:

- Medicines which, for certain reasons specified in the European Medicines Agency's guidelines for environmental risk assessment of medicinal products for human use[82], do not need to proceed to Phase II assessment:
    - Herbal medicines
    - Traditional herbal medicines
    - Natural remedies
    - Biological medicines
    - Naturally occurring substances such as vitamins, electrolytes, amino acids, peptides, proteins, nucleotides, carbohydrates, lipids
    - Vaccines without adjuvant
- Medicines where the active substance is reported in another SI unit than grams (e.g. IU, mol) are not included. (This accounts for approximately 1 percent of pharmaceuticals in Sweden, calculated as the number of entries in VARA.)
- Coccidiostats. These agents against protozoa (ATC code QP51A) are administered as feed additives to commercially raised broiler chickens and turkeys to prevent coccidiosis. The feed is not distributed via pharmacies. For information on these feed additives, see the Swedish Board of Agriculture's report Sales of veterinary medicines.[83]

Reporting

The statistics cover the reference years 2000–2024.

The statistics are reported in kilograms per pharmaceutical substance and CAS number[84]. Substances that are also presented by geographic region in the statistics database (see Table 2) are reported as kilograms of base substance, i.e. without salts, water molecules

[82] European Medicines Agency, EMEA/CHMP/SWP/4447/00 Rev. 1

[83] Swedish Board of Agriculture (2024)

[84] Chemical Abstracts Service number, international identification number for chemical substances. CAS registry

or similar components. This approach is used to minimize confidentiality issues and to make the results as useful as possible.

The statistics published in the database include more than 1,600 different active pharmaceutical substances. For most of these substances, knowledge of environmental impact is limited. Therefore, no classification has been made based on potential environmental risks of the reported substances, and the statistics also include substances that may have negligible environmental impact.

Table symbol "..": This symbol indicates either a zero value or that the value is not reported because of the risk of disclosing individual information, as the underlying data are protected by confidentiality under Chapter 24, Section 8 of the Public Access to Information and Secrecy Act (2009:400).

Negative values: For a small number of substances, negative values are reported for a single year. This phenomenon may occur when a previously reported quantity has been corrected by the reporting entity. Negative values should therefore always be assessed together with the values for other years for the same substance.

Uncertainties

Quality control of the sales data at the eHealth Agency includes validations and checks of prohibited values and combinations of values. The coverage and quality of the data is considered to be very good.

For prescribed pharmaceuticals and pharmacies' sales data for medicines sold as self-care, the reporting rate is high and the statistics are of good quality. However, errors in individual variables may occur.

For OTC medicines (self-care) sold outside pharmacies, the non-reporting rate is 10–15 percent. This proportion is calculated based on the number of vendors that reported data for at least one month per quarter, which may mean that they reported for one, two or three months, since it is possible to report all months of a quarter in a single file. In the data received, partial non-reporting is considered to occur, in other words that not all medicines sold are reported from the vendor. The results for these data should be interpreted with this in mind.

Annex 4 History of the compiled statistics

2025-06-03: Statistics for years 2000–2024 published, including revision of statistics for years 2015–2023. Addition of reporting of substances according to the UWWTD and the proposed Priority Substances Directive, by base substance, point of sale, sales channel and geographic region.

2024-10-04: Revision of the method for improved relevance and higher quality. Addition of pharmaceuticals sold outside pharmacies. Addition of CAS numbers. SFÄ recalculated to base substance. Reporting of SFÄ by base substance, point of sale, sales channel and geographic region. Clarified documentation regarding exclusion of pharmaceuticals in animal feed.

2024-06-17: Revision of the model for improved relevance and higher quality. First publication in the eHealth Agency’s statistics database for reference years 2015–2023.

2022: The first version of the model was developed.