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Välvald

Swedish Pharmacy Association/SA Service AB
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Sveriges Apoteksförening

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Q&A
Välvald – Pharmacies' Guide for Greater Transparency

1 Basic questions about Välvald

1.1 What is Välvald?

Välvald is the pharmacy sector's guide to which pharmaceutical companies are more transparent about their sustainability work and sets requirements for responsible manufacturing.
The aim is to guide those customers who want to make conscious choices to the pharmaceutical companies that satisfy our requirements for greater transparency. In the longer term we want to tighten the criteria, so that Välvald will promote more sustainable production of pharmaceuticals.

1.2 How can a customer see the Välvald symbol?

Those over- the-counter (PTC) products that satisfy the requirements in the guide have the Välvald symbol placed by their products at pharmacies. The symbol is placed next to the medicine on the shelf or next to the product in online sales.

1.3 Why have the pharmacies produced their own guide to more transparent pharmaceutical companies?

We know that there are major environmental problems linked to pharmaceutical production, but pharmaceutical companies are not required to openly provide information about their production. Consequently, we know little about how the medicines sold at pharmacies in Sweden are produced.

More and more pharmacy customers are asking questions about environment and sustainability, but because of the lack of transparency in the pharmaceutical industry, we cannot answer these questions. Today, there is no established environmental or

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sustainability labelling system for medicines, so we have chosen to launch Välvald, to help the customers make more considered choices.

1.4 What does the Välvald guide mean?

Those pharmaceutical companies that satisfy the requirements in the guide will have the Välvald symbol placed beside their products at pharmacies. Välvald guides you as customer to the companies that are more transparent and open about their sustainability work. The guide does not guarantee that the medicine in question is produced more sustainably than any other, because the pharmaceutical companies do not provide such information. The guide only shows which companies prepare an externally audited sustainability report and are members of the pharmaceutical industry's international organisation PSCI, which promotes greater transparency and sustainability in the supplier chain. In addition, the company demands that the manufacture of the medicine takes place with respect for human rights, workers' rights, the environment and free from corruption. Välvalds criteria are developed annually in line with customers' expectations and national / international work in progress.

1.5 Why does Välvald only apply to OTC medicines?

Pharmacies sell three categories of products: prescription-only medicines, OTC medicines, and other pharmacy retail goods. By law, all pharmacies must sell all prescription-only medicines. Here, the state should be able to impose requirements in connection with purchasing of medicines, but under current legislation, this is not possible. For retail goods, there are several established ecolabels, such as Good Environmental Choice (Bra Miljöval) and The Swan (Svanen).

1.6 What requirements must a pharmaceutical company satisfy?

Pharmaceutical companies with the **Välvald** symbol by their products satisfy four requirements:

- The company[1] must report its sustainability work according to the reporting framework, GRI Standards, or an equivalent standard. The sustainability report must be audited by an independent party.
- The company[2] must be a member of the PSCI sector organisation, which promotes transparency and common sustainability requirements for pharmaceutical manufacturers.
- The company shall require compliance with the principles of the PSCI or equivalent in the supply chain for the OTC products, ie. on manufacturing units and suppliers

[1] If the company is a subsidiary and does not prepare its own sustainability report, it must be included in the parent company's sustainability reporting, which must satisfy the requirement.
[2] If the company is a subsidiary, it is the parent company that is audited.

- The company shall answer questions regarding participation in PSCI´s work and the outcome of risk analyses for suppliers of PTC products.

Products containing diclofenac are exception from Välvald. Sweden's pharmacies have a sector agreement on shelf-displayed information about the possible negative effect of diclofenac on nature, and that the product should therefore be used with caution.

1.7 What do you want to achieve with the guide?

We want to promote more sustainable production of medicines. Using consumer power, we want to increase pressure on the pharmaceutical companies to ensure that their medicines are produced sustainably and transparently. 2022 about 350 products from fifteen pharmaceutical companies satisfy the pharmacy sector requirements. (See which companies on the Apoteksföreningens website.) More companies are working to satisfy the criteria. The requirements will be reviewed and updated annually in dialogue with the pharmaceutical companies and other actors such as researchers and stakeholders. Over time, we want to be able to impose sustainability requirements at product level.

1.8 Why is pharmaceutical production a problem?

All types of production have a negative impact on the environment, and the manufacture of pharmaceuticals is no exception. For many years, research has shown that large quantities of pharmaceutical residues are discharged during manufacture. Research also shows that pharmaceutical residues can be harmful to people and the environment. A lot of these problems have become apparent in India and China, countries where there is also a high risk of human rights and workers´ rights violations and a high degree of corruption.

The pharmaceutical industry is under no obligation to show where and how their pharmaceuticals are manufactured. Consequently, we in Sweden know very little about how the medicines we use are manufactured. The pharmacies feel it is wrong that we in Sweden can be healthy at the expense of people, animals, and nature.

1.9 What environmental problems do medicines in Sweden cause?

Most pharmaceutical residues are discharged when pharmaceuticals are manufactured. Therefore, Välvald focuses on engaging with the manufacturing industry.

The concentrations of pharmaceuticals measured in the environment in Sweden are small, because here, discharges mainly occur after use. The residues are then diluted through water treatment plants and reach Swedish streams and rivers in smaller concentrations.

The ways in which pharmaceutical substances affect the environment vary greatly. Our water treatment plants cannot treat certain pharmaceutical residues. Most of these types

of substances are the ones sold on prescription only in Sweden. The only substance that is sold OTC in Sweden is diclofenac. Since 2015, Sweden has regulated how much diclofenac may be discharged into our waters, with the permitted limits shown in the regulation on particularly polluting substances issued by the Swedish Agency for Marine and Water Management (Havs- och Vattenmyndigheten). These limits are exceeded. To help reduce discharge of diclofenac, the Swedish Pharmacy Association has a sector agreement on providing information about the negative impact of diclofenac on the environment. Therefore, products containing diclofenak are excluded in the Välvald scheme.

The pharmacies take responsibility for collecting excess and unused medicines (medicinal residues) to prevent them entering the environment inappropriately. Every year, around 1400 tonnes of excess and unused medicines are collected by pharmacies.

1.10 Who is behind Välvald?

The guide is the pharmacy sector's common initiative, enabling the sector to place requirements on the pharmaceutical industry. Välvald is administered by the sector association, the Swedish Pharmacy Association, in which all pharmacies in Sweden are represented. The pharmaceutical companies pay nothing to have the symbol beside their product – the pharmacy sector pays the entire cost.

1.11 Aren't other medicines good?

All medicines sold at Swedish pharmacies satisfy stringent requirements regarding quality, which the customers can always feel confident about. Välvald is a guide that simply shows that the companies behind the products satisfy the requirements regarding transparency and sustainability, about which we currently get information from the companies.

1.12 Why do you sell medicines that do not satisfy the requirements?

The pharmacies' responsibility is to sell all medicines approved by the Swedish Medical Products Agency (Läkemedelsverket). We want to make it easier for the consumer to make more conscious choices, but the customer's medical needs always come first.

1.13 Why do the pharmaceutical companies not provide information about pharmaceutical production?

The pharmaceutical industry cannot or will not provide information about production because of competition. The information is available and provided to authorities and regions under confidentiality agreements. But neither pharmacies, researchers, journalists nor customers receive that information, which means that it´s not possible to review

production. New Zeeland is the only country in the world whose equivalent to the Medical Products Agency publishes such information publicly on its website.

Other global industries have made good progress on the issue of transparency and sustainability. We want the pharmaceutical industry to follow their example, catch up, and surpass them. This is our way to exerting pressure on pharmaceutical companies to become more transparent and sustainable regarding manufacture of pharmaceuticals. We want to show the companies that the customers see transparency and sustainability as competitive advantages, not disadvantages.

1.14 Which companies satisfy the criteria, and how is the guide updated?

2022 about 350 products from fifteen pharmaceutical companies satisfy our requirements. We know that more are on the way, but have yet to satisfy all requirements. The list of which products satisfy the requirements is updated annually. In dialogue with pharmaceutical companies and other actors, the criteria will be updated continually. Our aim is to be able to place sustainability requirements at product level.

1.15 Where can I find more information?

For information about the guide, see http://www.sverigesapoteksforening.se or valvald@sverigesapoteksforening.se

2 More detailed questions about Välvald

2.1 How are prescription-only medicines purchased, and what environmental requirements apply there?

The Medical Products Agency decides which medicines can be sold in Sweden. By law, all pharmacies must sell all prescription-only medicines that have been approved by the Medical Products Agency. Here, the state should be able to place requirements in connection with approval of medicines for sale in Sweden, but this is not possible under current legislation. The authorities The Medical Products Agency, e-Hälsomyndigheten and Dental and Pharmaceutical Benefits Agency (TLV) have been commissioned to develop and prepare a trial activity with an environmental premium in the reimbursement system. The trial will be conducted during the years 2024 to 2027. We see this as positive.

By leading the way and introducing Välvald for OTC medicines at pharmacies, we want to encourage decision-makers and public agencies to take action to improve the situation regarding prescription-only medicines. We want all parties to take their responsibility for creating a more sustainable pharmaceutical sector.

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2.2 Why can I not choose a medicine that is environmentally friendly?

Today, the pharmacies are unable to get information on how medicines are produced. We need greater transparency about the manufacture of medicines sold at the pharmacies, so we are taking a first common sector-wide step by developing Välvald for OTC medicines. For the prescription-only assortments, it is TLV that decides on the model for generic substitution, for which there are currently no environmental requirements. We hope that our work with the Välvald guide will result in the pharmaceutical companies becoming more transparent so that, in time, we will be able to guide the customers to environmentally friendly medicine.

2.3 Why is it called a guide? Isn't it a label?

In order to be called an ecolabel, we must be able to guarantee that every single product is manufactured with little environmental impact. We cannot do this today because the pharmaceutical companies are not transparent about how their products are manufactured. Välvald is based on publicly available information and offers companies to submit answers to questions asked. Our objective is that Välvald will become an ecolabel in time.

Today we can only guide consumers to the OTC medicines from the pharmaceutical companies that communicate in a transparent way about their environmental and sustainable work and can ensure that they demand on responsible manufacturing. The criteria for getting Välvald have been developed since 202. The pharmaceutical companies now having to answer questions about responsible manufacturing of individual products. This means that all a company´s products do not automatically get the symbol Välvald.

2.4 What can a customer do to find out about how medicines are manufactured, and demand that Sweden should place environmental requirements when approving medicines?

As a consumer, you can put pressure on politicians to change TLVs possibility to place environmental requirements when buying medicines. You can also contact the pharmaceutical companies and ask questions about their pharmaceutical production from an environmental perspective. When you buy OTC medicines, you can look for the Välvald symbol.

2.5 Are you not denigrating the medicines that you sell by problematising the manufacture of pharmaceuticals, and only promoting certain suppliers?

We are raising an important issue that few people are aware of, i.e., that production of medicines can harm people and the environment. Our guide Välvald is a first sector-wide

step. We now need to get more consumers, politicians and decision-makers interested, so that we can bring about change further ahead.

2.6 How can you ensure that this will become a long-term engagement?

The pharmacies' view is that, if the issue of sustainable pharmaceutical manufacture is to be driven successfully and responsibly, it must be done across the sector. This will enable us to engage with the companies as a sector, rather than working as individual pharmacies. For some time, the Swedish Pharmacy Association has been driving the issue that environment should be included as a criterion when choosing 'the periodic product'.

In 2018, the Swedish Pharmacy Association decided to develop a common sector guide for OTC medicines, an initiative that Apotek Hjärtat had started several years earlier. The plan is that the requirements will be reviewed annually, and continually updated in dialogue with pharmaceutical companies and other stakeholders.

2.7 Why have you chosen these particular criteria?

Because the pharmaceutical industry is not transparent, we can currently only use information that the pharmaceutical companies make available externally. From 2022 we require companies to answer product specific questions about responsible manufacturing Over time, we hope that transparency in the sector will increase, and that we will be able to place more stringent requirements to ensure that individual products are sustainably manufactured.

2.8 One of the criteria for Välvald is that the pharmaceutical company prepares sustainability reports according to GRI Standards. Do the pharmacy companies themselves satisfy that requirement?

The requirement that the pharmaceutical company prepares a sustainability report is because we want to ensure that their medicines are manufactured under good working conditions and without discharge of pharmaceutical substances. If a company reports its sustainability work according to an accepted standard, such as GRI Standards or similar, this shows that the company is transparent about how they are working with sustainability issues[3]. We also require that the sustainability report be audited and approved by a third party, which is another sign of transparency. We will gradually be making the requirements more stringent, with the objective in the future of being able to place sustainability requirements at product level.

Most pharmacies work with environmental and sustainability issues. Many of the larger pharmacy chains prepare sustainability reports. But the pharmacy actors differ,

[3] If the company is a subsidiary and does not prepare its own sustainability report, it must be included in the parent company's sustainability reporting, which must satisfy the requirement.

everything from large chains to privately run individual pharmacies. This means different conditions for driving environmental and sustainability work. One important environmental aspect for pharmacies concerns buying in goods. We are now working across the sector to ensure that the suppliers of OTC medicines satisfy our requirements according to Välvald.

2.9 Are you not risking excluding small pharmaceutical companies by imposing your requirements?

The requirements are such that even small pharmaceutical companies can satisfy them. We want the pharmaceutical company to openly report how medicines are manufactured in terms of, for example, working conditions and discharge of pharmaceutical substances.

PSCI has two different levels of membership, and we accept both levels to not exclude smaller companies that do not have the same resources to actively participate in working groups. Välvalds criteria are not higher that the criteria recommended by the Procurement Authority for the region´s procured medicines, which are formulates so that smaller companies are not excluded.

2.10 How do you screen companies?

The screening is based on which companies are members in PSCI. We then go through which companies sell OTC medicines in Sweden, either via the parent company or via subsidiaries. Then we review if the company (the parent company or the subsidiary) have an approved sustainability report that is also audited by a third party. After that the company have to answer questions to criteria three and four at product level. Products containing diclofenac do not have the Välvald label.

2.11 Does Välvald also apply for medical devices?

Välvald only applies for OTC medicines. We want to promote sustainable pharmaceutical production, because we know that there are large sustainability risks linked to production today, including discharge of pharmaceutical substances that have a negative impact on people and nature. Medical devices also have an environmental impact, but we are not working across the sector on this product category. It is up to each pharmacy company to place requirements on these suppliers and products.

2.12 How do you involve the pharmaceutical companies in developing the criteria?

To ensure that our requirements are appropriate, the Swedish Pharmacy Association holds continual dialogue with the pharmaceutical industry and other stakeholders.

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2.13 Is there not a risk that the sustainability guide will mislead the customers? You are not placing any direct requirements on the manufacturing process.

There is currently no other guide for environmental or sustainability issues regarding pharmaceuticals anywhere in the world. Välvald is not perfect, but it is a first sector-wide step towards the objective of sustainable pharmaceutical production. If the companies see that the the customers are making conscious choices when they buy OTC medicines, they will hopefully be encouraged to become more transparent about their manufacturing.

2.14 Is it really credible that a sector association is driving this work? Shouldn't it be driven by an independent organisation?

The vision with Välvald is that it will promote sustainable pharmaceutical manufacture. Today, there is no independent organisation that drives an ecolabelling scheme for medicines, so we see it as the pharmacies' responsibility to do something until an independent organisation develops a better alternative. Because Välvald does not guarantee that a specific medicine is sustainably produced, it does not satisfy the requirements for what is defined as ecolabelling.

2.15 There is already environmental information about pharmaceutical substances in FASS. Is this the same information on which your system is based?

No, the environmental information in FASS is entered by the pharmaceutical companies themselves, and audited for quality by a third party, IVL Svenska Miljöinstitutet. The environmental assessment model is based on an estimated risk analysis of discharge in Sweden when patients have used medicines. It shows whether there is a risk that the medicine is environmentally hazardous when it reaches nature, whether the medicine is easily biodegradable, or has potential to become bioaccumulated in aqueous organisms. The model says nothing about how the pharmaceutical companies ensure that pharmaceutical residues are not discharged to nature in connection with manufacturing.

2.16 Why don't you introduce proper ecolabelling even if no pharmaceutical companies can satisfy the criteria?

The customers are already asking questions about 'green medicines' at pharmacies. We don't believe that an ecolabel for which no medicine can satisfy the criteria would lead anywhere. It is the pharmaceutical companies we want to reach, and few of them understand that the customers actually want this. With Välvald we can hopefully show that the customers are making an active choice based on transparency and sustainability. Greater transparency is therefore a competitive advantage, and not a disadvantage.

2.17 Are you not tricking the consumers into thinking that they are are choosing a 'green medicine', when it isn't that?

We are always careful to explain that Välvald is not an ecolabel. Our criteria are not perfect. We want to improve the criteria so Välvald can contribute to a sustainable pharmaceutical production.

2.18 Why do you make exceptions for certain substances? It must be better to also use these medicines from more transparent companies.

Medicines that contain diclofenac are exempted from Välvald. This is because the Swedish Pharmacy Association has a sector agreement to provide information about the substance's negative impact on the environment. We feel that it would give the customers mixed messages if Välvald were displayed next to these products on the shelf. Most medicines that contain diclofenac are now only available on prescription, but other products in gel form remain in the OTC assortment. Pharmacy staff have great knowledge and give advice on which medicines should be used and when. Sometimes other substances can work just as well, and sometimes not.

The risk pattern for diclofenac concerns discharge in connection with use. This differs from the criteria for Välvald. This may be perceived as misleading, but our view is that it would also be misleading to show the symbol in connection with products with a particularly high impact on the environment.