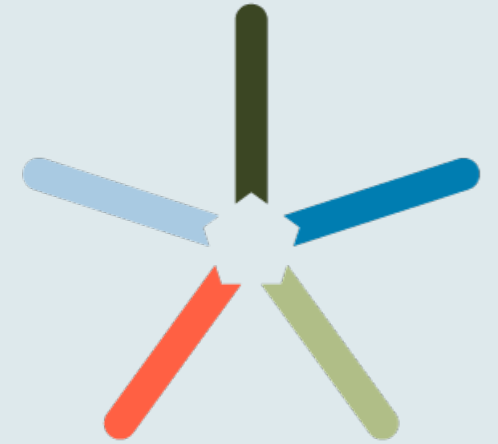


FINOSE becomes Joint Nordic HTA-Bodies



JNHB Launch 3 June 2024

Welcome and Opening of Meeting

Director General Agneta Karlsson, TLV



- **FINOSE –
Start of the Nordic collaboration**
- **New JNHB website**
- **New JNHB guidelines**
- **JNHB going forward**
- **Questions**

Agenda

FINOSE becomes Joint Nordic HTA-Bodies

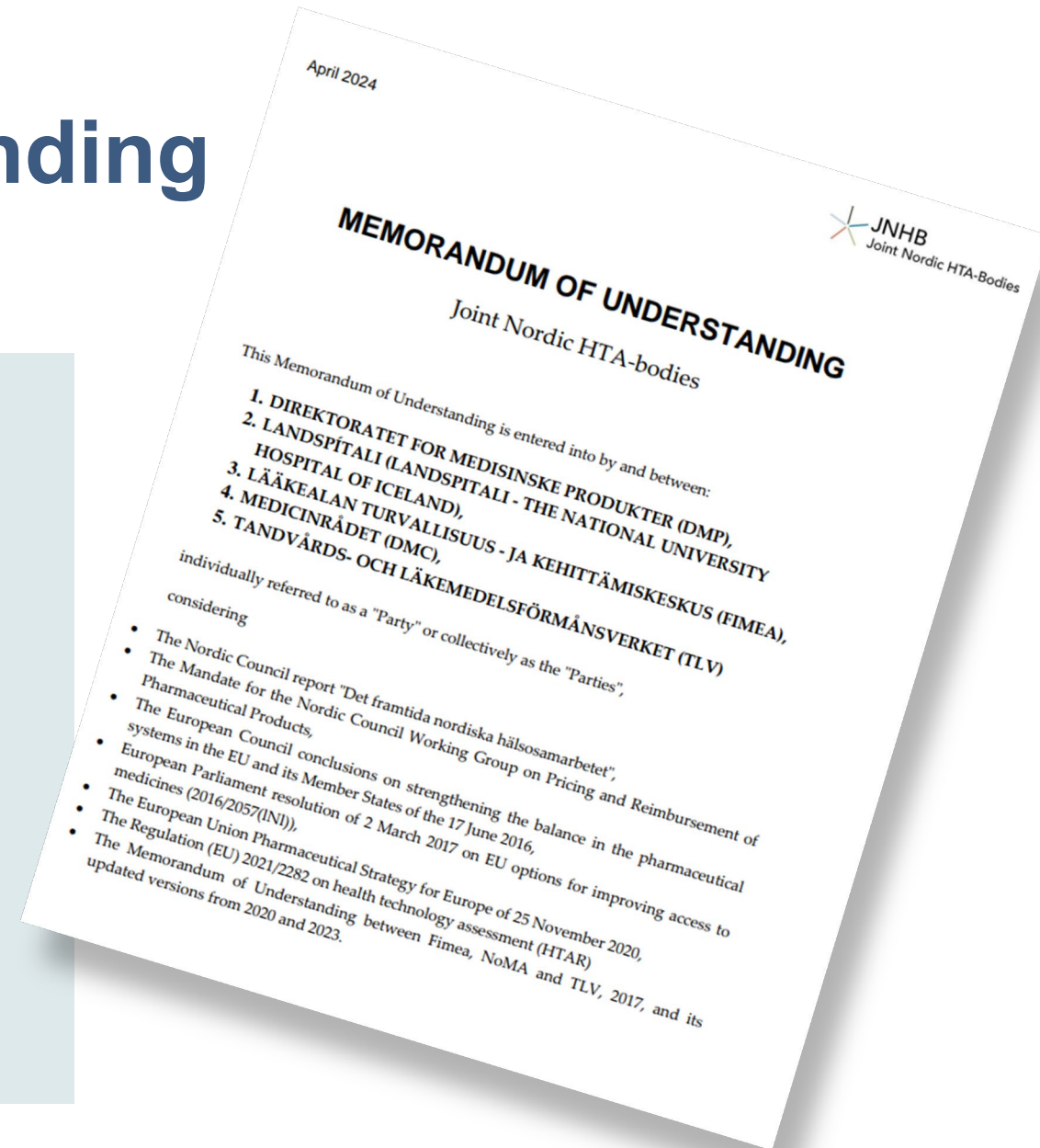


Stockholm April 2024

- **FINOSE initiated as bottom-up initiative from the FI, NO, SE authorities**
- **Launched as a pilot project in March 2018**
- **MoU renewed in April 2024**
- **The Danish Medicines Council enters the collaboration May 2023**
- **Landspítali, The National University Hospital of Iceland enters the collaboration as observers September 2023, full members April 2024**

Memorandum of Understanding

- The basis for the JNHB collaboration
- Defines scope and legal basis
- Defines roles and responsibilities
- Open formulations gives freedom to develop the collaborations



JNHB Waiver of Confidentiality

Allows the HTA agencies to share confidential information during the assessment

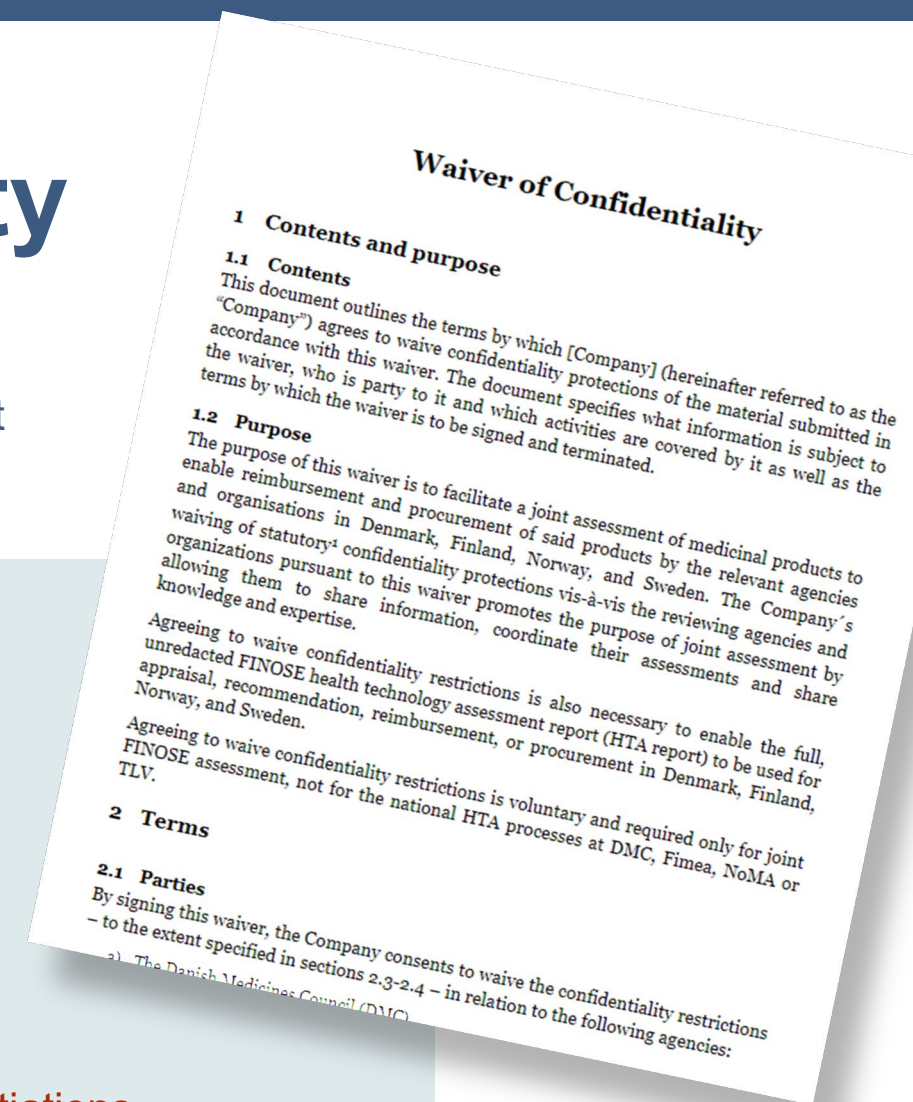
Allows the price negotiating parties to receive the unredacted HTA reports

The HTA bodies:

- The Danish Medicines Council (DMC)
- The Finnish Medicines Agency (Fimea)
- Landspítali - The National University Hospital of Iceland
- The Norwegian Medicines Agency (NoMA)
- The Swedish Dental and Pharmaceutical Benefits Agency (TLV)

Parties involved in price negotiations and/or recommendations:

- Amgros I/S in Denmark
- Representatives of the Finnish university hospitals participating in price negotiations
- Representatives of Landspítali - The National University Hospital of Iceland participating in price negotiations
- Sykehusinnkjøp HF, divisjon legemidler (LIS) in Norway
- The new therapies council (NT-council) in Sweden.



JNHB

Best practice from the Nordic HTA bodies



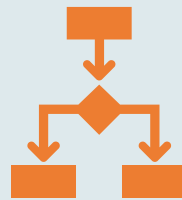
Sharing of resources and knowledge – high quality in assessments



Less divergence in HTA methodologies and evidence requirements



Supports timely and equal access for Nordic patients



Adaption to the JCA-process in the upcoming HTA regulation



Supports joint Nordic price negotiations



A flexible system beneficial for both companies and HTA agencies – single point of contact

- **FINOSE –
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The new JNHB website



About us

Welcome to the Nordic collaboration JNHB

The Nordic collaboration JNHB offers efficient and transparent assessments of medicinal products with a view to reimbursement or procurement in the five countries Denmark, Finland, Iceland, Norway and Sweden

[Read more](#)

[About](#)
[Working with JNHB](#)
[Suitable products](#)
[Assessments](#)
[News](#)

NEWS

June 3 2024

- Launch of JNHB, the Joint Nordic HTA Bodies

[Read more](#)

April 18 2024

- Finose now includes all Nordic countries

[Read more](#)

May 11 2023

- Finose collaboration prolonged and strengthened by entry of the Danish Medicines Council



NEWS

June 3 2024

- Launch of JNHB, the Joint Nordic HTA Bodies

[Read more](#)

April 18 2024

- Finose now includes all Nordic countries

[Read more](#)

May 11 2023

- Finose collaboration prolonged and strengthened by entry of the Danish Medicines Council

[Read more](#)

All relevant documents regarding joint Nordic assessments

Process guideline:

[JNHB process guideline](#)

Submission dossier template:

[Submission dossier template](#)

[Submission dossier template](#)

Q&A:

[Q&A](#)

Waiver of confidentiality:

[Waiver of Confidentiality 2024](#)

[Waiver of Confidentiality 2024](#)

Memorandum of understanding:

[Memorandum of understanding 2024](#)

JNHB - NED collaboration:

[JNHB - NED collaboration June 2024](#)

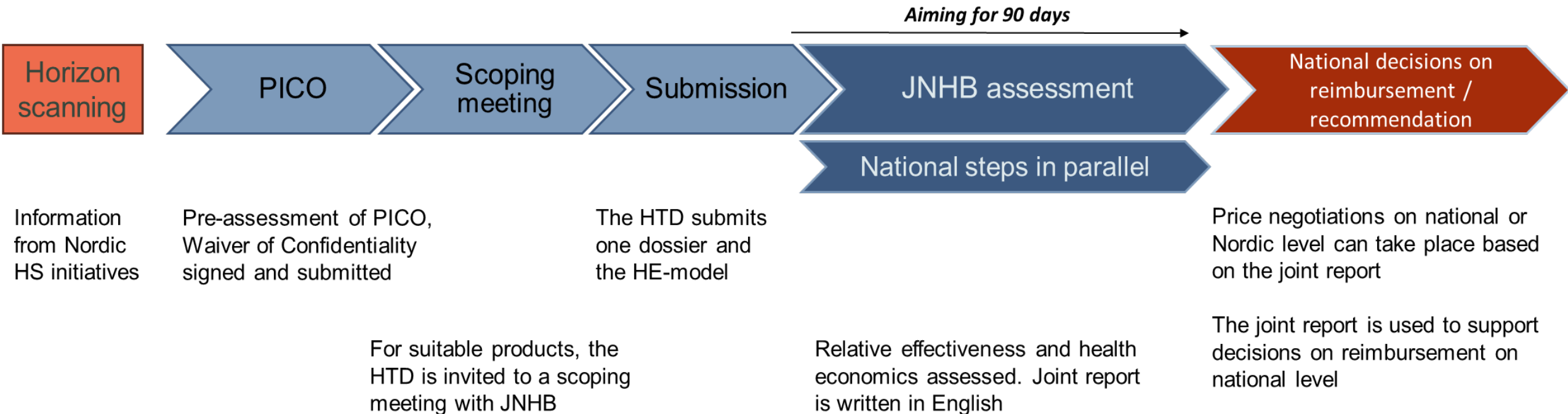
www.jnhtabodies.org

Reach the JNHB-team
via: contact@jnhtabodies.org

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The JNHB process – Joint HTA and national decision making

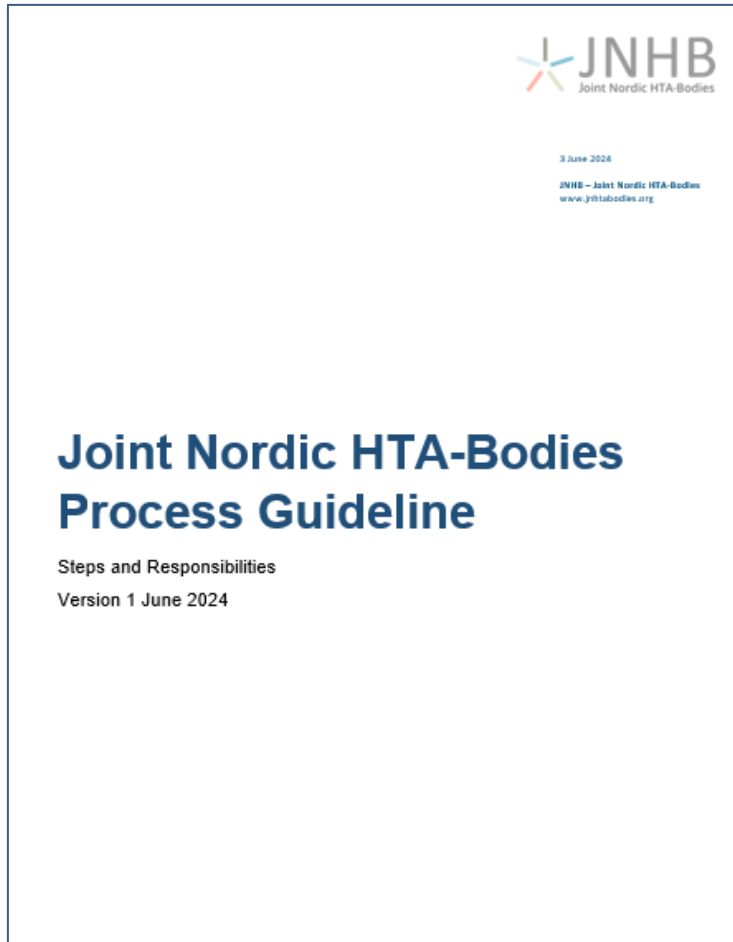


Horizon scanning – Products suitable for joint HTA through JNHB

- Products with similar treatment practices in Denmark, Finland, Iceland, Norway and Sweden,
- Products that require a cost utility analysis, CUA, for the health economic assessment
- Products used in inpatient care
- Products with new active substances
- Extension of indications*
- Products suitable and of interest for joint Nordic negotiations

*From 2024 JNHB will consider assessing extension of indications for suitable products.

JNHB Process Guideline



June 2024




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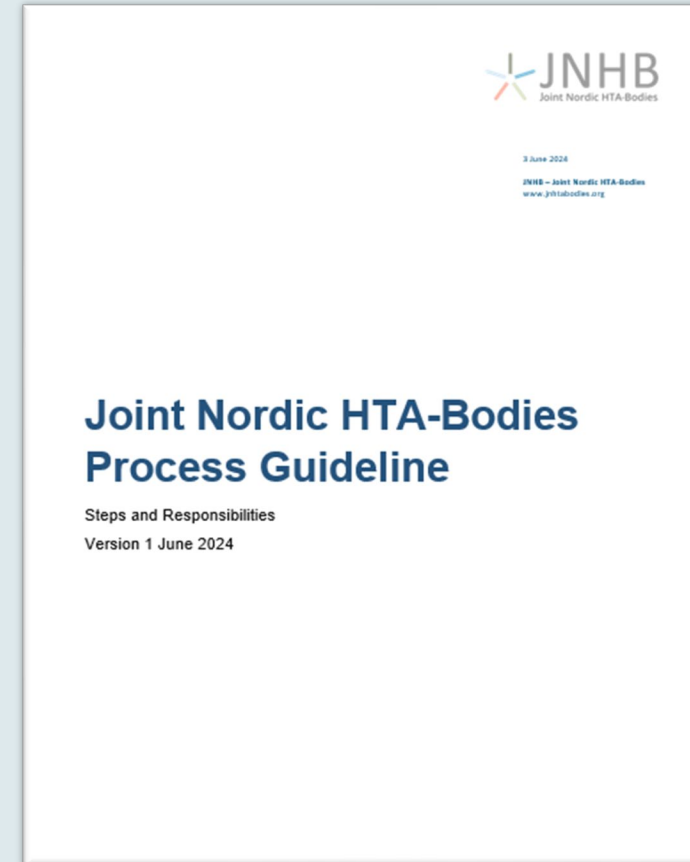
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- Aims to support assessors during the JNHB assessment process
- Increase transparency of the JNHB process for HTDs engaging with JNHB.

JNHB Process Guideline

Contents

- Process descriptions
- How to handle the PICO
- How to build and send the dossier
- Timelines of the assessment
- Roles and responsibilities



JNHB Process Guideline

Roles and responsibilities

- An assessor, a co-assessor and reviewers appointed for each assessment
- The assessor is also responsible of coordinating the assessment
- The assessors share the work based on their availability and preferences
- The reviewers read and comment on the draft reports
- An agency can also be an observer in an assessment, e.g. if the assessment is out of the agency's remit

JNHB Submission Dossier Template

3. June 2024
JNHB – Joint Nordic HTA-Bodies
www.jnhtabodies.org

JNHB Submission Dossier Template

For Health Technology Assessment of Medicinal Products

Version 1 – June 2024

Company	
Medicinal Product (INN, Brand [®])	
Relevant therapeutic indication	
Company contact	<i>Name and email address</i>
Date of submission	

www.jnhtabodies.org

1 (29)

- Aims to describe the content of the dossier needed for a joint Nordic HTA

JNHB Submission Dossier Template

- **Mapping of differences between HTA bodies**
- **Identify differences for which country-specific input may be needed**
 - **Discount rates**
 - **Preference for instrument and source of tariffs for utility values**
 - **Currency**
 - **Prices for medication**
 - **Unit prices for resource use**
 - **Patient time and indirect costs (not included in all countries)**
 - **Budget impact vs. expected sales**
 - **Calculation of severity of the disease**

Country-specific input at a glance

- **Same health economic model structure for all countries**
 - **The submitted model should be flexible and adjustable to all countries**
 - **The model should allow an easy and unambiguous way to get results for each country**
 - **The country-specific input could preferably be included in the form of drop-down menus to allow the assessment team to switch between the settings in the model**
 - **The country-specific input are described in the submission dossier template**
- **No country-specific requirements for:**
 - **Adjustment for background mortality**
 - **Age-adjustment of utility values**

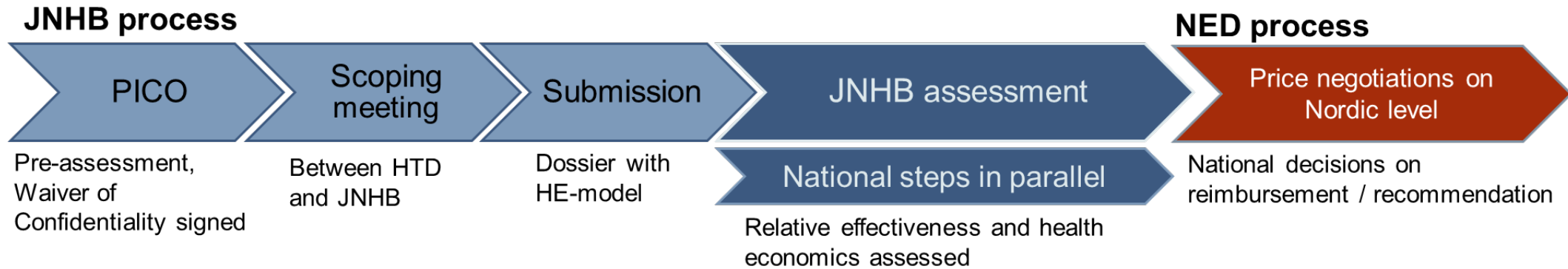
JNHB-report vs. National appendices

- **The JNHB-report will report results with model settings and currency for the HTA body performing the health economic modelling**
- **National appendices**
 - **Summary in national language**
 - **Results in the national currency**
 - **Model settings pertinent to that specific country**
 - **Specific national descriptions**
 - **Calculations related to disease severity**
- **Aim to finalize National appendices simultaneously with the JNHB-report**

Q & A document is available from the webpage

Collaboration between Nordic Pharmaceutical Forum and JNHB

Points of contact between JNHB and New Expensive Drugs, NED throughout the HTA and negotiation processes



1. Horizon scanning

Information from Nordic HS initiatives

Points of contact between JNHB and NED

2. Before assessment-initiation

JNHB gives NED a heads-up that an assessment may be initiated

3. Upon assessment-initiation

JNHB shares preliminary assessment timelines with NED

4. At assessment-finalization

Meeting where JNHB presents conclusions of assessment for NED

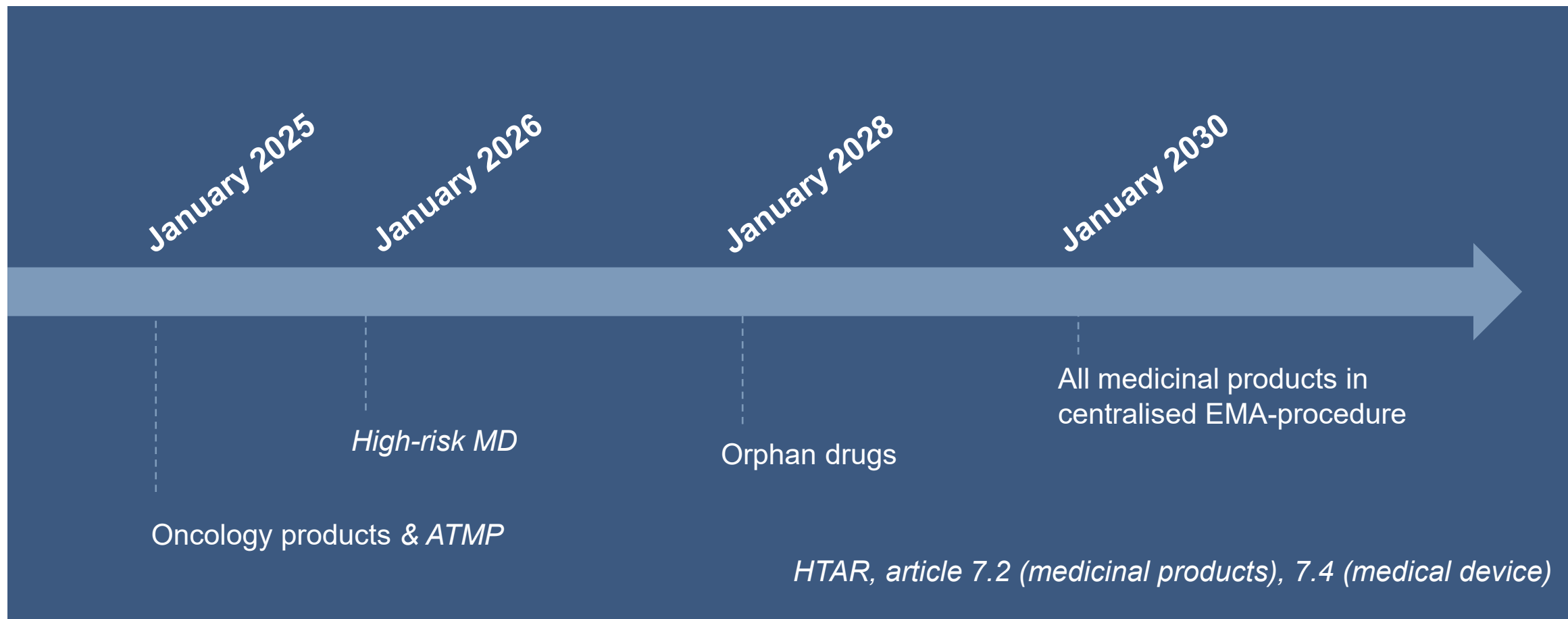
5. At negotiation-finalization

NED informs JNHB whether the negotiations led to an agreement

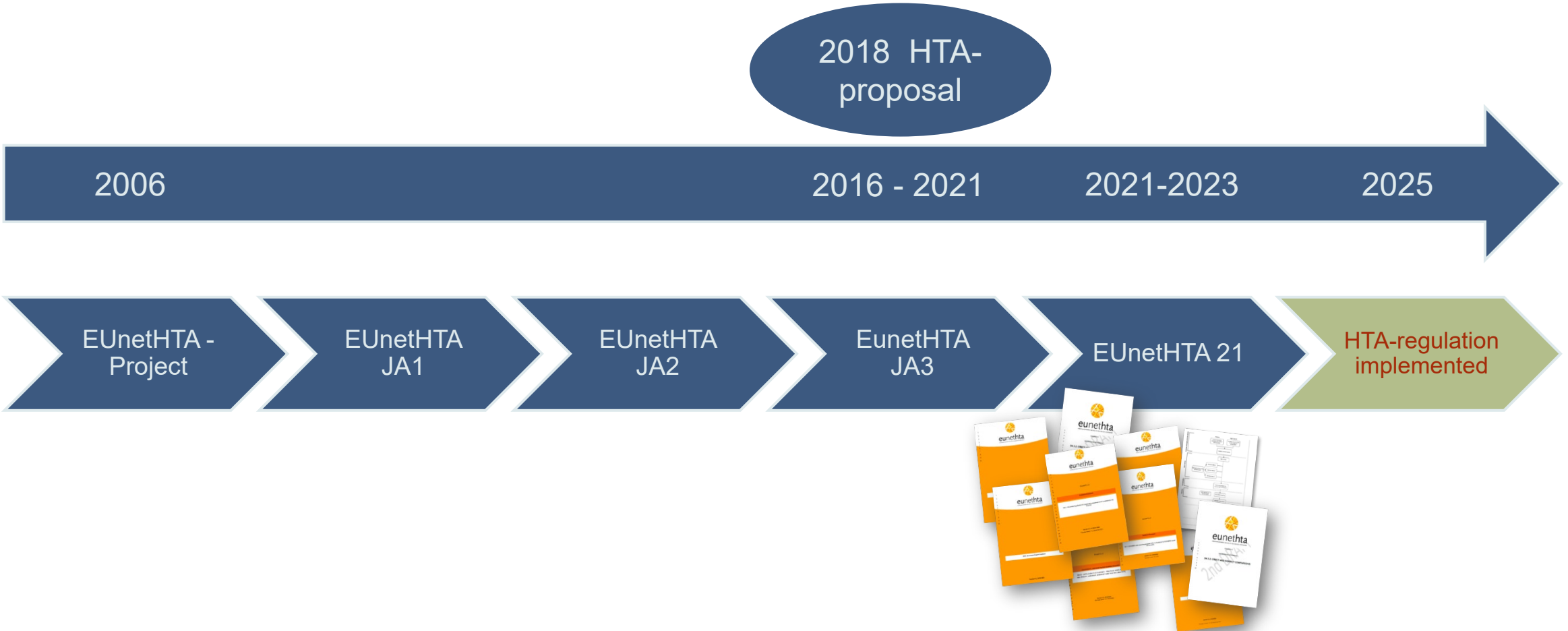
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The HTA regulation will be implemented step-wise starting from January 2025



The History of European HTA Collaboration (EUnetHTA)



Structure of HTA-R work at EU-level



EUROPEAN COMMISSION

(DG-SANTE, HTA-secretariate)

COORDINATION GROUP (CG)

Chair: Roisin Adams (IE)

Co-chair (medicinal products): Niklas Hedberg (SE), Co-chair (medical device): Marco Marchetti (IT)

MPG

Subgroup for Development
of methodological and
procedural guidance

Chair/Co-chair: DE/PT

JCA

Subgroup for Joint Clinical
Assessments

Chair/Co-chair: FR/NL

JSC

Subgroup for Joint
Scientific Consultations

Chair/Co-chair: DE/ES

EHT

Subgroup for Identification
of Emerging Health
Technologies

Chair/Co-chair: DK/IT

COMMITTEE ON HTA

(DG-SANTE, Member state representatives)



Adaptions of JNHB to HTA regulation

- Several JNHB members have had prominent roles in EUnetHTA (JA1-JA3), the EUnetHTA21 tender period and are actively involved in the implementation of the HTAR.
- JNHB members are represented in the Coordination Group and all the sub-groups.
- This extensive experience and involvement can ensure that JNHB is uniquely well prepared for the upcoming implementation of the HTAR in 2025 and we are confident that the transition will not have a major impact on the JNHB processes.

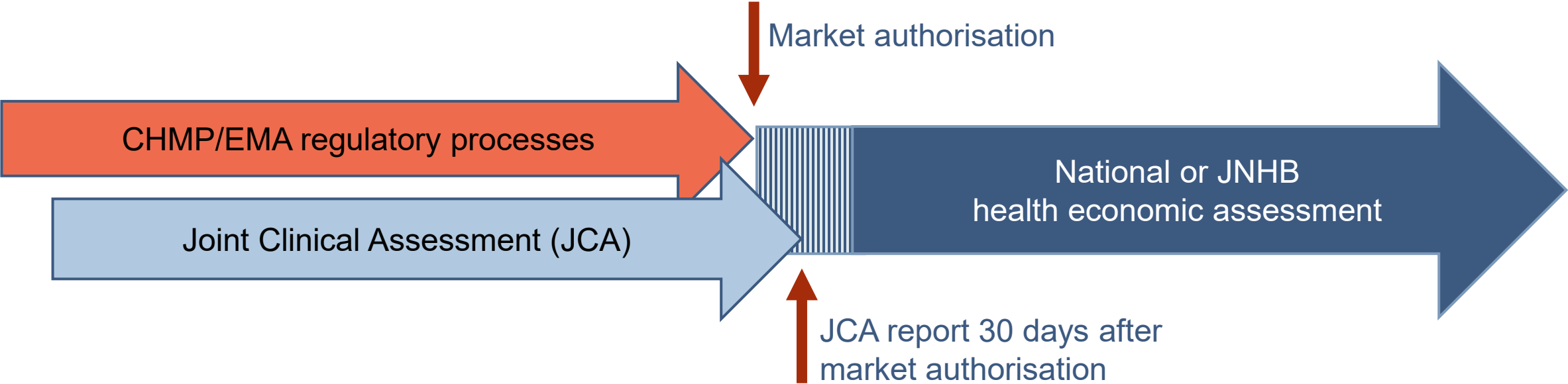


Adaptions of JNHB to HTA regulation

- In line with the intention expressed in the HTAR, JNHB will consider JCA reports as valid documents in a JNHB submission and is committed to avoid duplications of requests to developers.
- JNHB has been a practice ground for pragmatic PICO discussions, and we are confident that our joined participation in the HTAR PICO scoping process will facilitate alignment among the Nordics to the best possible extent.



Adaptions of JNHB to HTA regulation



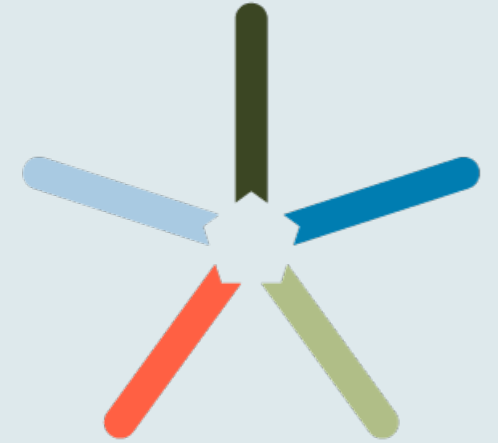
JNHB going forward

- Goals for JNHB
 - Increase the number of joint assessments
 - Decrease divergence in methodology and evidence requirements
 - Improve JNHB process and increase transparency of joint work
- Publication and possibility to comment on JNHB documents
 - Available at website www.jnhtabodies.org
 - Process guideline
 - Submission dossier template
 - Possibility for organisations to comment; 10 June to 10 July 2024, contact@jnhtabodies.org

- **FINOSE –
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Agenda

Questions & More Information



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