Välvald

CRITERIA DOCUMENT

VERSION 4.0

Date of entry into force: October 1, 2025

Sveriges Apoteksförening

Table of Contents

This document is a translation of the current criteria document for Välvald 4.0 (in Swedish). In case of differences between the two, the Swedish version of the criteria document is the governing one.

Background

In the production of pharmaceuticals, it is not uncommon for drug residues to reach the environment. Manufacturing often takes place in other parts of the world, which means that we in Sweden can become healthy at the expense of people, animals, and nature in other countries. This is something we at the pharmacies find problematic.

Today, there is no established environmental or sustainability labeling for pharmaceuticals. There are also no requirements for pharmaceutical companies to openly show how their production is conducted. As a result, we know very little about the manufacturing of the medicines sold in Swedish pharmacies. Increasingly, pharmacy customers are asking questions about the environment and sustainability, but due to the lack of transparency within the pharmaceutical industry, there is no way to answer these questions.

As an industry, we want to help change this. Pharmacies want to see responsibly produced medicines, and to help customers make more informed choices, the Swedish Pharmacy Association has decided to launch Välvald.

Välvald

Välvald - the pharmacies' requirements for a more responsible pharmaceutical manufacturing - guides pharmacy customers to the over-the-counter (OTC) medicines that meet the industry's standards for responsible pharmaceutical manufacturing.

The Välvald logo is displayed in connection with OTC medicines that meet Välvalds standards. It can be found on the shelf edge in stores and next to the product via e-commerce on the country's pharmacies.[1]

Välvald is managed and administered by the sector organization, the Swedish Pharmacy Association, which represents Sweden's pharmacies.[1] The operational work is handled by a secretariat together with a working group in which all member companies can participate. Read more about the Swedish Pharmacy Association: www.sverigesapoteksforening.se.

Which products can be included?

OTC medicines sold in pharmacies on the Swedish market, either at a physical pharmacy or through a pharmacy company's e-commerce, can be included in Välvald.[2] Products containing diclofenac are excluded from Välvald. The Välvald secretariat requests a list of OTC medicines from the eHealth Agency for review, which forms the basis for which products that can be included in Välvald.

Products that cannot be included in Välvald are dietary supplements, medical devices, traditional herbal medicinal products, natural remedies, and herbal medicines.

1 Välvald is found at Apotek Hjärtat, Apoteket AB, Kronans Apotek, ApoEx, Apotea, ApoHem and SOAF-pharmacies (Sveriges oberoende apoteksaktörers förening).
2 The classification of medicines for human use is described in the Medicines Act (2015:315) and the Swedish Medical Products Agency's regulations (HSLF-FS 2021:90) on the approval for sale of human medicines, chapter 6. When a medicine is approved for sale, the Medical Products Agency shall specify whether the medicine is classified as prescription-only or over-the-counter.

What is required of us as a company?

The company can apply for the OTC medicines where the company holds the Marketing Authorization Holder (MAH) status. The company is required to provide the requested information and documentation for the OTC medicines it applies for to be included in Välvald.

All specified requirements (Välvald 4.0) must be met, in accordance with the description provided in this criteria document, for a company and its products to be included in Välvald. The OTC medicines that are assessed by the Välvald secretariat to comply with the criteria may be included in Välvald.

The company is responsible for ensuring that the requirements are met throughout the entire criteria period. During the validity period of the criteria, the company must, without undue delay, inform the Välvald's secretariat of any changes regarding the information provided in the application. The company is responsible for ensuring that the product(s) continue to comply with the criteria following such changes.

Cost and signing of license agreement

For the companies that apply to be included in Välvald, an administrative cost is charged as below. The fee applies to the number of articles[3] that the company applies for, regardless of whether they are then found to meet the requirements or not. If an article, for any reason, has its approval withdrawn, the fee will not be refunded.

Fee

Companies applying for 1–5 articles:	30 000 SEK
Companies applying for 6–30 articles:	45 000 SEK
Companies applying for 30* articles:	60 000 SEK

The company must also sign a license agreement to be included in Välvald. It states that an article that does not meet the criteria may be withdrawn at any of the continuously recurring opportunities to apply for Välvald or for Välvald to exclude articles that no longer meet the criteria.

The Swedish Pharmacy Association has no financial profit motive and Välvald is financed partly through fees mentioned above, partly from an annual contribution through members of the association.

Process for application and assessment of compliance

Välvald offers companies the opportunity to apply to be included in Välvald on one to two occasions per year.

Brief about the application process

1) Välvald's office sends out an offer about the opportunity to be included in Välvald 4.0 to all companies listed on the product list retrieved from the E-health authority (see under "Which products can be included in Välvald?").
2) Companies wishing to be included in Välvald must respond to the offer in accordance with the communicated timeframe and provide requested information in full (see further under "Criteria") to ensure compliance.
3) Välvald's office reviews the submitted documentation and assesses compliance with the requirements. If necessary, additional questions are asked to the applying company for clarification.
4) Välvald's office returns to the companies with the results of the completed review, and where relevant, lists all approved articles.

[3] Per NPLPACKAGEID

Välvald's office may also request supplementary information linked to set requirements for approved products throughout the criteria period.

When Välvald 4.0 enters into force, Välvald 3.0 ceases to apply. Existing companies therefore need to apply again for products that they wish to be included in Välvald.

Handling of information

Information submitted by the companies will only be handled by Välvald's office and will not be shared with the sector association's members or the public. Provided information is saved as long as current criteria apply (version 4.0).

Validity and development of Välvald

Välvald was introduced in all pharmacies in February 2021 (Välvald 1.0). Criteria are continuously developed in line with customer expectations, upcoming legislation and national/international ongoing work.

The decision on the current criteria (version 4.0) was taken by the Swedish Pharmacy Association's board on the 10th of December 2024. Current criteria apply for the period 1 July 2025 up to 31 December 2027. The criteria period may change regarding, for example, possible restrictions based on legislation[4].

Earlier versions: Välvald 1.0 (Feb 2021 - Jan 2022), Välvald 2.0 (Feb 2022 - Jan 2023) and Välvald 3.0 (Feb 2023 - September 2025).

Criteria Välvald 4.0

The pharmacies' requirements for a more responsible pharmaceutical manufacturing consist of the following four criteria areas (1-4).

In addition to the above, two complementary areas are included where information that can provide increased knowledge about the companies' work and current situation is collected for future criteria development (Looking ahead area A-B). The OTC medicines included in the company's application to Välvald must comply with all requirements.

For each criteria area, there is a clarified overall purpose, specified requirements and a description of how compliance with requirements is to be verified.

Criteria area 1 - Traceability

Criteria area 2 - Requirements regarding responsible manufacturing conditions

Criteria area 3 - Identification, prioritization and management of potentially negative effects

Criteria area 4 - Management of actual negative effects (deviation management) in the manufacturing sites

Looking ahead area A – Environmental information

Looking ahead area B – Climate emissions from manufacturing

[4] Assessment is made with the support of applicable legal advice.

CRITERIA AREA 1 Traceability

Purpose

Traceability throughout the supply chain is important in the work towards responsible pharmaceutical manufacturing. Information about where the manufacture of active pharmaceutical substance and formulation of pharmaceuticals takes place is also a prerequisite for being able to evaluate compliance with Välvald's other criteria areas (2-4).

REQUIREMENT

1.1 The company must provide information on where the active pharmaceutical substance is manufactured and where the pharmaceutical formulation takes place.

The information must include the name of the manufacturing/formulation site with associated address/es, for all current manufacturing sites. The company must indicate whether specified sites are part of the company's own operations and/or if they are in the company's supply chain.

Verification of compliance

The company must provide information according to the requirements for the items included in the company's application to Välvald. If necessary, the company can indicate which articles are covered by the same documentation.

The company is proposed to provide requested information in Välvald's response form. Companies that wish to provide information in their own format must ensure that the requested information is easy to identify.

CRITERIA AREA 2 Requirements regarding responsible manufacturing conditions

Purpose

The OTC medicines included in Välvald must have been manufactured under responsible manufacturing condition, i.e. with respect for human rights, with protection of the environment and with combating corruption. It is therefore important that requirements for this have been set at all relevant manufacturing sites.

REQUIREMENT

2.1 **Manufacturing in own operations**

In cases where the company has its own manufacturing, the company must have policy commitments that establish that the manufacturing of active pharmaceutical ingredients and/or formulation of pharmaceuticals takes place under responsible manufacturing conditions, that is, with respect for human rights, with protection of the environment and with combating corruption.

Policy commitment(s) must at least correspond to PSCI's principles (v. 3.0) and must apply to all relevant manufacturing facilities.

2.2 **Manufacturing within the supply chain**

In cases where the company has manufacturing at a supplier, the company must set written requirements that the manufacture of active pharmaceutical ingredients and/or formulation of medicines takes place under responsible manufacturing conditions, i.e. with respect for human rights, with protection of the environment and anti-corruption.

The requirements must at least correspond to the PSCI principles (v. 3.0) and shall be imposed on all relevant manufacturing sites in the supply chain (first tier), which shall also accept them in writing. If all or part of the manufacturing is subcontracted (second-tier), the company must be able to demonstrate that the requirements for the first-tier supplier include a pass-through clause that ensures that equivalent requirements are imposed on all relevant manufacturing sites in the supply chain.

Verification of compliance
Companies shall provide evidence of compliance at the relevant manufacturing sites as listed below, depending on whether manufacturing takes place:

- Own operations: policy commitment(s) covering at least the PSCI's principles.
- At first-tier supplier: written requirements that have been imposed on, and accepted by, the relevant manufacturing sites. Written requirements mean, for example, a contract, a signed code of conduct or an annex to a supplier agreement. Acceptance means a dated signature or equivalent.
- With a subcontractor: if all or part of the manufacturing is subcontracted, the company must be able to demonstrate that the requirements for the first-tier supplier (see above) include a pass-on clause that ensures that equivalent requirements are applied to all relevant manufacturing sites in the supply chain.

The company must provide information on how policy commitment(s) and/or requirements correspond to PSCI's principles in the response form provided by Välvald. PSCI's principles are publicly available here.

CRITERIA AREA 3 Identification, prioritization and management of potentially negative effects

Purpose

The OTC medicines included in Välvald must have been manufactured under responsible manufacturing conditions. It is therefore important that the company regularly identifies and prioritizes potential negative effects (here "sustainability risks") regarding human rights, workers' rights, the environment and corruption (in accordance with PSCI's principles) and takes appropriate measures to manage prioritized risks.

REQUIREMENT

3.1 The company must have identified and documented analysis of sustainability risks. The risk analysis must:

a) At least include manufacturing of active pharmaceutical substance and pharmaceutical formulation for the actual OTC medicin.

b) At least include identification of potential negative effects, based on geographic location, regarding
- human rights and workers' rights
(PSCI's principles (v. 3.0) ch. 3, sections 1–7 and ch. 4, sections 1–3)
- environment (PSCI's principles (v. 3.0) ch. 5, section 2 & 6)
- corruption (PSCI's principles (v. 3.0) ch. 2, section 2)

c) Include, for all main areas[5] in b), relevant and credible independent sources, such as index data

d) Be completed within the last 24 months.

3.2 In cases where the company does not address all identified risks, the company must apply a model for risk prioritization. The prioritization of risks should be based on the severity and likelihood of the negative impacts.

3.3 The company must take appropriate measures to manage prioritized risks.

[5] The main areas refer to human rights, workers' rights, environment and corruption.

Verification of compliance

The company must provide verifying documentation demonstrating compliance with requirements 3.1-3 as specified below. Clarify, if necessary, which articles are covered by the same documentation.

3.1. The documentation provided by the company to Välvald's office must state (show):

- That the sustainability risk analysis covers potential negative impacts on responsible manufacturing conditions according to requirements 3.1 a) and b)
- The information sources used for the risk analyses (the company should not include information about measures already taken to minimize/mitigate risks, as this will be addressed under requirement 3.3).
- The result of the risk analysis for each OTC medicine
- The dates when the risk analysis was conducted/updated. The requirement that risk analysis must be conducted within the last 24 months applies to each review process during the criteria period.

The risk analysis must cover all actual manufacturing sites (according to requirement 1.1), meaning both the company's own operations and/or suppliers. It is important to identify the risks that exist. Identifying sustainability risks does not constitute a deviation from Välvald's criteria.

3.2. When prioritising risks, the documentation provided by the company to the Välvald office must show how risks have been prioritised.

3.3. For verification of criteria 3.3, it is required that the company certifies that the requirement is complied with, unless otherwise stated.

Appropriate measures include at a minimum obtaining more information on how each manufacturing facility manages the identified potential sustainability risk. Examples of appropriate measures may be assessments according to EcoVadis, audits within the framework of PSCI, distribution of self-assessment questionnaires, capacity-building actions, engagement in multi-stakeholder initiatives/industry organizations, etc.

CRITERIA AREA 4 Management of actual negative effects (deviation management)

Purpose

The OTC medicines included in Välvald must be manufactured under responsible manufacturing conditions. Therefore, it is important that the company takes appropriate actions in cases where deviations from PSCI's principles are identified at a manufacturing facility.

REQUIREMENT

4.1 The company must have procedures in place to ensure that appropriate actions are taken to cease identified *actual* negative impacts (deviations from PSCI's principles). If the adverse effects cannot be immediately reversed, the company shall minimise the extent of these effects. The procedures must at least cover the OTC medicines for which the company is applying to be included in Välvald.

Verification of compliance

For verification, the company is required to certify that the requirement is being met, unless otherwise specified.

AREAS OF INTEREST Environmental information and climate emissions during manufacturing

Purpose

With the goal of developing Välvald's criteria to contribute to increased sustainability performance, information is gathered here that can give the Swedish Pharmacy Association additional knowledge about the companies' work and current situation. Orientation for these areas is based on ongoing and upcoming regulatory requirements, development of relevant frameworks as well as the expectations and interest of the outside world.

REQUIREMENT

AREA A – Environmental information

Provide information on whether environmental information has been developed and is generally available for the OTC medicines that the company is applying to include in Välvald.

Publicly available environmental information means that information is available on a free website with no requirement for membership, payment or similar. Environmental information refers to information on persistence, bioaccumulation, toxicity and environmental risk., produced in accordance with the European Medicines Agency's, EMA's latest guidelines, FASS's latest published guidelines for environmental information for medicinal products or another equivalent publicly available model for environmental information.

If environmental information is not available, please describe the reasoning behind this.

AREA B – Climate emissions from manufacturing

Describe the current (or planned) ability to report the greenhouse gas emissions associated with the manufacturing of the active pharmaceutical ingredients and the formulation of the OTC product.

Describe the current goals for reducing greenhouse gas emissions from the manufacturing of active pharmaceutical ingredients and the formulation of OTC product.

Verification of compliance

The company must provide answers in free text format. If the company has provided a response, it will be considered approved, regardless of the content of the response.

Definitions

Risk analysis[6]	An analysis of the adverse impact on people, environment, and society (on the basis of stipulated requirements) that the company can cause, contribute to, or be directly linked to.
Supply chain	A company's own business operation and its supplier chain.
Supplier chain	A company's suppliers and their subcontractors throughout the chain.
MAH	Market authorization holder (holder of sales permits)

[6] Definition according to "UN Guiding Principles on Business and Human Rights", and the "OECD Due diligence guidance for responsible business conduct"