CBG MEB
MEDICINES EVALUATION BOARD

MEB Science Policy 2025-2029

Marjon Pasmooij

GOOD MEDICINES USED BETTER

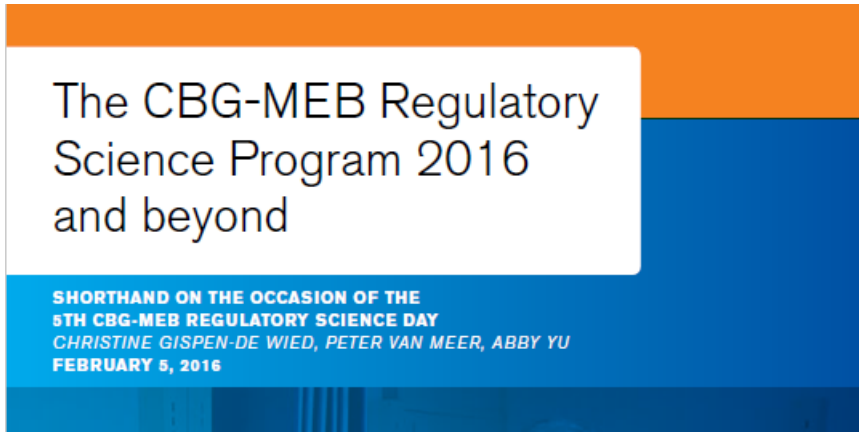
Regulatory Science

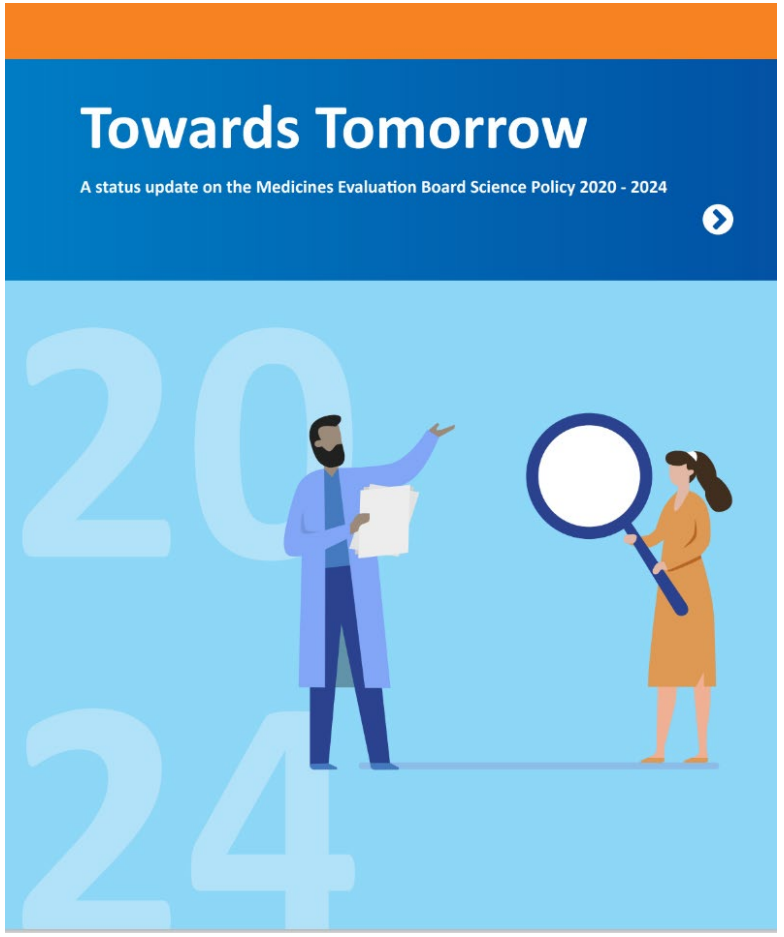
Regulatory Science is an **applied science** which, via various scientific disciplines, assesses internal regulations and policy in relation to the assessment of the entire life cycle of medicines.

New insights contribute to 'evidence based regulatory practice': It involves answering questions such as: ***are we doing things properly, do adjustments need to be made on the basis of new knowledge and are we prepared, based on our current knowledge and expertise, for change and innovation?'***

Regulatory Science also aims to **develop and improve instruments, standards and methods** used to assess medicines in terms of efficacy, risks and quality and **improve and innovate of the system** as a whole.

Regulatory Science since 2011…



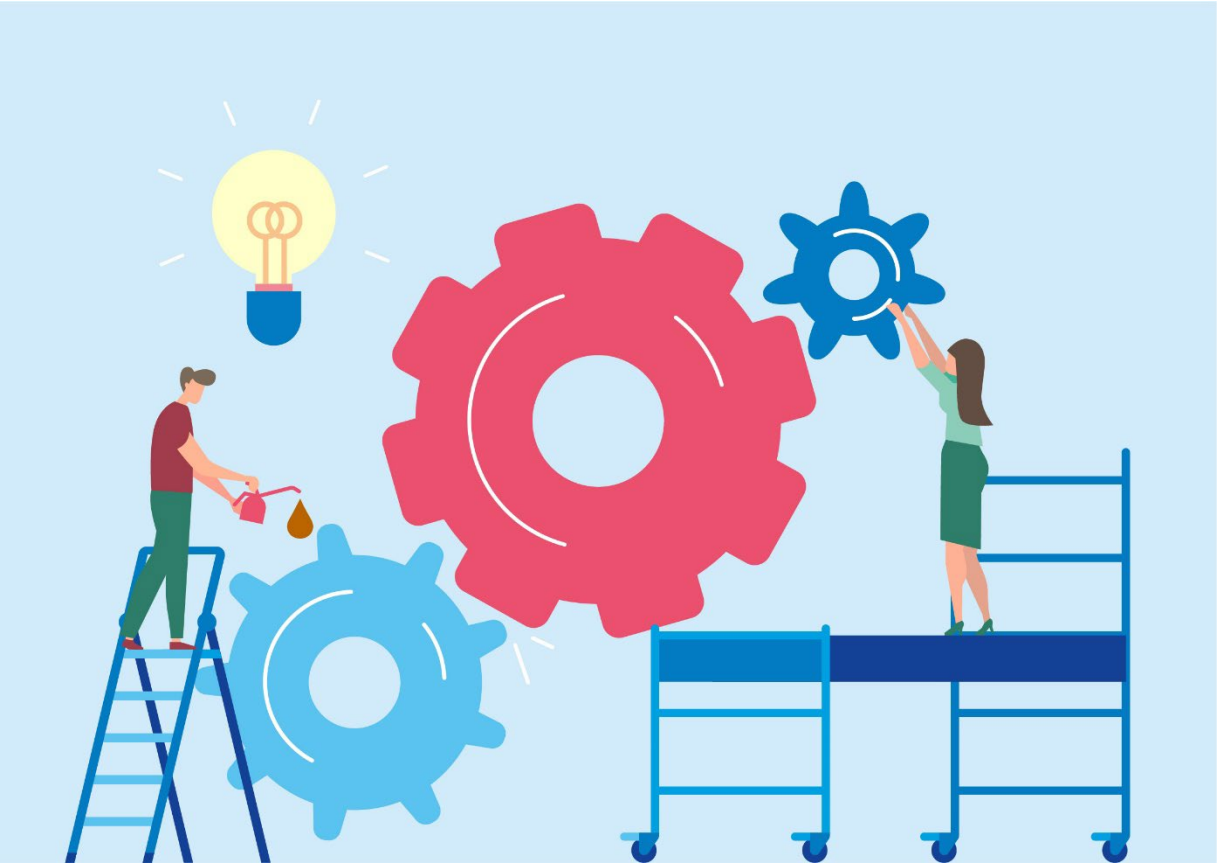


Regulatory Science research

We apply two guiding principles for our scientific activities:

1) system improvement (including optimisation and deregulation) and

2) innovation that adds value to the role and responsibilities of the MEB (modernisation).



PhD students (internal + external)

Naam
Anne Taams

Naam
Audrey Hermans

Naam
Bram Storosum

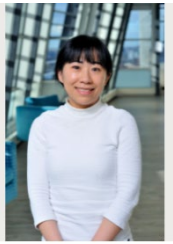
Naam
Britt Duijndam

Naam
Christine van Hattem

Naam
Doerine Postma

Naam
Donya Moslemzadeh

Naam
Emma van Dijk



Naam
Tzu Chien

Naam
Loes den Otter

Naam
Loes Maton

Naam
Lucina-May Nollen

Naam
Lysbeth Bakker

Naam
Njeri Kamau

Naam
Noa Rosenberg

Naam
Pieter Annema

Naam
Puck Roos

Naam
Esther Lubberts

Naam
Fabian Windführ

Naam
Geeske Grit

Naam
Jose Gepanaga

Naam
Rafaella Buzatu

Naam
Renske Grupstra

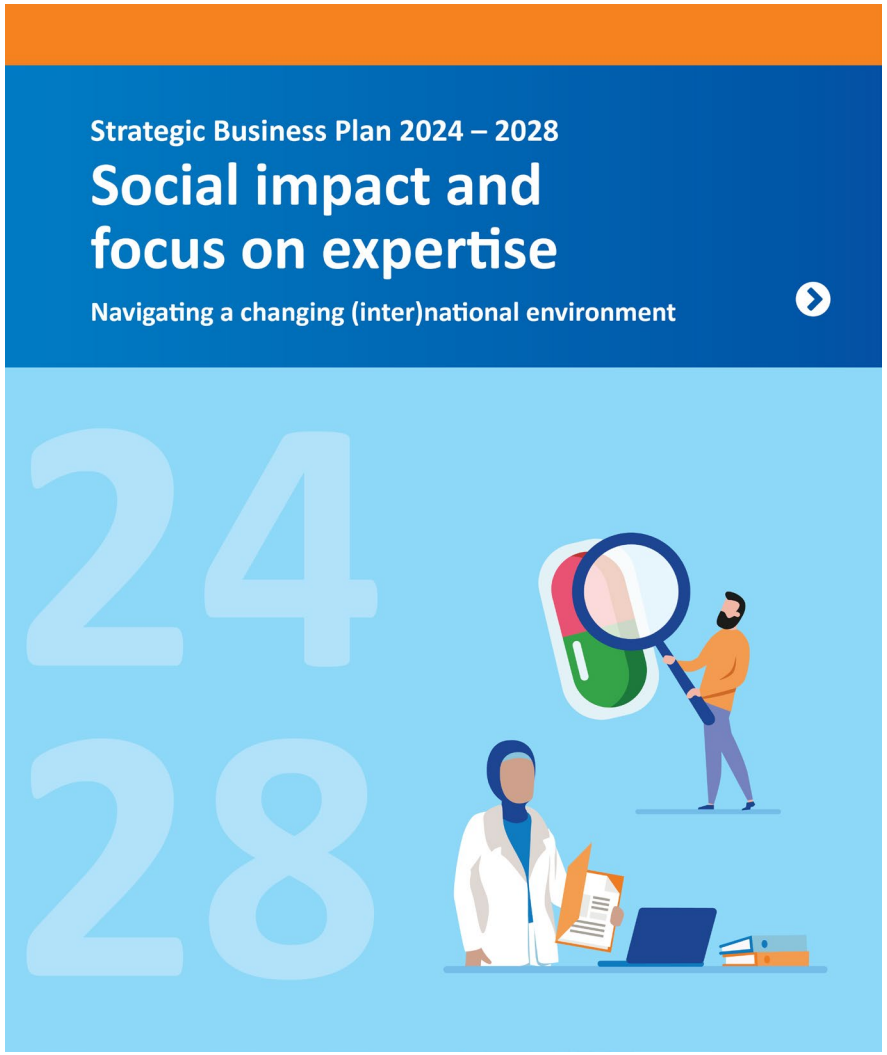
Naam
Sem Cohen

Naam
Sharon Essink

Naam
Stefan Verweij

26 PhD students

Focus themes 2025-2029



Replacement, reduction & refinement of animal studies

Data-driven assessment

Personalised medicine

New pharmaceutical legislation

Replacement, reduction and refinement of animal studies (3Rs)

- Evaluates the added value of animal research in medicine development, as animal studies are not always translatable or necessary.

- Contributing to reducing the number of animals used in research.

    - Applicability of alternative models
    - Need for Animal studies in International Guidelines

- EMA 3Rs working party and EMA non-clinical working party

- National Growth Fund projects (Oncode Accelerator, Centre for Animal-free biomedical translation, NXTGen Hightech)

Data-driven assessment

- Real-World data
- Patient experience data and patient participation
- Model-informed decision-making
- European Medicines Regulatory Database

"The MEB will actively pursue broader collaboration with patient organisations and representatives in our scientific regulatory projects"

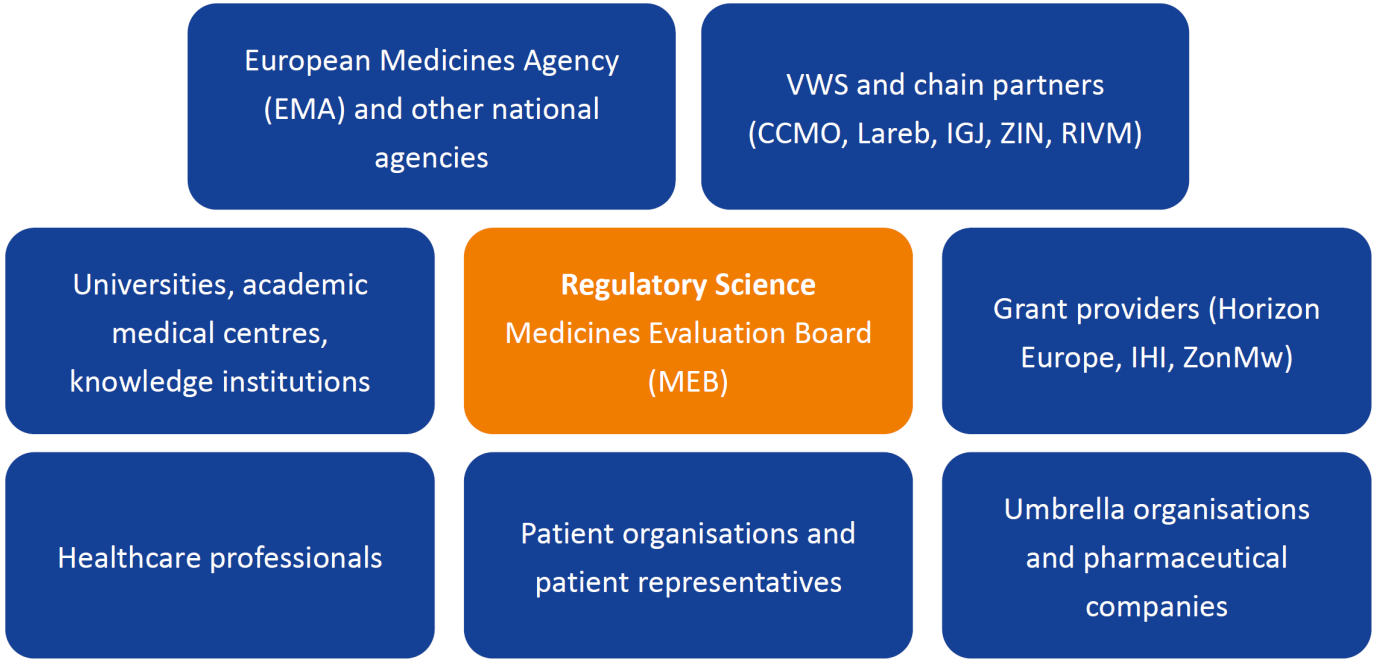
Personalised medicine

- Advanced Therapy Medicinal Products (ATMPs)
- Technological innovations
- Biomarkers
- Rare diseases

New pharmaceutical legislation

- On 26 April 2023 the EC published proposals to revise the EU pharmaceutical legislation.
- New concepts are introduced such as platform technologies, adapted frameworks and regulatory sandboxes.
- Practical implementation e.g. through new EMA guidelines.
- MEB will focus on system-level research how the proposed measures can be operationalized -> optimal implementation of the new legislation.

Collaboration



EMA-HMA European Platform for Regulatory Science Research

Barbier et al., Nat Rev Drug Discov, 2025

MEB Science Policy 2025-2029

Regulatory Science LinkedIn

Or www.cbg-meb.nl

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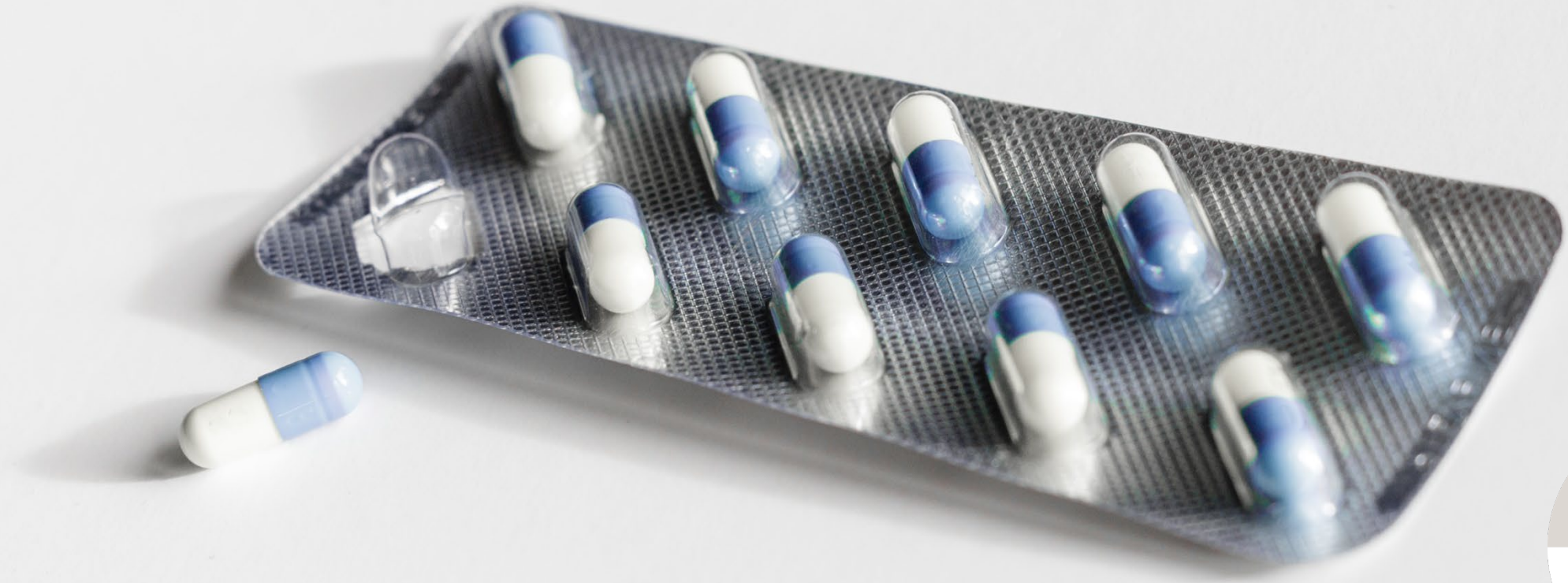

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