# CRITERIA DOCUMENT VÄLVALD

Version 3.0

Date of entry into force: February 2023

# Contents

# Background

Välvald is the pharmacies' guide for greater transparency. Our vision is to promote sustainable pharmaceutical manufacture. The guide is the pharmacy sector's common initiative to place requirements on the pharmaceutical industry. Välvald is administered by the sector organisation, the Swedish Pharmacy Association, in which all pharmacies in Sweden are represented.

Välvald was introduced at all pharmacies in February 2021 (Välvald 1.0), and the criteria were most recently updated in February 2022 (Välvald 2.0). The Välvald criteria are developed in line with customer expectations, upcoming legislation, and current national and international initiatives. The ambition is to develop Välvald into the world's first sustainability label for medicines.

The Välvald logo can be seen beside over-the-counter (OTC) medicines that satisfy the requirements in the guide. The label is displayed at all the country's pharmacies, on the shelf edge in shops and together with the product details for online sales.

# Period of validity

The updated criteria (version 3.0) were adopted by the Board of the Swedish Pharmacy Association on 7 June 2022. The criteria apply for the period 1 February 2023 - 30 June 2025.

# Procedure for assessing compliance with the criteria

Companies (parent company or subsidiary) that satisfy Criteria 1 and 2 are invited to submit documentation for screening in relation to Criteria 3-6.

The documentation is requested by the Välvald office, which then assesses compliance with the criteria on the basis of the submitted verifying documentation (more information under each criterion).

A company must satisfy all criteria before its products can be included in the Välvald guide. The OTC medicines deemed to comply with the criteria will have the Välvald symbol displayed alongside the product.

The company must sign an affirmation of truth regarding the company and the compliance of its products with the criteria, and submit a signed licence agreement.

***Confidential information***

'Confidential information' comprises company secrets, information about business relations with a party or companies in the group that includes the party, information that concerns parties or other companies in the same group as the party, or other information that, in the transfer, is stated to be confidential, or otherwise can be realistically regarded to be of a confidential nature.

Information submitted by the companies deemed to be of a confidential nature according to the above will be handled confidentially by the Välvald office. Conditions regarding confidential information and secrecy will also be managed through licensing agreements with each company included in Välvald.

# Välvald criteria

## 1. Sustainability Reporting

*The company must report its sustainability work according to GRI Standards or some other international framework for sustainability reporting. The sustainability report must be audited by an independent party.*

***Background and purpose***

By reporting its sustainability work according to an accepted standard, such as GRI Standards or similar, the company is showing that it is transparent about how it is working with sustainability issues. The sustainability report must also be audited and approved by a third party, which is another sign of a company's transparency.

***Verification of compliance***

The pharmaceutical company's sustainability report for the immediately preceding accounting year must be published on the company website. The report must be based on GRI Standards or some other international framework for sustainability reporting. The report must be audited by an independent party according to standards such as RevR6, ISAE3000, and AA1000AS.

In cases where the pharmaceutical company is part of a group, the parent company's sustainability report is reviewed. The description of the group's sustainability work must include the pharmaceutical company in question.

## 2. Membership of PSCI

*The company must be a member of the industry organisation, Pharmaceutical Supply Chain Initiative (PSCI).**

** The company must have joined PSCI no later than 1 September 2022.*

***Background and purpose***

PSCI is a non-profit business membership organisation with around 50 members in the pharmaceutical and healthcare industry. PSCI is a collaboration platform that aims to promote responsible supply chains in the industry, for example by members sharing the results of audits. The companies that are members of PSCI undertake to respect and comply with the PSCI conditions for membership. Read more about PSCI here.

***Verification of compliance***

Publicly available information through the PSCI website. Both 'associate' and 'full' membership categories satisfy the criteria. In cases where the pharmaceutical company is part of a group, the parent company's membership is accepted.

## 3. Communication of Policy Commitment

*The company must require, in writing, compliance with PSCI principles, or corresponding principles, in the supply chain* for OTC products.*

** Here, the supply chain is limited to all tiers from production of the active pharmaceutical substance to sale of the OTC medicine.*

***Purpose***

When a company joins PSCI, the company must publicly display the PSCI principles. According to the PSCI principles, company must respect human rights, labour rights, environmental protection, and anti-corruption. It is important for Välvald that the principles or corresponding requirements are communicated throughout the supply chain, i.e. both within the company's own operation and in the supplier chain. The complete PSCI principles are available here.

***Verification of compliance***

The company must submit information about the products for which the company is the Market authorisation holder (MAH). The company must also verify compliance by submitting documentation about a number of randomly sampled products that supports compliance.

Random sample products and delimitation of the supply chain with regard to verification

Sample products are selected by the Välvald office. A minimum of ten products are selected, or the equivalent of at least 10% of the number of OTC products for which the company states that requirements have been placed. If the company has fewer than 10 products, all products will be selected.

When sample products are assessed for compliance, the focus in the supply chain is limited to production of the active pharmaceutical ingredient (API).

Documentation requested

The company must submit documentation proving that it has requested compliance with PSCI principles or corresponding, and that this has been accepted in writing[1] by all suppliers of the API in the sample products. If the API is manufactured within the company's own operation, this is stated. In such cases, documentation proving that corresponding requirements are applied within the company's own operation is to be submitted instead[2].

Information submitted by the company will be treated as confidential by the Välvald office. Information provided will be saved for as long as the prevailing criteria are applicable (version 3.0).

Assessment of compliance

Documentation must be provided for all selected sample products. The documentation must show that the requirements placed completely correspond with the PSCI principles, and that the requirements have been placed and accepted in writing by first-tier suppliers. If these two parts are satisfied, then all the OTC medicines for which the company has answered 'yes' can be included in the Välvald guide. The OTC medicines for which the company answered 'no' will not be included in Välvald. If the company cannot prove compliance of the sample products, the company and its OTC medicines cannot be included in Välvald.

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[1] *'Written requirements' are requirements placed in writing and accepted by the first-tier supplier(s) in writing for the sample product in question, through for example agreements, a signed code of conduct, or an appendix to a supplier agreement. Accepted requirements must include a requirement that these shall be communicated in the supplier chain.*

2 *Documentation relating to corresponding requirements for the company's own operation concerns the company's own policy commitment(s) that embrace the PSCI principles.*

## 4. Risk Analysis

*a) The company must have carried out and documented risk analyses* based on the PSCI principles or equivalent for the supply chain** relating to the OTC medicines.*

*b) The company must have procedures in place for prioritising risks and taking suitable measures to ensure that the risks identified for OTC medicines are managed.*

** See description of risk analyses under 'Purpose' below.*

** *Here, the supply chain is limited to all tiers from production of the active pharmaceutical substance to sale of the OTC medicine.*

***Purpose***

The reason for requiring that the company conducts risk analyses is to ensure that the company regularly identifies and prioritises risks of non-compliance with PSCI principles (i.e. relating to human rights, labour rights, environment, and anti-corruption) and takes suitable measures to manage these risks. As risks are constantly changing as a result of new business relations, changes in production, new legislation, etc., risk analyses should be carried out at least in conjunction with such changes. It is important to ensure that all types of risks relating to the requirements (i.e. human rights, labour rights, environment, and anti-corruption) are captured in the risk analyses, both regarding the company's own operation and in the supplier chain. Risk refers to both actual and potential adverse impact on the basis of the requirements stated.

It is important that the company also has procedures in place for identifying risks in the supplier chain. Information gathering is crucial for the risk analyses, and the process should be based on internal and independent external expertise, and can involve consultation on material risks with individuals, their representatives, and groups that may be impacted.

It must be emphasised that identification of a risk does not, in itself, mean non-compliance with the Välvald criteria. It is important to identify the risks that actually exist. What is important is that the company has procedures in place for taking appropriate action on the basis of its analysis of its extent of leverage in addressing the adverse impact ('causes', 'contributes to', or 'directly linked to' according to The UN Guiding Principles on Business and Human Rights and the OECD Due Diligence Guidance for Responsible Business Conduct).

***Verification of compliance***

The company must submit information about the products for which the company is the MAH.

<u>Information requested</u>

The company must submit a response that shows:

- whether each OTC medicine is covered by the company's risk analyses. The responses must be entered on the product list provided by Välvald.
- whether the company complies with Criterion 4 b). Responses are entered on the form provided.

Information submitted by the company will be treated as confidential by the Välvald office. Information provided will be saved for as long as the current criteria are applicable (version 3.0).

<u>Assessment of compliance</u>

Criterion 4 a): The OTC medicines that the company has included in its risk analyses, i.e. answered 'yes', can be included in the Välvald guide. The OTC medicines for which the company answered 'no' will not be included in Välvald.

Criterion 4 b): The company must have answered 'yes' to the question on compliance with requirements.

***Information requirements - Criteria 5 and 6***

The aim is to develop the Välvald criteria to improve sustainability performance, so these requirements enable information to be collected that can give the Swedish Pharmacy Association further knowledge about the companies' work and current status. If the company has submitted a response, this is regarded as approved, regardless of the content of the response.

The nature of these information requirements is steered by current and upcoming regulatory requirements, development of relevant frameworks, and external expectations and interest.

## 5. Impact on Climate

*Do you assess your impact on climate in accordance with the GHG Protocol[3] Scope 1 and/or 2 and/or 3 or some other equivalent framework? Do you have objectives and targets to limit your impact on climate?*

*The company must submit free-text responses.*

## 6. Transparency in the Supply Chain

*Could you make available to the Välvald office a review of the supply chain* for individual OTC medicines? In your response, please state if any information could be provided under conditions of confidentiality, including named suppliers and address, for both your own factories and those of third-party manufacturers.*

*The company must submit free-text responses.*

** Here, the supply chain is limited to all tiers from production of the active pharmaceutical substance to sale of the OTC medicine.*

***Verification of compliance***

The company must submit information in the form of free-text responses.

Information requested

The company must submit free-text responses in the form provided. Information submitted by the companies will be treated as confidential by the Välvald office. Information provided will be saved for as long as current criteria are applicable (version 3.0).

Assessment of compliance

If the company has submitted a response, this is regarded as approved, regardless of the content of the response.

## Exception

*OTC products containing diclofenac are excepted from Välvald.*

[3] *Greenhouse Gas Protocol | (ghgprotocol.org).*

# Definitions

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| ***Risk analysis*** | 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 authorisation holder |
| ***Human rights*** | 'Human rights' refers to compliance with the UN Universal Declaration of Human Rights (1948), the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. |
| ***Labour rights*** | 'Labour rights' refers to compliance with the International Labour Organisation's eight Fundamental Principles and Rights at Work, the UN Convention on the Rights of the Child, Article 32, the labour rights legislation, including provisions on wages, hours of work, leave, and social insurance protection, that applies in the country in which the work is carried out, and the occupational safety and work environment legislation that applies in the country in which the work is carried out. |
| ***Environmental protection*** | 'Environment' refers to compliance with the environmental protection legislation that applies in the country in which the work is carried out, and indicates that the operation is carried out with consideration for the company's surrounding environment. |
| ***Anti-corruption*** | 'Anti-corruption' refers to compliance with the UN Convention Against Corruption and the bribery legislation that applies in Sweden, in the country in which all or parts of the product are manufactured, and any other country's laws that otherwise govern the company's operation. |
| ***The GHC Protocol*** | The GHG Protocol (Greenhouse Gas Protocol) was developed by the World Resources Institute (WRI) and the World Business Council on Sustainable Development (WBCSD) as a global standard for measuring, managing, and reporting emissions of greenhouse gases. The Protocol is the most widely used standard in the world. More information here Greenhouse Gas Protocol \| (ghgprotocol.org). |

** Definitions according to The UN Guiding Principles on Business and Human Rights and the OECD Due Diligence Guidance for Responsible Business Conduct.*