

From expertise to impact: Science as the foundation for regulatory innovation

Science Policy 2025-2029



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Foreword

The Medicines Evaluation Board (MEB) grounds its statutory tasks in scientific evidence. Science therefore forms the foundation of our work: assessing the efficacy, safety, and quality of medicines for humans and animals, as well as providing scientific advice.

In a world where technological and societal developments follow one another in rapid succession, it is essential that we, as an organisation, continue to learn, innovate, and reflect. Regulatory science supports us in this. It enables us to contribute through scientific research to both the quality of our assessments and the development of the regulatory system as a whole.

With this science policy, we set the course for our scientific strategy in the coming years. We are building on previous efforts and choosing to deepen our focus on four central themes. At the same time, we maintain the flexibility to respond to questions arising from the assessment process or from our national and international networks.

We invest in the development, embedding, and practical application of knowledge. We aim to translate research findings into our daily practice, as much as possible. And we do not do this alone. We are committed to strengthening and expanding collaboration with fellow authorities, universities, patient organisations, umbrella organisations, and European partners. Our goals are also achieved thanks to the contributions of (PhD) students and through participation in scientific advisory committees within research projects with a regulatory component. In this way, we collectively contribute to a future-proof assessment process and to safe, effective medicines for everyone who needs them.

We thank all those who contributed to the development of this science policy. We look forward to continuing to build – together – a solid scientific foundation for our work in the years ahead.

Ton de Boer
Chair

Paula Loekemeijer
Secretary of the Board and Director of the Agency

Summary

Scientific foundation

At the Medicines Evaluation Board (MEB), science and scientific data form the foundation of our statutory tasks. These tasks include assessing the efficacy, safety, and quality of medicines for humans and animals, as well as providing scientific advice to pharmaceutical companies and academic research groups. We strengthen this scientific foundation by conducting research in the domain of ‘regulatory science’.

In addition to researching the questions that influence the assessment of a medicine’s efficacy, risks, and safety, we investigate issues concerning the regulatory system itself. In doing so, we apply two guiding principles: 1) system improvement (including optimisation and deregulation) and 2) innovation that adds value to the MEB’s role and responsibilities (modernisation).

Strategic Business Plan

This science policy is a further elaboration of the strategic directions set out in the Strategic Business Plan 2024-2028 (SBP), specifically with regard to scientific developments. It also builds upon the previous MEB Science Policy 2020-2024. The topics and focal points from these policy documents, enriched by internal consultation and external exploration, have served as the starting point. This policy is written in relation to both the national and international context in which the MEB operates, as well as the developments taking place in the field of regulatory science.

Themes

In recent years, many changes have occurred – for medicines authorities, healthcare providers, patients, and the pharmaceutical industry alike. These developments will continue in the years ahead. To remain responsive to these changes and continue delivering high-quality work, the MEB has decided, in the SBP 2024-2028, to focus more strongly on specific areas of expertise. This greater focus is also reflected in the science policy, which has led to the identification of four main themes in the coming years, the MEB will commit to working on these four themes. However, as the MEB also wishes to remain flexible in responding to other developments that may significantly impact our responsibilities and public health, the themes below are intended as guides and are not exhaustive.

- 1. Replacement, reduction, and refinement of animal studies (3Rs)**
- 2. Data-driven assessment**
- 3. Personalised medicine**
- 4. New pharmaceutical legislation**

Foresight

We remain prepared for new developments that may influence the assessment process, with foresight and context analyses, including collaboration with the EU Innovation Network. The organisation of pipeline meetings further contributes to this effort.

Developing and securing knowledge

To make the most of knowledge from regulatory science, we invest in the development, continuity, and sharing of knowledge – both internally and within our network. This includes considering the implementation of results from the start of a research project. We also systematically evaluate whether outcomes contribute to our statutory duties. In addition, we actively follow relevant external research in the field of regulatory science, ensuring that important findings are brought into the organisation and applied in practice.

Collaboration

Regulatory science is embedded in an international network. That is why we collaborate extensively on scientific activities with academic groups, chain partners, other knowledge institutions, and fellow authorities (such as national medicines authorities and the European Medicines Agency). We also place great value on involving patient organisations and patient representatives in scientific projects, to enhance the relevance and applicability of research outcomes.

A recent example is the European Platform for Regulatory Science Research, which promotes collaboration among not-for-profit organisations across Europe and beyond. We also participate in various public–private partnerships, such as the Regulatory Science Network Netherlands (RSNN) and Innovative Health Initiative (IHI) projects, which also include patient representatives and pharmaceutical umbrella organisations. Through continuous collaboration and knowledge exchange within our network, we are able to implement solutions that make medicines regulation faster, more efficient, and more adaptable.



1 MEB and science

Everyone who uses a medicine should be able to trust it. As an independent medicines authority, the Medicines Evaluation Board* (MEB) advises on and assesses the efficacy, safety, and quality of medicines for both humans and animals. This applies to medicines in the Netherlands, and – together with our European counterparts – to medicines in Europe. The MEB also promotes the appropriate use of medicines by the right patients. We do this in the interest of public health.

1.1 Scientific foundation

Scientific is one of the MEB's three core values. Science and scientific data form the foundation of our statutory tasks. Scientific analysis of data is central to weighing the benefits and risks of medicines during the assessment process. Innovations in how the MEB evaluates and regulates medicines are likewise grounded in scientific insights.

In addition, providing scientific advice to pharmaceutical companies and academic research groups is an important statutory responsibility. This advice can cover the entire product lifecycle – from pharmaceutical quality aspects and the preclinical research phase to post-marketing variation proposals.

* Where reference is made to the MEB, this refers to both the [Medicines Evaluation Board Agency](#) and the [Medicines Evaluation Board](#). This Science Policy is supported by both the agency and the Board.

To fulfil this core (legal) task, an independent scientific basis and access to scientific data are essential. Ensuring knowledge continuity and staying up-to-date with new developments are therefore of critical importance to the MEB.

The knowledge gained during assessments contributes to building expertise among our staff. During the assessment process, our staff also have the opportunity to consult external experts on the latest scientific or technical developments. We play a prominent role in various European scientific committees and working groups, further supporting the exchange of (scientific) knowledge. Scientific-knowledge development thus takes place to a large extent during the assessment process itself.

WE APPLY TWO GUIDING PRINCIPLES FOR OUR SCIENTIFIC ACTIVITIES: 1) SYSTEM IMPROVEMENT AND 2) INNOVATION

At the same time, the assessment process gives rise to research questions that go beyond individual dossiers and affect the medicines evaluation system as a whole. As an organisation, we must find regulatory responses to new scientific developments. As stated in the [MEB Strategic Business Plan 2024-2028](#) (SBP)¹ assessment processes are becoming increasingly complex. Many new medicines use emerging technologies – for example, nanotechnology, gene technology, mRNA technology, and immunotherapy. The MEB is also receiving more applications involving medical devices with a medicinal component or in vitro diagnostics linked to a medicine. Additionally, personalised medicines are on the rise, and there is increasing use of novel technologies and data sources, such as real-world data and artificial intelligence (AI).

We therefore reinforce our scientific foundation by conducting research in the domain of **regulatory science**. In addition to researching questions that influence the evaluation of efficacy, risks, and safety of medicines, we explore issues related to the regulatory system itself. 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).

Regulatory Science is an applied scientific discipline that, drawing on various academic fields, evaluates existing regulations and policies related to the assessment of the entire lifecycle of medicines. By providing insights, it contributes to evidence-based regulatory practice: *are we doing the right things? Do we need to make adjustments based on new knowledge? Are we – with our current knowledge and expertise – prepared for change and innovation?* Regulatory science focuses both on the development and improvement of the tools, standards, and methods used to assess medicines in terms of efficacy, risks, and quality, and on the enhancement and innovation of the regulatory system as a whole.

1.2 Objective

The scientific activities of the MEB serve multiple purposes:

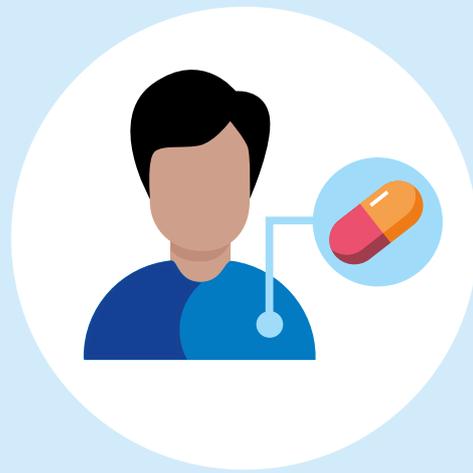
- **To continue to ensure the availability and accessibility of medicines for patients** by having the latest scientific insights, innovations, tools, and expertise for the high-quality assessment of medicines.
- **To innovate and improve our regulatory system** through continuous evaluation of existing regulations and by influencing international guidelines and policies.
- **To safeguard the future-readiness of the organisation** by anticipating and contributing to new and innovative developments.
- **To embed and secure knowledge in our work** by translating scientific insights and results into daily (assessment) practice.
- **To inspire and support the development of (potential) staff** by enabling them to combine research, supervisory, or teaching activities with assessment work.
- **To combine our internal expertise with the knowledge and capabilities of academic groups and other knowledge institutions** by contributing to a strong (inter)national scientific and regulatory network.

WE ENSURE THAT OUR EFFORTS IN
THE FIELD OF REGULATORY SCIENCE
BENEFIT THE (INTER)NATIONAL
NETWORKS IN WHICH WE OPERATE

To achieve this, we invest in our staff, scientific education, and research, which is based on this multi-year science policy. In this policy, the MEB sets out the role and importance of science for the organisation, the themes in which we invest, how we implement scientific results, and the means by which we do so. The policy provides guiding frameworks for the years ahead.

1.3 Development

This science policy is a further elaboration of the strategic directions outlined in the SBP, specifically regarding scientific developments. It also serves as a continuation of the [MEB Science Policy 2020-2024](#). Using the topics and focus areas from the 2020-2024 science policy and the SBP as a starting point, the MEB additionally conducted an internal consultation and an external exploration to further shape this policy. The policy is written in relation to both the national and international context in which the MEB operates and in relation to ongoing developments in the field of regulatory science. We have taken into account the developments and plans of, among other parties, the Ministry of Health, Welfare and Sport (VWS), the European Medicines Agency (EMA)^{2,3,4,5} the Heads of Medicines Agencies (HMA), and the International Coalition of Medicines Regulatory Authorities ([ICMRA](#)). Investment in knowledge through regulatory science features prominently on the agendas of organisations such as the EMA and the US Food and Drug Administration ([FDA](#)). We ensure that our efforts in the field of regulatory science benefit the national and international networks in which we operate.



2 Themes

In recent years, many changes have occurred, affecting medicines authorities, healthcare providers, patients, and the pharmaceutical industry alike. These developments are expected to continue in the years ahead. To remain responsive to these changes and continue delivering quality, the MEB has decided, in its SBP 2024-2028, to place greater focus on specific areas of expertise. This increased focus is also reflected in the science policy, resulting in four main themes: (1) replacement, reduction, and refinement of animal studies (the 3Rs), (2) data-driven assessment, (3) personalised medicine, and (4) new pharmaceutical legislation. Over the coming years, the MEB will invest in these four themes. The themes are interconnected, with overlaps between them, and they apply across various domains of the medicine lifecycle (pre-registration, registration, and post-registration phases).

For all of these themes, the MEB – together with its fellow regulatory authorities – must formulate regulatory responses to the related developments. The reduction of animal testing, the use and handling of data, a more personalised approach to health, and changes in laws and regulations are just a few examples. The new European legislation, data-driven approaches, and other technological innovations will have a major impact on the organisation. These developments require us, as an organisation, to continuously scrutinise and improve our assessment system. For each theme, we clarify what we aim to achieve in the coming years and how science connects with regulatory activities across the relevant domains.

Through regulatory science, the MEB also aims to remain flexible in responding to other developments that may significantly impact our mandate and public health, as was the case during the COVID-19 pandemic. The MEB considers it important to base its research programme on questions arising from within the organisation and our (international) regulatory network. The themes described below are therefore intended to guide and are not exhaustive. Research questions arising from the assessment process may warrant further investigation, even if they do not align directly within the described themes. After all, we want to ensure that our staff are equipped with relevant and up-to-date scientific knowledge, so that we can perform our core tasks to the highest possible standard.



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

The development of medicines for both humans and animals involves research using laboratory animals. The MEB critically assesses the evidential value of animal testing, as animal studies are not always translatable or necessary. In addition, the MEB considers it important to contribute to reducing the number of animals used in research. For these reasons, we conduct research into the applicability of alternative models to assess the efficacy and safety of medicines. We also evaluate the necessity of animal studies as described in international guidelines. Furthermore, we identify the most efficient methods of safety assessment for new classes of medicines, aiming to minimise the use of animal studies and deploy alternative, non-conventional research methods, such as organoids, computer models, and human tissues and cells. Our goal is to move towards a scenario in which animal testing is only conducted when it demonstrably adds value.

We realise this ambition by conducting research at the MEB on the replacement, reduction, and refinement of animal studies. These so-called 3Rs aspects are discussed at the European level in the EMA 3Rs working group and the EMA non-clinical working group, where we also contribute to the development of guidelines. Internationally, we collaborate on ICH guidelines, drawing on the knowledge we have acquired. In the coming years, we will focus on 3Rs research in collaboration with various national and international research partners and consortia. This includes participation in national Growth Fund projects such as [Oncode Accelerator](#), the Centre for Animal-Free Biomedical Translation ([CPBT](#)), and [NXTGEN Hightech](#). The results of our 3Rs research are also used during the scientific advice procedure, when companies or academic groups ask questions about a medicine's development plan and the associated use of animal studies. Our research in the field of the 3Rs significantly contributes to the reduction of animal testing in regulatory frameworks at the international level.

2.2 Data-driven assessment



Real-world data

While clinical trials remain necessary for assessing the efficacy and safety of medicines, the complementary role of real-world data (routinely collected data related to patients' health status and the care that they receive) is becoming increasingly important in the context of medicine authorisation and pharmacovigilance. [DARWIN EU](#) provides evidence from European real-world databases on diseases, populations, usage, efficacy, and safety of medicines. The intention is for DARWIN EU to eventually connect the regulatory network with the [European Health Data Space](#), which is expected to further increase the use of health data.

The EMA has recently published guidance on the use of real-world data as real-world evidence^{6,7} (evidence obtained through the analysis and interpretation of real-world data). These guidelines offer tools and standards for using such data, but many questions remain about when studies based on or supplemented with real-world evidence from various sources (including DARWIN EU and patient registries) are sufficiently robust for regulatory decision-making. In the coming years, we aim to better

understand the purposes for which the use of real-world evidence is suitable. Using so-called ‘estimands’ (a framework for defining the treatment effect to be estimated), we also aim to define more precisely the research questions to be answered using real-world data, and to identify the suitable data sources and analysis methods. We also investigate, using state-of-the-art epidemiological techniques (including target trial emulation and estimands), how bias and confounding in different real-world datasets can be minimised.

INVOLVING PATIENT ORGANISATIONS AND REPRESENTATIVES IMPROVES THE RELEVANCE OF REGULATORY SCIENCE PROJECT OUTCOMES

Patient experience data and patient participation

Collecting and incorporating patient perspectives and experiences ensures that newly approved medicines meet patient needs. While patient-reported outcomes (PROs) are often used to evaluate the efficacy of treatments such as pain medication, this is less common for medicines targeting other diseases. For chronic conditions and in the field of oncology in particular, various stakeholders advocate for a more thorough evaluation of quality-of-life impacts as experienced by patients. This requires careful planning during the clinical trial design phase, with appropriate attention to the collection, analysis, evaluation, interpretation, and communication of these outcomes. In this context, a recently launched project involving the European Organisation for Research and Treatment of Cancer ([EORTC](#)), the EMA, the MEB, and the University Medical Center Groningen examines patient preference studies to determine clinically relevant changes in PROs in anti-cancer medicine trials. The MEB is committed to enhancing the value of this data and supporting its use in regulatory decision-making within the European network.

Involving patient organisations and representatives improves the relevance of regulatory science project outcomes. Therefore, the MEB collaborates with various patient organisations, including Alzheimer Europe in the [IMI EPND project](#) and the Dutch Kidney Foundation in [PRIME-CKD](#), which focus on biomarkers for neurodegenerative diseases and chronic kidney disease, respectively. In the coming years, the MEB will actively pursue broader collaboration with patient organisations and representatives in our scientific regulatory projects.

European medicines regulatory database

In collaboration with Utrecht University, the MEB is working on the publicly accessible European medicines regulatory database (EMRD). The goal of the EMRD is to make key regulatory information about EMA-assessed medicines findable, accessible, interoperable, and reusable (FAIR) for a wide audience. The first version of the EMRD will be available in 2025.

The EMRD contains information from regulatory sources on all medicines approved by the European Commission (EC) since the EMA was established in 1995. As of December 2024, this includes 1,816 medicines. The EMRD includes systematically gathered and validated data on these medicines, as well as all regulatory documents released over time into the public domain. These include European public assessment reports (EPARs), summaries of product characteristics (SmPCs), EC decision texts, and webpages from both the EMA and EC – currently more than 60,000 documents in total. This information can support patients, healthcare providers, researchers, medicine developers, and regulatory assessors in the use, development, and evaluation of medicines. In the coming years, the focus will be on further developing the EMRD in collaboration with end users, so that more historical regulatory information can be utilised to support the use, development, and assessment of medicines.

Model-informed decision-making

Artificial Intelligence (AI) is playing an increasingly important role in decision-making related to medicine development and regulation. AI technologies can be applied to optimise preclinical research, clinical trials, and pharmacovigilance. This will create new opportunities for more efficient medicine development and personalised treatments. In this way, the use of AI is approaching the level of formal scientific evidence that is currently supporting medicine dossiers. However, the use of AI also brings new challenges. It raises (ethical) questions about when these often-complex methods – trained on large datasets – yield sufficiently reliable results and how these results should be properly interpreted. International developments in this area are moving quickly, including the development of the (draft) ICH M15 Guideline, which is expected to result in more frequent use of AI-based methodologies in medicine dossiers in the future.

WE FOCUS ON THE RESPONSIBLE USE OF AI TECHNOLOGIES THROUGHOUT THE ENTIRE MEDICINE LIFECYCLE

As MEB, we consider it important to stay up-to-date with developments in the field of AI in order to respond proactively to opportunities and risks. The MEB focuses on the responsible use of AI technologies throughout the entire medicine lifecycle. We are closely collaborating with the European regulatory network on the implementation of the [AI workplan](#).⁸ In addition, we are conducting research, in partnership with the Swedish Medical Products Agency, into proposals for the use of AI in European scientific advice and qualification procedures as well as in EMA registration procedures. Specifically, we focus on the appropriate role and credibility of AI models in regulatory decision-making. We are also exploring the opportunities of AI on improving efficiency and aim to invest more in this in the coming years.



2.3 Personalised medicine

Advanced therapy medicinal products (ATMPs)

Europe has now worked for 15 years with a distinct category of innovative medicines known as ‘advanced therapy medicinal products’ (ATMPs). In recent years, the focus has been on identifying and removing obstacles to the development of ATMPs. There is now a strong need in the field for harmonisation of production processes, collaboration to pool expertise, and a more efficient approach to product development. The MEB has a role to play in this. For example, the MEB coordinates the [Dutch ATMP Committee](#) and participates in the [Special Interest Group Advanced Therapies](#) within the Regulatory Science Network Netherlands ([RSNN](#)), seeking to promote knowledge development and sharing about ATMPs and their regulation.

Academic product development is especially important for (ultra-)rare diseases. At the same time, the required infrastructure, regulatory complexity, and funding barriers make it difficult to independently and sustainably bring these products to the market. The MEB supports various initiatives to establish a national infrastructure and promote collaboration among all parties involved in ATMP development, including participation in and advising on [DARE-NL](#) and [FAST](#).

Our focus includes research into technological innovations such as in vivo genome editing, epigenetic reprogramming, and manufacturing process optimisation. The development of new methods – such as the use of real-world data, bioinformatics, and single-cell genome analysis – also requires additional knowledge and risk analysis. We also conduct research to better understand critical quality attributes of ATMPs, such as the genome stability of induced pluripotent stem cells and potency assays for cell therapies. We incorporate the latest scientific developments into the scientific advice we provide. All of this increases the consistency of our decisions, enhances the quality of our advice, and ensures that we can continue to make an important contribution to international discussions on this topic in the coming years. Identifying bottlenecks in the context of changing legislation and regulations also requires staying in contact with various stakeholders. All these efforts contribute to faster access to these innovative medicines for patients.

Technological innovations

The regulatory system is built around existing technologies. New technologies often face regulatory hurdles because they do not yet fit into the existing framework. The MEB aims to accommodate technological innovations, as these may enable entirely new treatment options such as cell therapy or gene editing. Innovations in manufacturing – such as platform technologies, computational models for process optimisation, and 3D printing – can also lead to faster access to medicines, reduced production costs, and increased manufacturing capacity (e.g. during shortages). To support this, the regulatory system must evolve in line with technology, guided by scientific insights, while safeguarding patient interests – namely, the availability of safe and effective medicines.

The MEB actively contributes to the EMA Quality Innovation Group (QIG). Established in 2023, the QIG aims to facilitate the implementation of innovative pharmaceutical technologies related to the design, manufacturing, and quality control of medicines. The MEB conducts research on various of these innovative approaches, including platform technologies and computational modelling.

Biomarkers

Biomarkers are measurable genetic, molecular, or biological indicators in patients that can be used to diagnose disease processes, monitor the progression of disease or treatment, and predict treatment efficacy. They also play a key role in personalising treatment by enabling the selection of the most suitable therapy for individual patients based on their unique characteristics. Companion diagnostics (CDx) are crucial in this context, as they identify specific biomarkers that help determine which patients are most likely to benefit from a particular therapy.

We are investigating the role of biomarkers and CDx in various regulatory processes, including marketing authorisations, scientific advice, qualification procedures, and EMA consultation procedures. This research focuses on key aspects of a development trajectory, including the design of clinical studies, statistical methods, outcome measures, patient selection, control groups, and potential use of real-world data. One of the main challenges is the adequate validation of biomarkers, requiring robust scientific methods to establish their reliability, reproducibility, and clinical relevance.

The MEB is also actively involved in several biomarker-related projects. We are conducting research on biomarker thresholds for chronic kidney disease ([PRIME-CKD](#)) and on the use of biomarkers in developing treatments for neurodegenerative diseases ([EPND](#)). The MEB works closely with patient organisations on these projects. Through this research, we aim to contribute to better clinical decision-making, faster drug development, and improved patient care.

Rare diseases

Although rare diseases are individually uncommon, they collectively affect a significant number of people globally due to the sheer number of conditions – estimated between 6,000 and 8,000. For most rare diseases, no approved medicines are currently available. Much of the research in this area takes place at academic institutions, including the European Reference Networks ([ERNs](#)) and [RARE-NL](#). Increasingly, medicine development and registration are being undertaken by non-industrial entities.

The MEB will conduct research into ‘orphan designations’ – the special status granted to medicines for rare diseases that provide developers with benefits such as scientific support and market exclusivity. This research will examine both industrial and non-industrial developers and trace the development pathway of these medicines. The results can offer valuable insights into medicine development by non-commercial parties.

Since many rare diseases have few treatment options, drug repurposing can be a valuable strategy for developing new therapies. Therefore, specific attention will be given to repurposing existing authorised medicines for new indications. In 2025, results from the EMA and HMA pilot on drug repurposing for not-for-profit organisations and academic institutions will be published. The MEB participates in the Medicines Repurposing International Network ([MeRIT](#)) and is actively involved in exploring how regulatory authorities can support drug repurposing. Research will focus on how often repurposing occurs among authorised medicines, in which therapeutic areas, and how existing data can be used for regulatory decision-making.

In addition to developing new treatment options, defining relevant outcomes is also crucial. Another area of focus is the development and use of core outcome sets in clinical studies. These sets allow for better comparisons across studies and reflect what patients consider important. Core outcome set initiatives highlight the importance of patient perspectives and multidisciplinary collaboration in defining meaningful outcomes. The MEB aims to support the development of core outcome sets and will actively contribute to several such initiatives.

THE REGULATORY SYSTEM WILL UNDERGO SIGNIFICANT CHANGES



2.4 New pharmaceutical legislation

On 26 April 2023, the European Commission published proposals to revise the EU pharmaceutical legislation, aimed at addressing several structural issues. To accommodate new therapies and technologies, these proposals introduce new concepts such as platform technologies, adapted frameworks, and regulatory sandboxes. They also include several measures to better address unmet medical needs. For instance, criteria are introduced that determine whether a medicine meets an ‘unmet medical need’, which will be linked to access to initiatives such as [PRIME](#). Also added are provisions to stimulate drug repurposing. The regulatory system will undergo significant changes; for example, EMA committees and working groups will be restructured, and electronic submission will become the standard. Environmental considerations will also receive greater attention, including the introduction of a central system (monograph) for substance-based environmental risk assessments with stricter conditions for the approval of medicines.

The MEB acknowledges the necessity of these proposed measures but recognises that further specification is required to ensure successful implementation. Details on the practical implementation will be determined only after the legislative revision has been finalised, for example through the development of new EMA guidelines. Implementation activities are expected to begin in 2026. The success of these proposals depends on how they are further developed. The MEB will therefore focus on system-level research into how the proposed measures can be operationalised. This includes topics such as platform technologies and drug repurposing. The results will inform future European discussions on the optimal implementation of the new legislation.



3 Implementation

In this chapter, we describe how we plan to carry out the scientific activities related to the previously outlined themes. Given the multi-year nature of this policy, we will not invest in all themes simultaneously with the same intensity. Choices will be made in the coming years based on various factors, such as their urgency for public health, their impact on our core tasks, relevance to our daily work, and the availability of external project funding.

3.1 Collaboration

The MEB is part of an international regulatory system. Most of our core tasks related to marketing authorisation and pharmacovigilance are performed in collaboration with other national medicines authorities and the EMA. Regulatory science is an international field; for this reason, we work closely with academic groups, other knowledge institutes, and fellow authorities in our network when carrying out scientific activities. Of course, as an organisation we are also part of a national healthcare chain, which may be impacted by the results of scientific research. We therefore aim to align and complement our own research agenda with those of national and international partners, wherever possible.

Through ongoing collaboration and the sharing and exchange of knowledge within our network, we can implement solutions that make medicine regulation faster, more efficient, and more flexible. Since much of the regulation and decision-making takes place at the European level, it is essential to connect with (international) chain partners. Joining forces across the international network also creates

opportunities for larger-scale research. This strengthens the knowledge and capacity not only of regulatory authorities and the academic community but also of pharmaceutical companies, ensuring that research outcomes benefit the entire network.

Our collaboration with other organisations takes various forms. For example, several MEB staff members hold academic appointments, enabling active mutual knowledge exchange. During their PhD trajectories, PhD candidates operate at the intersection of scientific research and our assessment practice. These projects are part of long-standing collaborations with Dutch universities and academic medical centres. On various themes – such as the 3Rs and ATMPs – we have concrete coordination and cooperation with national partners in the healthcare chain. This helps ensure that the outcomes of scientific research are relevant to our regulatory system and to others in the healthcare ecosystem.

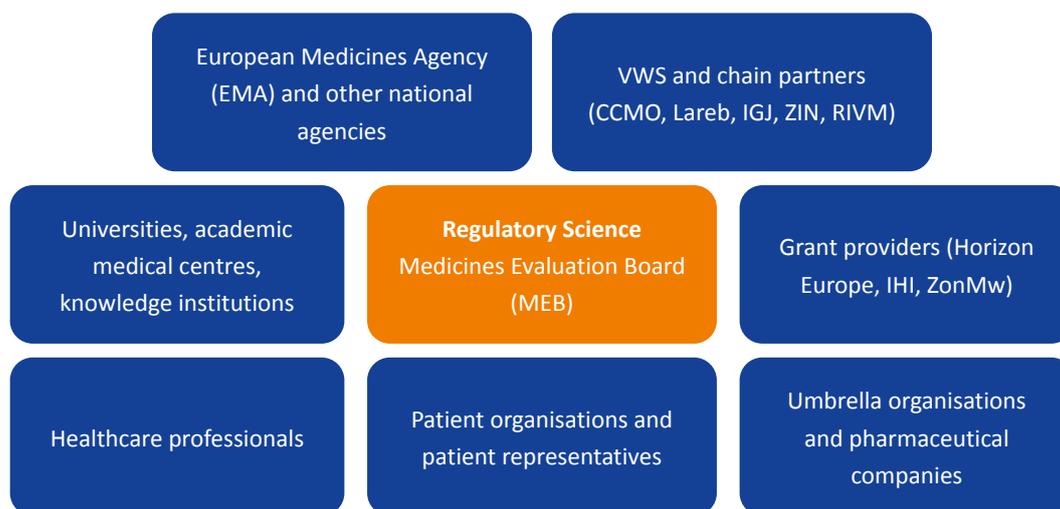
THE EUROPEAN PLATFORM FOR REGULATORY SCIENCE RESEARCH IS AN INITIATIVE THAT AIMS TO PROMOTE AND STRENGTHEN COLLABORATION IN EUROPE AND BEYOND

We also play a prominent role in European collaboration with other national agencies and the EMA in key scientific working groups and steering committees, such as the [Network Data Steering Group](#) and the EU Innovation Network ([EU-IN](#)). We are active in (inter)national research projects funded by [ZonMW](#), the Innovative Health Initiative ([IHI](#)), and [Horizon Europe](#). We will maintain and strengthen these valuable partnerships in the coming years.

One initiative we would like to highlight is the European Platform for Regulatory Science Research ([EPRSR](#)).^{4,9} This is an initiative of the EMA and HMA that aims to promote and strengthen collaboration in regulatory science research among not-for-profit organisations in Europe and beyond. In 2025, the MEB will co-chair the platform during its first year, together with the EMA and an academic chair yet to be appointed. The main objectives of the EPRSR are to 1) promote and accelerate regulatory science research; 2) improve the quality and impact of regulatory science research and its outcomes; and 3) enhance regulatory procedures, standards, and the development and use of medicines.

At the same time, we ensure that research and knowledge-sharing with partners do not interfere with our core tasks and responsibilities. For this reason, the MEB generally does not enter into direct, individual collaborations with pharmaceutical companies conducting scientific research in the context of medicine development. However, the MEB is regularly involved in scientific projects that include regulatory authorities, academic research groups, and pharmaceutical companies (i.e. public-private partnerships). These are non-competitive research environments that aim to improve the regulatory system as a whole. In such multi-stakeholder projects, the role of a regulatory authority like the MEB is important to ensure that developments within the project align with regulatory requirements.

This is also reflected in our participation in the Regulatory Science Network Netherlands ([RSNN](#)), a public-private partnership that provides a neutral platform for exchanging key regulatory knowledge with all stakeholders and for helping to shape the research agenda. An MEB representative chairs the RSNN alongside representatives from academia and industry. In 2025, RSNN will celebrate its 10th anniversary, marking a decade of joint contributions to regulatory science and enhanced collaboration among industry, academia, patient representatives, government agencies, and other experts in the broader field of regulatory science.¹⁰



3.2 Coordination

To create as much coherence as possible between the various scientific activities carried out by the MEB, they are coordinated – and in many cases organised – by a single department within the organisation. This concerns both scientific research and educational activities that strengthen the assessment process in terms of content or methodology.

By centralising these activities in one place, we maintain a clear overview of knowledge development and knowledge continuity in the previously described themes and in regulatory science more broadly. It also makes it easier to continuously improve and adjust scientific initiatives and the coherence between them. This enables us to efficiently align research questions with available research capacity and to establish cross-links between disciplines and departments. This does not mean that scientific initiatives are only carried out from a single department. The implementation and supervision of scientific research, as well as the organisation of various educational activities, take place across different departments within the MEB. These efforts are closely coordinated with various working groups to optimise the alignment between scientific research and knowledge continuity. Another major benefit of centralising scientific activities within the organisation is the presence of a clear point of contact for external stakeholders. This strengthens connections with external scientific initiatives and collaborative partners and enhances our position in the international network.

3.3 Foresight

To anticipate changes in the world of medicine development and regulation, the MEB actively engages in foresight efforts and regularly conducts context analyses. We do this together with other medicines agencies through the EU Innovation Network ([EU-IN](#)). The outcomes of these foresight studies and analyses help guide the MEB's scientific activities and contribute to shaping the research agendas of key organisations and networks around us. This ensures that research aligns appropriately with regulatory requirements, thereby supporting the timely availability of medicines.

Another way in which we implement horizon scanning is by monitoring scientific research in which the MEB is not directly involved. Various academic groups conduct research in regulatory science that may be relevant to our assessment work. We ensure that important findings are brought into the organisation and applied in practice.

Pipeline meetings

At the end of 2024, the MEB resumed the organisation of pipeline meetings. A pipeline meeting is a session in which the MEB engages with a company about its upcoming innovations and plans in the field of medicine development. Two to three pipeline days will be scheduled each year. The MEB will

determine the topic for each pipeline day in advance, and companies will be able to register to participate. For each pipeline day, the MEB will invite a maximum of three companies for a meeting. Pipeline meetings provide the MEB with valuable information needed to prepare for future developments. They enable effective anticipation of scientific expertise needs, guideline discussions, technological changes, and advances in medicine development.

3.4 Research

Within the previously defined themes, there is a wide variety of research questions, which may originate from different sources. Recurring issues or dilemmas encountered during the assessment of applications or when drafting scientific advice may lead to the formulation of research questions. Research questions or proposals may also be submitted by external parties, such as universities or large consortia. The MEB determines the appropriate type of research for each question, depending on the topic, the scope, urgency, available budget, and the contribution expected from the MEB. When approving research proposals, the relevance and necessity of the research for our work are important considerations.

We distinguish between various types of scientific research projects, such as multi-year PhD trajectories, research conducted by internal staff, and (inter)national research projects. Some research questions may be addressed by students during scientific internships. The research projects will generally lead to one or more of the following outcomes: increased scientific knowledge, a system improvement, or the development of a new tool for assessment. We consider in advance the potential impact of these outcomes on the organisation and our regulatory system.

Data-driven research

As outlined in the MEB SBP 2024-2028, advances in information technology and data will lead to changes in the way we work. The MEB will renew its current ICT environment and further develop and optimise its assessment processes to adapt to these changes. Data-driven working is a guiding principle in the development of a robust, future-proof ICT infrastructure. These developments also include opportunities for scientific research, with particular attention to internal data analysis capabilities such as R or Python.

Evaluation research

We continue to invest in evaluation research and outcome measurements, following the completion of scientific projects to determine whether current regulations and procedures are appropriate and whether research outcomes sufficiently contribute to our statutory tasks. We attach great importance to the regulatory impact of scientific output and approach this with due diligence.

Patient participation

The MEB maintains contact with patient umbrella groups and patient organisations across various areas of expertise. The MEB may consult patient organisations to incorporate the patient perspective into assessments or the scientific research we conduct. Actively involving patients in scientific research undertaken by the MEB is intended to optimise the quality of the research and the applicability of its outcomes. Research proposals reviewed by the Science Committee must include an appropriate approach for patient involvement, addressing the assessment of relevance and feasibility from a patient perspective. The way in which patients or their representatives are involved may vary between research projects.

Science Committee

The MEB promotes and funds scientific research. The Science Committee has been established to embed this in the organisation and monitor the coherence and quality of the research. Appointed by the Board, the Science Committee consists of members from the Board and staff from various disciplines within the MEB who are closely involved in research. The Committee's tasks include advising

on the MEB's research-related activities, deciding on participation in both large and small research projects and their funding, and coordinating and monitoring the research in which the MEB engages. The Science Committee thus plays a key role in the implementation of this policy.

To determine which research proposals qualify for funding, the Science Committee uses an evaluation framework. The Committee assesses the study designs of submitted proposals on aspects such as quality, feasibility, and practicality. The implementation plan is also evaluated. For the assessment of patient involvement plans, the Committee works with the Board member specifically responsible for patient perspectives. In deciding which proposals to support, the Committee also considers the fit with the research themes and the relevance of the research question for the MEB.

3.5 Developing and securing knowledge

The MEB aims to apply the results from regulatory science as much as possible within the regulatory process and to maintain a high level of knowledge of relevant scientific developments among its staff. This not only enhances knowledge and improves assessments but also brings inspiration and a fresh perspective to our work. For that reason, we invest not only in scientific research but also in knowledge development and continuity, both within our organisation and across our (inter)national network.

Implementation of research results

To ensure that research outcomes are actually applied in the assessment process, we pay close attention from the outset of each research proposal to how the researcher plans to implement the findings – or to whom implementation responsibility will be delegated. We also ensure that the relevant disciplines, working groups, and experts are involved from the start, maintaining a continuous focus on integration and cross-pollination within the organisation. This means that each research proposal must describe how its outcomes will be communicated with relevant stakeholders inside and outside the MEB and what is needed to embed the results into our daily work. In this way, we ensure the results are ultimately secured within the organisation, for example because they lead to policy changes.

Internal education at the MEB

In the interest of scientific-knowledge development, the MEB uses internal education as a bridge between scientific research and the assessment process (and vice versa). Scientific education is focused on collective knowledge development – meaning that the content is relevant to one or more departments or disciplines within the organisation. Education can be driven by both results from scientific research and essential knowledge and expertise gained by staff through the assessment process itself. Education supports the implementation of research results, advances knowledge on the policy themes, reflects current developments, and serves as a source of inspiration.

To support this, we organise several thematic meetings per year for our staff, where both internal and external experts are invited to speak. We also hold regular meetings open to all staff, where students and PhD candidates present their research findings. Additionally, we make sure to internally leverage relevant knowledge and expertise from our collaborative partners and share applicable research outcomes from academic research groups so this knowledge can be applied in our assessments.

Scientific research may also lead to changes in our daily work, which in turn can require different or new competencies and skills from our staff. Developmental needs may also arise from within the organisation – for instance, concerning the execution or supervision of scientific research. These types of educational questions may go beyond the scope of this science policy and are coordinated and developed in close collaboration with the department of Human Resource Management & Organisation to ensure alignment within the overall educational activities of the MEB.



EDUCATION SUPPORTS THE IMPLEMENTATION OF RESEARCH RESULTS, ADVANCES KNOWLEDGE ON THE POLICY THEMES AND REFLECTS CURRENT DEVELOPMENTS

External education by the MEB

We use the MEB's internal expertise to improve the quality of knowledge of regulatory science and medicines in our international working environment. For example, we contribute to [EUPATI-NL](#), a training programme for patient representatives. We also help educate doctors, pharmacists, and other healthcare professionals on medicine regulation and the proper use of medicinal product information. In addition, we provide targeted training to academic groups about the regulatory requirements for medicine development. The MEB also participates in and organises various (international) conferences and contributes by providing expert speakers.

Publication policy

Our scientific publications contain valuable information. The MEB makes this information widely accessible, although not all content may be published without restrictions. For this reason, we operate under a publication policy which includes internal screening to ensure the correct use of the MEB affiliation. Publications are reviewed for consistency in reporting, confidentiality, and potential impact on the Board. This helps safeguard the quality of scientific contributions made by MEB staff. We also encourage open-access availability of our scientific publications.



4 Funding

The MEB considers it important that all its activities, including its scientific work, are supported by appropriate funding. We therefore continuously pay close attention to how the costs of scientific activities are covered. The research budget is a structural component of the MEB's annual budget, and scientific activities are explicitly included into the organisation's annual plan. In addition, we actively seek external sources to finance research activities. A significant portion of our research projects is funded through external sources, including grants from [Horizon Europe](#), the Innovative Health Initiative (IHI), and the [Dutch National Growth Fund](#).

The MEB chooses to allocate the majority of its research budget – whether through direct funding or in-kind contributions – to research questions aligned with the themes outlined in this science policy. Provision is also made for the funding of research outside these themes, although this constitutes a smaller share of the overall budget. We primarily fund applied research and, to a lesser extent, fundamental research.

THE MEB CHOOSES TO ALLOCATE THE MAJORITY OF ITS RESEARCH BUDGET TO RESEARCH QUESTIONS ALIGNED WITH THE THEMES

For each research project, we assess the kind of contribution requested and what the MEB can provide. In the case of PhD trajectories and internships, MEB staff provide supervision, and we often contribute financially by covering part of the PhD candidate's salary or offering an internship stipend. For (inter)national research projects, the MEB's contributions can be very diverse – such as participating directly in the research project or joining a working group, advisory board, or steering committee. The MEB may also participate in the grant application phase for external funding of a research project, provided that our independent position is not compromised. The effort and funding requested are weighed in the decision on whether to participate in a research project. We also refer to the document published by the EU Innovation Network (EU-IN) regarding the involvement of the EMA and individual member states in research: [Considerations for research / project teams seeking competent authority participation in externally funded regulatory science and public health research projects related to medicinal products](#).¹¹

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Abbreviations and definitions

AI	Artificial Intelligence
ATMP	Advanced Therapy Medicinal Product
CCMO	Central Committee on Research Involving Human Subjects
CDx	Companion Diagnostics
CPBT	Centre for Animal-Free Biomedical Translation
DARE-NL	Dutch infrastructure for cancer-specific ATMP Research
DARWIN-EU	Data Analysis and Real World Interrogation Network EU
EC	European Commission
EMA	European Medicines Agency
EMRD	European Medicines Regulatory Database
EORTC	European Organisation for Research and Treatment of Cancer
EPARs	European public assessment reports
EPND	European Platform for Neurodegenerative Diseases
EPRSR	European Platform for Regulatory Science Research
ERNs	European Reference Networks
EU	European Union
EU-IN	EU Innovation Network
EUPATI-NL	European Patient Academy on Therapeutic Innovation Netherlands
FAST	Centre for Future Affordable Sustainable Therapy Development
FDA	United States Food and Drug Administration
HMA	Heads of Medicines Agencies
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Collaboration of Medicines Regulatory Authorities
IGJ	Health and Youth Care Inspectorate
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
MEB	Medicines Evaluation Board
MeRIT	Medicines Repurposing International Network
PRIME-CKD	Personalized drug Response: IMplementation and Evaluation in Chronic Kidney Disease
PRO	Patient-Reported Outcomes
QIG	Quality Innovation Group
RIVM	National Institute for Public Health and the Environment
RSNN	Regulatory Science Network Netherlands
SBP	Strategic Business Plan
SmPCs	Summaries of Product Characteristics
VWS	Ministry of Health, Welfare and Sport
ZIN	National Health Care Institute
ZonMW	Netherlands Organisation for Health Research and Development
3Rs	Replacement, Reduction and Refinement of animal studies



Anyone who uses medicines should be able to trust them. That is what the Medicines Evaluation Board (MEB) is working on each and every day, in the Netherlands and in Europe. Good medicines used better.

Medicines Evaluation Board
PO Box 8275
3503 RG Utrecht
The Netherlands
+31 88 – 224 80 00
english.cbg-meb.nl