Välvald

CRITERIA DOCUMENT VÄLVALD

Version 2.0

Date of entry into force: 6 February 2022

Background

Välvald was introduced at all pharmacies in February 2021. According to the vision, Välvald will promote sustainable pharmaceutical manufacture. The Välvald criteria are developed annually in line with customer expectations and ongoing national and international initiatives.

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. The pharmaceutical companies currently do not pay to have the Välvald symbol beside their product – the pharmacy sector is responsible for the entire cost.

Adopted criteria

The updated criteria (version 2.0) were adopted by the Board of the Swedish Pharmacy Association on 6 September 2021. The requirements are divided into four criteria; see below under 'Välvald criteria'. A company must fulfil all four criteria, and submit all relevant documentation for the over-the-counter (OTC) medicines, before the Välvald symbol can be displayed beside its products.

Procedure for assessing compliance with the criteria

The screening begins with an assessment of Criterion 2, i.e. which companies are members of PSCI.

Information is then collected about which of these companies sell OTC medicines in Sweden, either via the parent company or via subsidiaries. Companies (parent company or subsidiary) deemed to comply with Criterion 1 (and 2) are then screened with regard to Criteria 3 and 4. These companies are invited to submit documentation for assessment.

The companies that submit documentation as above, and whose products are deemed to comply with the criteria, will be included in the Välvald system. The symbol is displayed beside all relevant products.

Products containing diclofenac are excepted from Välvald; see below under 'Exceptions'.

Time framework

The deadline for joining PSCI is 1 November 2021. Companies that become members after this date can be included in Välvald from 2023.

Products that are part of a company's assortment as of 12 November 2021 can be included in Välvald. Products introduced to the assortment after this date can be included in Välvald from 2023.

Companies that satisfy Criteria 1 and 2 are invited to submit documentation for assessment of Criteria 3 and 4 1-5 November, 2021. The companies are expected to respond no later than 19 November 2021.

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.

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.

Background and purpose 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. The sustainability report must also be audited and approved by a third party, which is another sign of a company's transparency.

2. Membership of PSCI

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

** The company must have become a member of PSCI no later than 1 November 2021.*

Verification of compliance Publicly available information about membership is published on 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.

Background and purpose PSCI is a non-profit business membership organisation with 52 members in the pharmaceutical and healthcare industry. PSCI is a collaboration platform that aims to promote responsible supply chains in the industry. Companies that are members of PSCI undertake to respect and comply with the PSCI conditions for membership. Read more about PSCI here.

3. Communication of policy undertaking

The company must require compliance with PSCI principles or corresponding principles in the supply chain for the over-the-counter (OTC) products, i.e. manufacturing units and suppliers must comply with the principles.

Verification of compliance The company is invited to submit information about the products for which the company is the MAH.

Information submitted by the company will only be handled by the Välvald office and the working group of sustainability experts and will be treated as confidential. Information provided by the company will be saved for as long as current criteria are applicable (version 2.0).

The OTC medicines for which the company requires written compliance with PSCI or corresponding principles in its supply chain (e.g., a signed code of conduct or an appendix to a supplier agreement), i.e. products for which the company answers 'yes', can be included in the Välvald guide.

Products for which the company answers 'no' will not be included in the Välvald guide.

Background and purpose When a company becomes a member of PSCI, the company must publicly communicate the PSCI principles. The PSCI principles stipulate that a company must respect human rights, labour rights, environmental protection, and anti-corruption. It is important for Välvald and the OTC products that the principles or corresponding requirements are applied throughout the supply chain, i.e. in the company's own operation and in the supplier chain. The PSCI principles are found here.

4. Participation in PSCI and outcome of risk analysis

Answer the following questions regarding participation in the PSCI work and the outcome of risk analyses for suppliers of OTC products:

a) *In 2020-2021, how has your organisation participated in the PSCI work?*
   - *Participation in working groups*
   - *Implemented audits*
   - *Participation in other activities*

b) *On the basis of your existing risk analysis, is any supplier of an active substance or manufacturer of a finished product (connected with the products relevant for Välvald) identified as high-risk on the basis of PSCI principles or corresponding principles?*

Verification of compliance The company is invited to submit information.

Information submitted by the company will only be handled by the Välvald office and the working group of sustainability experts, and will be treated as confidential. Information provided by the company will be saved for as long as current criteria are applicable (version 2.0).

A) If the company has submitted a positive response, compliance with the criterion is regarded as approved, with no assessment of the level of participation in the PSCI work.

B) The company submits information regarding the OTC medicines for which the company requires compliance with PSCI or corresponding principles in its supply chain, i.e. answered 'yes' for Criterion 3.

   If the company answers 'yes', i.e. has identified supplier(s) that are of high risk on the basis of PSCI principles, the company is approved.

   If the company answers 'no', i.e. has not identified supplier(s) that are of high risk on the basis of PSCI principles, the company is approved.

Background and purpose The aim is to develop the Välvald criteria to improve sustainability performance, so information is collected that can give the Swedish Pharmacy Association further knowledge about pharmaceutical companies' work and current status.

Exception
OTC products containing diclofenac are excepted from Välvald.

Definitions

Risk analysis	An analysis of the negative impact on people, environment, and society (on the basis of stipulated requirements) that the company can cause*, contribute to*, or be directly connected with*.
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 business 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.

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