Waiver of Confidentiality

1 Contents and purpose

1.1 Contents

This document outlines the terms by which [Company] (hereinafter referred to as the "Company") agrees to waive confidentiality protections of the material submitted in accordance with this waiver. The document specifies what information is subject to the waiver, who is party to it and which activities are covered by it as well as the terms by which the waiver is to be signed and terminated.

1.2 Purpose

The purpose of this waiver is to facilitate a joint assessment of medicinal products to enable reimbursement and procurement of said products by the relevant agencies and organisations in Denmark, Finland, Norway, and Sweden. The Company´s waiving of statutory[1] confidentiality protections vis-à-vis the reviewing agencies and organizations pursuant to this waiver promotes the purpose of joint assessment by allowing them to share information, coordinate their assessments and share knowledge and expertise.

Agreeing to waive confidentiality restrictions is also necessary to enable the full, unredacted FINOSE health technology assessment report (HTA report) to be used for appraisal, recommendation, reimbursement, or procurement in Denmark, Finland, Norway, and Sweden.

Agreeing to waive confidentiality restrictions is voluntary and required only for joint FINOSE assessment, not for the national HTA processes at DMC, Fimea, NoMA or TLV.

2 Terms

2.1 Parties

By signing this waiver, the Company consents to waive the confidentiality restrictions – to the extent specified in sections 2.3-3 – in relation to the following agencies:

a) The Danish Medicines Council (DMC)
b) The Finnish Medicines Agency (Fimea)
c) The Norwegian Medicines Agency (NoMA)
d) The Swedish Dental and Pharmaceutical Benefits Agency (TLV)

[1] The statues in question are the following: for Denmark; The Public Administration Act (433 2014-04-22) and the Public Access to Information Act (145 2020-02-24), for Finland; Act on the Openness of Government Activities (621/1999), for Norway; Act 19. June 2006 nr. 16 relating to the right of access to documents held by public authorities and public undertakings (Freedom of Information Act) and for Sweden; The Public Access to Information and Secrecy Act (2009/400).

e) Amgros I/S in Denmark
f) Representatives of the Finnish university hospitals participating in price negotiations
g) Sykehusinnkjøp HF, divisjon legemidler (LIS) in Norway
h) The new therapies council (NT-council) in Sweden.

In addition to the above listed agencies and their respective representatives, the waiver includes persons deemed necessary by the parties, such as contracted experts and officials.

2.2 Information

The information subject to this waiver is the material[2] contained in the cases listed in the table below. Only material submitted for – and relevant to – joint assessment, recommendation, reimbursement, or procurement is subject to this waiver.

Agency	Case number
DMC	
Fimea	
NoMA	
TLV	

All information intended to be used only for the purpose of a specific application to one of the agencies will be submitted separately, indicating clearly that the information disclosed is not covered by this waiver.

2.3 Treatment of information

The agencies listed in 2.1 will treat the submitted information in accordance with applicable national and/or EU law, which has precedence over any agreement. This waiver does not curtail any of the protections granted to the Company by law other than specifically – as described in this document – waiving secrecy in relation to the parties. The possibility of consenting to such an access to otherwise secret information follows from the national legislation of Denmark, Finland, Norway, and Sweden.[3]

The information submitted to the parties in accordance with this waiver will only be handled insofar as it is necessary for the explicit purposes stated in this document, or insofar as national and/or EU law requires it. The agencies, as well as any other such person mentioned in 2.1, shall ensure that any information and/or documentation obtained from the Company is handled safely, minimizing the risk for unauthorized

[2] The terms «information», «material» and «documentation» are used interchangeably and include all formats of data submitted.

[3] The relevant statutes are the following: for Denmark; The Public Administration Act (433 2014-04-22) and the Public Access to Information Act (145 2020-02-24), for Finland; section 29 in Act on the Openness of Government Activities, (621/1999; amendments to 907/2015 included), for Norway; Act 19. June 2006 nr. 16 relating to the right of access to documents held by public authorities and public undertakings (Freedom of Information Act) § 13 (3) jf. Act 10. February 1967 relating to procedure in cases concerning the public administration (Public Administration Act) § 13 a, for Sweden; chapter 10 section 1 in the Public Access to Information-and Secrecy Act.

access by any third-party including competitors, customers, and suppliers of the Company.

3 Duration and withdrawal

This waiver is in effect from the day of signing until it is withdrawn by the Company. Such a withdrawal shall be made in writing by the Company or a legal representative thereof and shall be addressed to one or several of the agencies listed in section 2.1 a-d (DMC, Fimea, NoMA and TLV). The Company does not need to provide a reason for withdrawing. If no notice of withdrawal is made by the Company, the waiver is in effect until the material is no longer needed for the purposes stated in section 1.2. An agency that receives a notice of withdrawal from the Company shall inform the other agencies.

Date:

_____ _____

Name Company signatory in print Signature

Company

Address

Registration number