NEED
Needs Examination, Evaluation and Dissemination

Needs-driven healthcare policy and innovation

A matter of science, policy and collaboration

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16 October 2024

Background

- First half 2024: Belgian Presidency of the Council of the EU

“Towards a needs-driven approach for innovation and health care policy to better address unmet needs”

- High-level conference:

“Health-related needs as drivers for healthcare policy and innovation”

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KCE
Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

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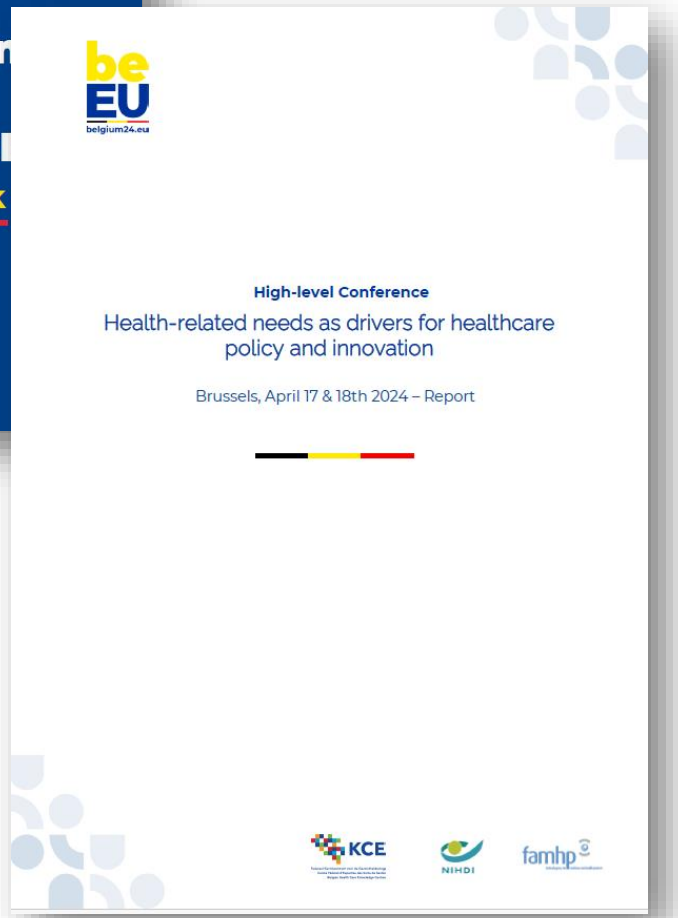
Content

- Presentation of NEED approach
- Outcomes from high-level conference
- EU Council conclusions



Council of the European Union

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NEED: Needs **E**xamination **E**valuation **D**issemination

Current pharmaceutical development framework = supply driven

Identification of financially attractive innovations (expected RoI)

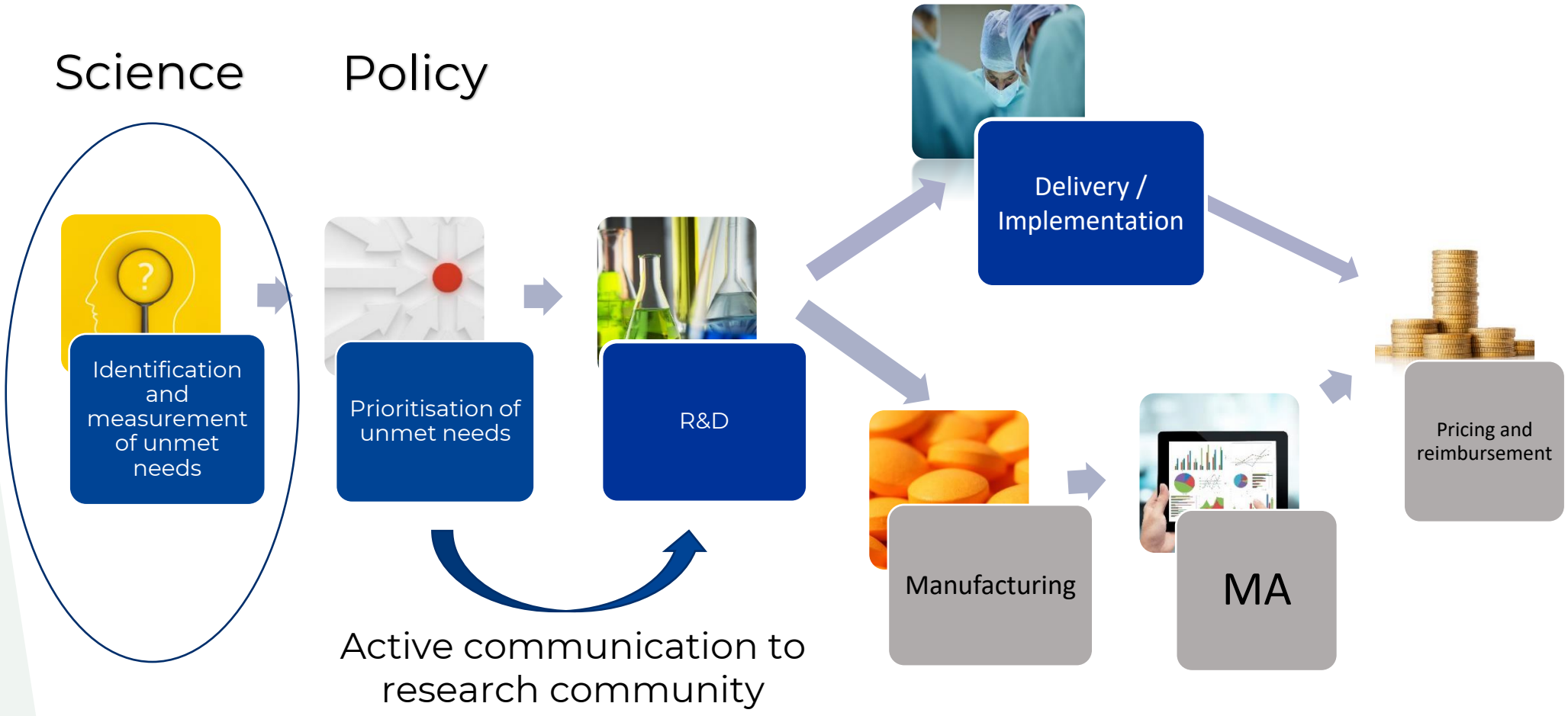
R&D

Manufacturing

Marketing authorisation

Pricing and reimbursement

Desired approach: needs-driven and pro-active



NEED approach: objective

NEED project (**N**eed **E**xamination, **E**valuation and **D**issemination)

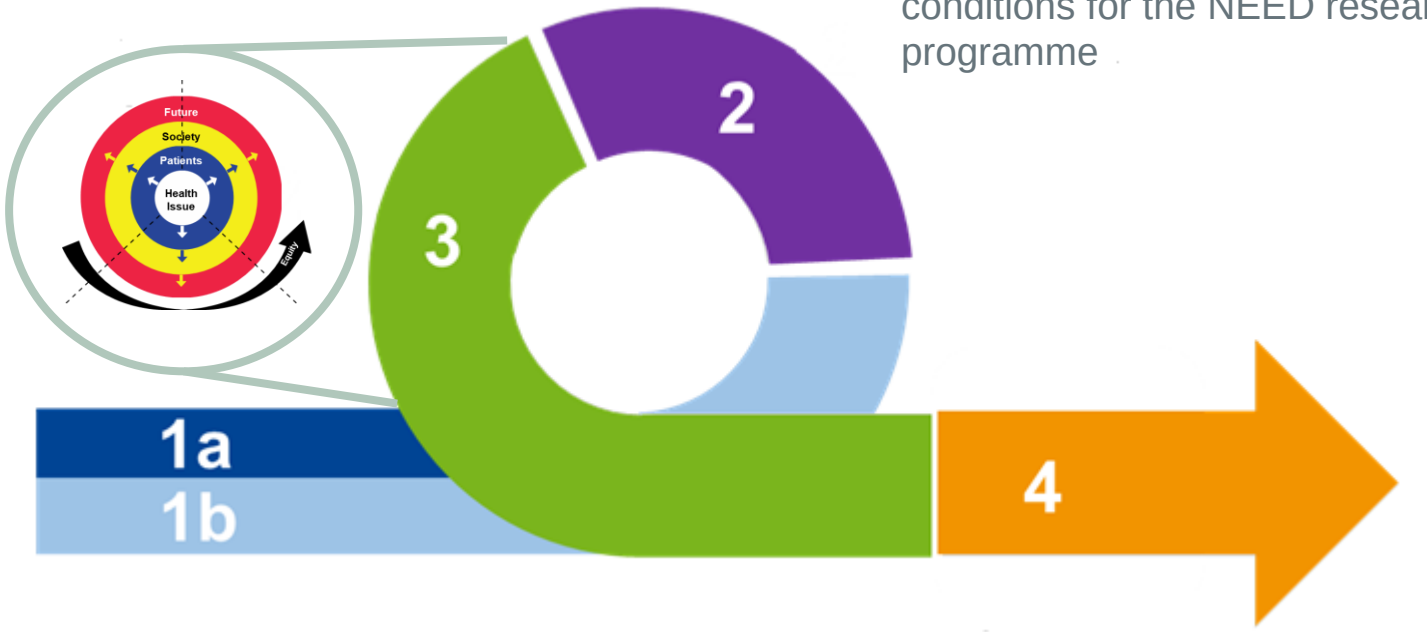
Create an **evidence database on patient and societal unmet needs** in different health conditions, based on **a framework with explicit criteria and indicators for identifying patient and societal unmet needs**

→ Inform & support needs-driven healthcare policy and innovation

Research and dissemination model NEED

Evidence collection on the criteria of the **NEED assessment framework**

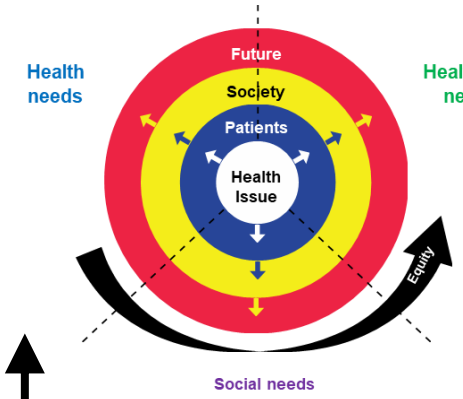
Prioritisation and selection of health conditions for the NEED research programme



- Existing databases
- **Call for topics** from patients/healthcare providers/public

Dissemination of NEED results

The NEED Framework: criteria



Dimensions

Domains	Patients	Society	Future
Health needs	Impact on: • Life expectancy • General HRQoL • Physical health • Psychological health • Autonomy	• Frequency • Transmissibility • Burden on informal caregivers	• Future burden of disease
Healthcare needs	• Effectiveness of Tx • Quality of care • Burden of Tx • Accessibility • Availability of clinical evidence	• Preventability • Value for money of standard of care	• Future economic burden
Social needs	Impact on: • Social life • Education • Work • Financial consequences	• Productivity losses • Environmental impact of standard of care	

Equity

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NEED database

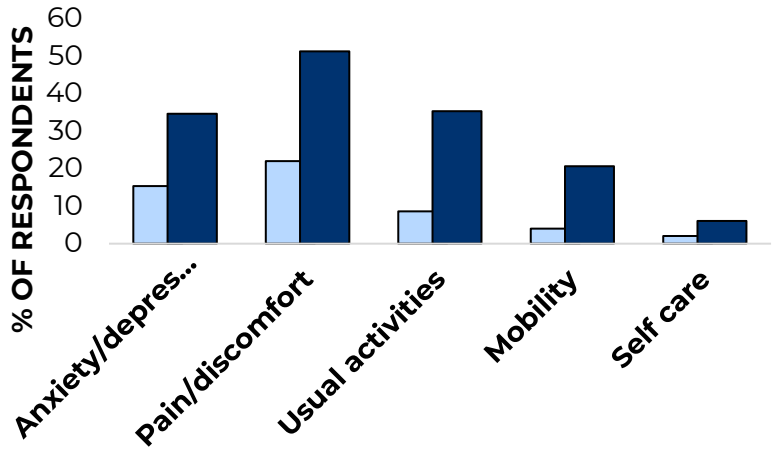
Health needs

Healthcare needs

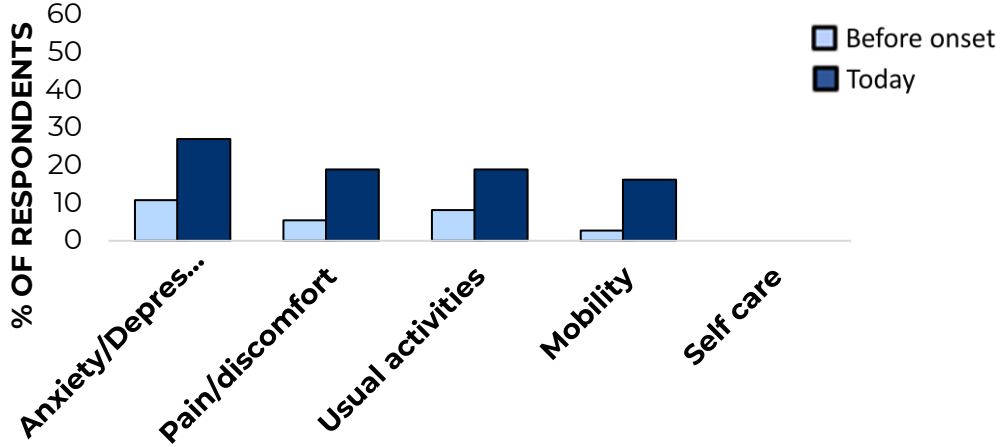
Social needs

Impact on general HRQoL

Crohn's disease



Melanoma



Accessibility of care

- **Crohn's:** 13% of those surveyed did not always receive care when they needed it
- **Melanoma**: 50% waited >3 months before consulting

Impact on work

- **Crohn's**: 45% reduced work or stopped working
- **Melanoma**: 20% reduced work or stopped working

https://healthinformation.sciensano.be/shiny/NEED/

High-level conference Belgian Presidency

Health-related needs as drivers for healthcare policy and innovation

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Conference programme

Session 1	Assessing disease-specific health-related unmet needs: creating the evidence base
Session 2	Steering innovation: smart research funding and regulatory incentives
Session 3:	A needs-driven approach is a holistic approach
Session 4:	Towards needs-driven health care systems

Closing session – High-level debate

Full report published: [EU presidency high-level conference: brochure & report (health-needs.eu)]

Scientific evidence base

Needs-driven system ≠ **demand**-driven system

- Move away from **supply-driven** approach and **emotions**

Urgent **need for scientific evidence** on unmet health-related needs

- **Evidence-based choices** require evidence
- Regional **variations** in needs and hence possible solutions

Rare diseases

- Rare ≠ high unmet need
- Focus on rare diseases is a political choice

Holistic approach

- medical needs → health-related needs (incl psychosocial)
- physical diagnostic models not applicable to **mental health**

Lifecycle approach

Lifecycle approach is needed, involving

1. the **identification** of the highest unmet needs on the individual and on the societal level
2. the creation of **smart and predictable** incentives towards health technology developers to steer R&D activities towards the highest needs
3. approval and reimbursement processes that take **performance** of new products on these needs into account

This requires a strong **collaboration** at the EU level:

- Identification of unmet needs in different regions / countries
- Focus on equity, rights, values
- Co-creation with patients, early engagement with patients: *"Patients often prefer management strategies over medication"*

Paradigm shift regulatory decision // reimbursement decision (HTA)

Evidence requirements

- Almost 60% of new drugs have not provided proof of added therapeutic value at MA (*Wieseler et al., BMJ, 2019*)
  → better alignment of **evidentiary requirements** regulatory and HTA level needed
- Coordination of public funding of **research and solutions** to unmet needs

Regulatory barriers & inequalities ➔ challenges to implementing solutions
(e.g. orphan devices)

- Breaking the silos

Incentives pharma legislation, scientific policy, pricing and reimbursement to be improved ito cost-effectiveness and evidence requirements

- maintaining **simplicity** in the system and **guiding** developers

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EU HTA Regulation

Unmet needs in the EU HTA Regulation (clinical assessment only!):

- Art 7: criterion for **choosing medical devices** to be assessed
- Art 17: criterion for **selecting products for JSC** → discuss whether evidence going to be provided incorporates outcomes that address unmet needs
- Art 22: criterion for **identifying emerging health technologies**, with potential of doing **assessment early**
- Voluntary cooperation: how to assess "impact on patients, public health and healthcare systems"

… but no definition provided in the HTA Regulation

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“Gearing the system towards the most pressing needs is complex and we have to cope with an existing ecosystem. This won’t be easy as it involves complex ethical and conceptual issues, but it is badly needed.”

Minister F. Vandenbroucke

Council conclusions

Council conclusions (9900/24)

- Set up independent needs-evidence database, identifying patient and societal needs using scientific approach
- Set up member-state driven mechanism for appraisal & prioritization of highest needs
- Different types of (health) interventions may provide solutions to identified patient and societal needs
- Use the evidence in research funding programmes, at EU and national level.

https://data.consilium.europa.eu/doc/document/ST-9900-2024-INIT/en/pdf

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- For more information, please visit: https://www.health-needs.eu
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Thank you for your attention

The NEED team and its partners