

# Annual Report 2024

Transformation, Innovation, Consolidation



**GOOD  
MEDICINES  
USED  
BETTER**

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## Preface

**A stronger network in Europe in which the Medicines Evaluation Board (MEB) and other authorities each deploy their expertise in the best possible way; that is the path that was set in motion in 2024. It was a year marked by many changes, during which the organisation focused on consolidation and innovation. Chair Ton de Boer and secretary/director Paula Loekemeijer look back at 2024.**

“We are seeing many changes where it concerns medicinal product development, the assessment of medicinal products and monitoring adverse reactions. Assessment reports are becoming more extensive and more complex, and tasks and powers are shifting. ‘Europe’ is becoming increasingly important in our work”, says Ton. Paula follows on from Ton by saying: “The international network is taking on a more steering, central role – a key focus of much of 2024. We are making sure we are better equipped to handle the challenges we face.”

How we wish to go about doing that is set out in the 2024-2028 Strategic Business Plan published in 2024. Ton: “A lot has changed over the years.” For the medicine authorities, as well as for healthcare providers, patients and the pharmaceutical industry. Those changes will continue in the coming years.” Paula: “This includes matters such as new European legislation, while technical innovations and the move towards more data-driven work are also set to significantly impact the organisation.”

The MEB wish to contribute to the Dutch and European network, which is where we add most value. Ton: “This means that we have to make choices to ensure that, together with the European network, we can continue to guarantee the efficacy and safety of medicinal products for patients in the best possible way. Strengthening ourselves by increasing our focus.”

To continue to deliver quality, the MEB must adapt to all of these developments. Paula: “That is why that focus is important. We have to take several factors into account. These include social relevance and the nature of the



scientific or substantive developments. Another important factor is where we stand as an organisation with our current knowledge, financial stability and impact at European level.”

In fact, the publication of the SBP was only the start in 2024. Paula: “We have been working hard on the implementation and are in the process of identifying the choices we will make - and where we want to be as MEB and MEB Agency in 2028. This process will continue into 2025.”

Ton and Paula are aware that all of those ambitions and changes in addition to the regular work caused a significant workload for the employees of the MEB in 2024. “All of the work that has been done and the ideas

contributed by the organisation regarding all of those developments deserve a great compliment.”

In this annual report, we report on the procedures and activities of the MEB in 2024. In the initial chapters, we will address several important issues that arose over the past year, including interviews concerning our role in Europe and the tasks of the Veterinary Medicinal Products Unit. The final chapters traditionally provide an overview of the main figures.

*Secretary/director Paula Loekemeijer  
Chairman Ton de Boer*



## The MEB in 2024

The year 2024 was a year in which a lot happened and changed. Various subjects, events and developments received our active attention.



### Medicine shortages

The MEB coordinates the Medicine Shortages and Defects Notification Centre together with the Health and Youth Care Inspectorate (Inspectie Gezondheidszorg en Jeugd, IGJ). Manufacturers of medicinal products and vaccines are obliged to report possible supply problems to this centre.

What stands out in the Notification Centre's annual report is that measures against shortages were deployed more frequently. Ton: "We have grave concerns about medicine shortages experienced by healthcare providers and patients. We are doing everything within our power to curtail the shortages or their consequences for patients as much as possible. For example, in 2024 the MEB authorised temporarily different packaging more often so that the same medicinal product with foreign packaging may be handed out to patients."

*"We are doing everything within our power to curtail the shortages or their consequences for patients as much as possible."*

Paula shares Ton's concerns: "Unfortunately, there is no ready-made solution to stopping medicine shortages. We remain committed to minimising the impact of shortages on patients as much as possible. Together with the IGJ, but also with other partners, such as the National Coordination Center for Medicines (LCG)."

### Bluetongue

For most of the veterinary sector in the Netherlands, 2024 was all about bluetongue disease, with the virus spreading among sheep and cows. Paula: "The colleagues of the MEB Agency, Veterinary Medicinal Products Unit (VMPU), worked hard on the assessment of several vaccines. As a result, the Minister of Agriculture, Fisheries, Food Security and Nature (LVVN) was able to issue a 'decision giving consent to use' for three vaccines against the virus within a short period of time in the spring. A wonderful result."

For more information on the Veterinary Medicinal Products Unit and the assessment of the vaccines, see the comprehensive interview on page 11 of this annual report.



### MEB Day

The fact that the work of the MEB is changing was the key element of the 2024 MEB Day, as were international developments relating to medicinal products. The theme was therefore 'Opportunities for tomorrow with today's challenges'. Ton: "Almost 500 doctors, pharmacists, scientists, patient representatives, veterinarians and representatives of the pharmaceutical industry and the government were guests at Tivoli in Utrecht. An equally-broad range of speakers engaged the audience as they discussed all opportunities and challenges in medicinal products. This included

subjects such as the use of real-world data in medicinal product dossiers or artificial intelligence and ethics.” New veterinary legislation, developments regarding ATMPs and the use of visuals to make medicine information easier to understand were also discussed.

### Cooperation with chain partners

The MEB collaborates with all manner of chain partners, both nationally and internationally. This is how we jointly aim to contribute to faster access to safe medicinal products. This includes for example collaboration with the National Health Care Institute, the IGJ or Netherlands Pharmacovigilance Centre Lareb, but also with the Department of Medicinal Products and Medical Technology of the Ministry of Health, Welfare and Sport (VWS).

“Towards the end of 2024 we signed a cooperation agreement with the Central Committee for Research Involving Human Subjects (CCMO), which intensifies the cooperation. We often have to deal with the same situations and products as we are both active in the area of medicinal products. This cooperation allows us to coordinate our work more effectively and provides us with greater insight into each other’s tasks and responsibilities”, explains Paula.

### Certification

The European medicine authorities work together closely. A benchmark programme for humane and veterinary agencies was formed following on from the above. This programme is known under the name of ‘Benchmarking of European Medicines Agencies (BEMA)’. “We were visited by three benchmarkers of other medicine authorities towards the end of February 2024”, tells Paula. “They assessed our processes for a period of three days. We received a good score for many indicators. As MEB, we score above the average of 18 agencies. A wonderful result.”

Our processes are in order according to Dutch standards as well. This was borne out by the fact that it was announced at the start of 2024 that the MEB’s ISO9001 certification was renewed for a period of three years. The auditors did not identify deviations.

### Pictograms

In 2024, the MEB also sought out cooperation in other areas as well. A fine example is the uniform set of pictograms, which was developed together with 16 other parties, varying from patient organisations to the government, industry organisations and the industry. “Together with these parties we worked on a uniform set of pictograms in order to make medicine information more understandable”, says Ton. The pictograms were tested among semiliterate persons and were presented to Minister Fleur Agema (VWS) at the start of 2025. Ton: “I am proud of this achievement and look forward to seeing these pictograms in practice.”

All things considered, this and many other events and developments meant that 2024 was an intensive year. A lot happened internally as well. For example, we were still working on the preparations for a new IT system in which incorporate our assessments. We worked on changing, renewing and strengthening our organisation in many different areas.

### Finances

The MEB Agency posted a positive result of €1.8 million in 2024. This is explained by €5.1 million higher income and €3.3 million higher costs than budgeted. The balance of €1.8 million was added to the equity. More details about the results can be found in the financial chapter.

## Together stronger in Europe

**Assessment and monitoring of medicinal products and vaccines ceased to be tasks confined within national borders long ago. We are further strengthening our collaboration with both the network of medicine authorities across Europe and the European Medicines Agency EMA. We are also observing changes in this network. The pressure on this European system is mounting. Aimad Torqui (department head Europe, Medicines Use and Veterinary) and Menno van der Elst (department head European Representation) address the related threats and opportunities and how we can cooperate internationally on achieving improvement.**

When regulating the safety, efficacy and quality of medicinal products for humans and animals we collaborate within a European system with other national medicine authorities and with the European Medicines Agency (EMA).



Assessments of applications for new medicinal products or (signs of) suspected adverse reactions are discussed within the European system, such as the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC). All countries of the European Union are represented in these committees. The EMA divides the rapporteurships over the registering countries.

“The work within the European committees is increasing”, explains Menno. “The number of medicinal products and procedures is growing and applications are becoming ever more complex. The same applies to the reports that have been become more comprehensive and extensive. The European network of medicine authorities has several problem areas. All of the above means that the division of rapporteurships in Europe is becoming increasingly difficult. In addition, new pharmaceutical legislation for medicinal products for humans will also change things.”

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*“The number of medicinal products and procedures is growing and applications are becoming ever more complex.”*

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That pressure arose over the past years and remained as great as ever in 2024. “The MEB traditionally assumes a large number of rapporteurships and co-rapporteurships, so we also noticed the pressure. All of those assessments took a lot work”, tells Aimad. “Whether we acted as (co) rapporteur or followed the assessments performed by others as Concerned Member State. We are proud of how our teams did all of that work.”

### Dutch colleagues in Europe

How did Menno and his team experience 2024? “It was a year in which a lot of people were relatively new in their function or role within the various European EMA committees. Naturally, you have to familiarise yourself with this role. You have to get to know your team and other committee members, assume your role. That worked out really well, 2024 really focused on this process.” Fortunately, the European representatives do not have to do it alone. “They are backed by teams of

experts who support the committee members. And the strength of that team defines how strong you are as a representative”, says Menno.

### New legislation

The new pharmaceutical legislation soon to be introduced in Europe places increasingly greater demands on the MEB Agency. The reason being that we provide the Ministry of Health, Welfare and Sport (VWS) with input for the negotiations within the council working groups that follow each other in rapid succession. Doesn't that add further strain on the relatively new colleagues in Europe?

Menno: “It certainly does, but it also helps that as relatively new representatives they offer a fresh perspective on the subject matter and are able to ask questions.”

There will be a lot of changes in Europe, partly as a result of that legislation. Aimad: “You see that things will change; some committees will disappear or take on a different role. What will that look like and how will we organise that work? And how will we ensure that the knowledge is safeguarded? These are important questions to already consider. It is therefore important to look ahead and assess what will be required in the future to continue performing the work efficiently, as its scope and complexity continue to grow.”

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*“We must be aware that have to do the work differently and to divide it differently.”*

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The word efficiency is mentioned. Aimad: “We must be aware that have to do the work differently and to divide it differently. Also on account of the pressure on the (European) network already mentioned by Menno. We will really have to work together more closely. Will we do things separately, or will we actually work together in knowledge centres or Centers of Excellence, or however you will be organising this? This is also something we are anticipating at the MEB here in the Netherlands. We do so by means of the Strategic Business Plan 2024-2028, which was formulated last year. This should now further crystallise into making choices.”

### Predictability and efficiency

Predictability is a very important aspect of being able to work efficiently. “And this where things become a little difficult in Europe”, tells Aimad. “Six of the ten applications for new medicinal products are not received at the moment they were announced. Sometimes they are even postponed multiple times. And not just within the European central procedures; we also see postponements and cancellations within the decentralised procedures (DCP).”

This makes it difficult to plan the work. Menno: “This is something that we notice very well here in the Netherlands at the operational level, because work is shifting and the peaks are getting higher, which results in high workload and sometimes comes with financial consequences. It places (additional) pressure on the efforts of the assessors. We are working on this within the European network, however. Where possible, by simplifying the assessment reports or by working with other countries in one version of reports. Forming multinational teams is also an option, whereby the required assessors come from different countries. But despite these efforts, shifting procedures will have a domino effect. All this takes a heavy toll on the workload.”



### Working together on improvement

Menno and Aimad advocate for developers of medicinal products to keep more to the announced moments for submission.

Aimad: “We are actively working on this. So that we can divide our work more effectively and increase the capacity within the network. For example, Menno is part of an EMA working group in which the medicine authorities search for solutions together with the industry. I myself am part of the HMA-EMA working group involved in resources and capacity in a broader sense. For the purpose of deploying capacity strategically with the emphasis on long-term solutions and structural improvements. In addition, our agency participates actively in IncreaseNET, which is a European project to increase capacity and knowledge at various medicine authorities in Europe.”

### TOPRA 2024 in Rotterdam

Stronger internationally through cooperation: that was the motto used in Rotterdam in late September 2024 during the annual symposium of TOPRA (The Organisation for Professionals in Regulatory Affairs). This is the international professional association of regulatory affairs professionals.

Over a period of three days, 60 speakers from 13 countries spoke about developments in regulatory affairs, concerning both medicinal products and vaccines for humans and animals. The MEB was co-organiser because the Netherlands acted as host country this year.



# Veterinary Medicinal Products: 3 bluetongue vaccines

Bluetongue received a lot of media attention in 2024. The virus spread among sheep and cows in the Netherlands. Erik den Hertog, veterinarian-epidemiologist and clinical assessor at the MEB Agency, Veterinary Medicinal Products Unit, was closely involved in the assessment of the bluetongue vaccines.



The Veterinary Medicinal Products Unit (VMPU) forms part of the agency (MEB). The VMPU assesses and monitors medicinal products and vaccines for animals at the direction of the Minister of Agriculture, Fisheries, Food Security and Nature (LVVN).

In April and May 2024, the VMPU assessed three vaccines against the bluetongue virus in a short period of time. This did not concern a marketing authorisation, but rather what is known as a 'decision giving consent to use'. Erik: "The assessment of the bluetongue vaccines involved a national procedure in accordance with Article 110 of the Veterinary Medicinal Products Regulation. The Minister of LVVN grants consent to use a non-registered medicinal product. Such a decision follows an accelerated procedure, which is only possible in emergency situations."

## Emergency situation

An emergency situation existed in the Netherlands in 2024. Since the outbreak in the autumn of 2023, tens of thousands of sheep and thousands of cows died as a result of the bluetongue virus. "This decision allowed us to ensure that the vaccine became available in a shorter period of time", Erik goes on to say.

Erik's response to the question whether that assessment process resulted in a lot of tension is very down to earth. "It is still an assessment. In that sense it was no different from other applications we examine. Of course, everything had to be done much quicker, also due to the demand from the market and politicians. That was the challenge, but we worked hard on it together."

The fact that Erik and his colleagues were able to move quickly was helpful in that respect. "We were able to handle this within our own team as it concerned a national assessment. And within the VMPU we have all knowledge and experience regarding vaccines."



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*"We worked hard together."*

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## Efficacy

Comments on the efficacy of the assessed bluetongue vaccines were received over the course of the year. Erik indicates that he and his colleagues still stand firmly behind the assessment. "Although the

vaccines reduce the symptoms and result in less disease, they could not prevent animals from dying. We made our statements and assessments based on the data available to us. The data from practice were not yet available at that time. That is why, at some point, we called on people to report adverse reactions and lack of efficacy. All things considered, the vaccines are effective in reducing illness, which is also confirmed by external experts.”

### **More than bluetongue**

Bluetongue received a lot of media attention in 2024. Of course, these were not the only developments in medicinal products and vaccines for animals. “From the Netherlands, we have assumed a large number of rapporteurships in Europe, in particular with respect to vaccines”, says Erik. “New veterinary pharmaceutical legislation has also since entered into effect in Europe. Over the past year, we have amended the most recent internal procedures and process in accordance with that new legislation.”



Other animal diseases such as bird flu and foot-and-mouth disease were also in the news in 2024. This involved less work for the VMPU team. “These are both animal diseases that must be reported and combatted”, Erik explains. “No vaccines are administered for these diseases at this time. Field trials concerning vaccines against bird flu are being conducted for which we received approval. And if the Minister were to decide that vaccines against such diseases have to be administered, we will have all of our knowledge about the vaccines ready.”

# The year in a nutshell

A lot of things happened in 2024. We have listed several key moments in this chapter: 2024 in a nutshell.

5 March

## More government measures needed to counter medicine shortages

The [annual report of the Medicine shortages and defects notification centre](#) showed that more measures were needed in 2023 to counter medicine shortages.



9 April

## New legislation concerning veterinary medicine packaging

Several [new European regulations](#) on veterinary medicine packaging were introduced in April. These include regulations on pictograms and abbreviations.

## March



11 March

## Little knowledge of the effect of herbal remedies on medicinal products

In March, we launched the campaign '[Know what you swallow](#)' together with the Netherlands Food and Consumer Product Safety Authority (NVWA). Recent studies show that many Dutch people are not sufficiently aware of the risks of the simultaneous use of herbal remedies and medicinal products. The campaign addresses this issue.

## April

4 April

## Rikje Ruiter sworn in as new Board Member

In April, vice chair Pieter de Graeff swore in [Rikje Ruiter as the newest Member of the Medicines Evaluation Board](#). She is a clinical pharmacologist and internist in geriatric care.



26 April, 13 and 24 May

### Three vaccines against bluetongue virus approved for use

In 2023 and 2024, bluetongue virus caused high mortality among (in particular) sheep and cattle. Three vaccines against the bluetongue virus were approved for use in April and May (see [1](#), [2](#) and [3](#)). The Minister of Agriculture, Nature and Food Quality (LNV) issued the decisions following positive recommendations by the Veterinary Medicinal Products Unit.

14 June

### MEB Day 2024: Opportunities for tomorrow with today's challenges

The central theme of the 2024 edition of the [MEB Day](#) was the changing world of medicines development. Various speakers from different backgrounds talked about the central theme: 'Opportunities for tomorrow with today's challenges'. The MEB introduced the visitors to the general outlines of the new Strategic Business Plan.



## May

8 May

### Eric Boersma became Vice Chair of the Board

Member of the Medicines Evaluation Board [Eric Boersma](#) succeeded Pieter de Graeff (picture) as Vice Chair of the Board in May.



## June

4 June

### State of Implementation 2023: The future is now

The MEB formulated a '[State of Implementation](#)' for the second year in a row. The House of Representatives wishes to use this document to increase attention for implementation. Trust in medicinal products remains the key issue for the agency; a topic reflected by this 'Stand van de Uitvoering' (State of Implementation).



27 June

### New Strategic Business Plan for the MEB

The [Strategic Business Plan 2024-2028](#) sets out the MEB's strategic course for the next four years. This plan prepares the MEB for the changes it will face in the years ahead.

## July

1 July

### Sabine Straus retired as PRAC chair

After six years as chair of the Pharmacovigilance Risk Assessment Committee (PRAC), Sabine Straus retired because she had reached the [maximum term](#).



## September

6 September

### Liana Martirosyan new vice chair of the Pharmacovigilance Risk Assessment Committee PRAC

The role of the MEB and the Netherlands in Europe is also reflected by our representation in Europe. For example, in the person of Liana Martirosyan. She was elected as the new [vice chair of the European Pharmacovigilance Risk Assessment Committee PRAC](#)



6 September

### The MEB started up pipeline meetings again

After an absence of several years, the MEB started the '[pipeline meetings](#)' again in 2024. Based on a thematic approach, we talk to medicines manufacturers about new plans and innovations in medicines development.



12 September

### Aimad Torqui member of HMA Management Group

Aimad Torqui was appointed as member of the Management Group of the [Heads of Medicines Agencies \(HMA\)](#). He has held this role since 12 September 2024 in addition to his role as department head at the MEB.



16 September

### Violeta Stoyanova retired as COMP chair

After six years as [chair of the Committee for Orphan Medicinal Products \(COMP\)](#), Violeta Stoyanova retired because she had reached her maximum term.

30 September

### The Netherlands hosted the TOPRA Symposium 2024

TOPRA is the international professional association of regulatory affairs professionals. The 2024 edition of the annual [TOPRA Symposium](#) was held in Rotterdam. The MEB played a prominent role at the symposium and the opening remarks were provided by director Paula Loekemeijer. Ton de Boer and Aimad Torqui participated in one of the panels.



## October

1 October

### Risk communication provided to healthcare provider more quickly

Since October, risk communication, such as the DHPC (Direct Healthcare Professional Communication) and recall letters, has been only one click away from healthcare providers. In consultation with the industry's branch organisations and the IGJ, the MEB has amended its policy so that from now on Marketing Authorisation Holders send the [risk communication by e-mail](#). This was previously done by post.



24 October

### From paper to digital package leaflets: the first trial started

After the European Commission had given the green light, a trial started in October in which the paper package leaflets was replaced with a [digital package leaflet](#), intended for medicinal products in hospitals. These package leaflets often failed to reach patients. A digital package leaflet provides doctors with the most current medicine information. It also makes it possible to divide stocks more effectively over countries, because the packaging does not contain a package leaflet. This helps counter medicine shortages.

24 October

### Hans Hillige sworn in as new Board Member

With [Hans Hillige sworn in](#), the Board was back to its full strength of seventeen members in October. Hans Hillige is a professor of Cardiology at UMC Groningen and he held different positions with the MEB for many years.



October

### You do not use opioids alone, an interview with medicines user Theo Foekens

In October, the MEB devoted online attention in different ways to strong painkillers such as opioids and how to use them correctly. We did so by conducting an [interview with expert by experience Theo Foekens](#).



October

### New policy for package leaflets and labels: positive list of pictograms expanded

In October, we set out our new policy concerning package leaflets and the labels of medicinal products. The main change is policy related to pictograms. The [Positive List of pictograms](#) was expanded on 12 February 2025. The list was supplemented with warnings and now also contains instructions for use. This set was drawn up in cooperation with various chain partners and stakeholders.

## November

4 November

### International Medicines Safety Week: How you can (sometimes) prevent adverse reactions

During the annual [International Medicines Safety Week](#), the MEB together with other medicine authorities in Europe and the Pharmacovigilance Centre Lareb draws attention to adverse reactions. This year, the theme is the prevention of adverse reactions.

December

### Cooperation agreement with CCMO

The (existing) [cooperation with the Central Committee for Research Involving Human Subjects \(CCMO\)](#) will be renewed in December. This cooperation offers both organisations the opportunity to learn more from each other. We hope it will also allow us to work more efficiently, with the end goal being that patients will have access to safe medicinal products sooner.

## December

19 December

### New policy for Compassionate Use Programmes

In December, the MEB published new policy for [Compassionate Use Programmes \(CUP's\)](#). A CUP makes it possible in distressing cases to treat patients with a medicinal product for which no marketing authorisation has been issued as yet.

# Medicinal products and vaccines for human use <sup>1</sup>



## Rapporteurships and co-rapporteurships assigned to the Netherlands through the centralised procedure (CHMP)

The responsibilities of the Committee for Medicinal Products for Human Use (CHMP) include assessing centralised applications for marketing authorisations for medicinal products. The Netherlands is one of the European countries that carries out a large number of assessments.

In 2024, the Netherlands was designated as rapporteur 12 times and 11 times as co-rapporteur. This is in line with previous years. See table 1.1a in the appendix for the number of (co)rapporteurships.

In 2024, Germany was assigned the most rapporteurships and co-rapporteurships (30). Austria, Poland, Sweden and the Netherlands followed with a total of 23 rapporteurships and co-rapporteurships each. Four countries were not assigned

any rapporteurships or co-rapporteurships. See table 1.1b for the European overview.

## Concerned

The figures in this chapter give an impression of the assessments in which are directly involved as rapporteur or co-rapporteur. Two countries always take the lead during European procedures. Not being one of those two does not mean that we are not involved. We follow the assessment as a 'Concerned Member State'. This is important to our CHMP representatives to have a well-founded position within the CHMP, but also to stay informed of developments and to be able to make the right considerations at a later moment. Especially in applications for new medicinal products. This also maintains the quality of the assessments, because each application is reviewed by more people.

## European cooperation

The MEB Agency has an important role in Multi National Assessment Teams (MNATs). In these teams, several countries tackle a rapporteurship together. This allows countries that do not act as rapporteur very often to gain experience. MNAT partnerships promote European cooperation. They

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<sup>1</sup> This chapter does not consider herbal medicinal products and homeopathic products. These products are discussed in a separate chapter: *Botanicals and novel foods*.

also help the MEB Agency manage its very high workload, especially in the area of chemical-pharmaceutical quality assessment.

Of all the rapporteurships assigned to the Netherlands in 2024, 5 were assigned as MNAT. Other countries assumed the chemical-pharmaceutical quality part on four occasions, and the quality and non-clinical part of the case on one occasion. In addition, the MEB Agency once participated as MNAT partner and carried out the non-clinical part.

### **Assigned pharmacovigilance rapporteurships (PRAC)**

The Pharmacovigilance Risk Assessment Committee (PRAC) plays an important role in monitoring the risks of medicinal products for human use in Europe. The PRAC provides recommendations to the CHMP and the Coordination Group for Mutual Recognition and Decentralised Procedures human (CMDh) on the risks of medicinal products that have been or will be authorised in the European Union.

In 2024, the MEB was assigned slightly fewer PRAC rapporteurships than in the previous year. Of the 9 PRAC rapporteurships assigned to the MEB in 2024, 7 were for new active ingredients. The MEB acted as PRAC co-rapporteur 12 times.

With 9 PRAC rapporteurships, the MEB continues to have a leading role within Europe. Sweden was assigned the most PRAC rapporteurships in 2024, followed by Germany, Denmark and the Netherlands.

Table 1.2a in the appendix shows the number of PRAC rapporteurships. Table 1.2b provides an overview of the allocation of PRAC rapporteurships between European countries.

### **Applications submitted through the decentralised procedure (DCP) and the mutual recognition procedure (MRP)**

The number of initiated decentralised procedures for which the Netherlands was the Reference Member State (RMS) was 213 in 2024. Germany was RMS for most DCP applications, followed by the Netherlands.

Of the European countries, the Netherlands was RMS of most mutual recognition procedures (MRP) in 2024. See Tables 1.3a and 1.3b in the appendix.

Table 1.3c shows how often the European countries were involved as Concerned Member State (CMS) in DCP and MRP applications.

### **Applications through the national procedure**

The number of applications submitted through the national procedure (excluding parallel imports, including duplex marketing authorisation procedures) continues to fluctuate between 60 and 80 per year. See Table 1.4 in the appendix. Most applicants prefer (or are obliged to conduct) a European procedure (centralised and DCP), which allows the product to receive marketing authorisation in several European countries simultaneously.

### **National applications for parallel imports**

In 2024, 212 applications for parallel import marketing authorisations were submitted, which is similar to 2023 when 224 applications were made. See table 1.5 in the appendix.



### Number of registered marketing authorisations and withdrawals following registration

In 2024, a total of 13,455 marketing authorisations were registered in the Netherlands. This number is slightly lower than the year before.

When a company makes a request for withdrawal of the marketing authorisation, the MEB looks at whether it is a critical product. For example, if there are no similar medicinal products in the same medicinal product group, the MEB will investigate what options are available to keep the product on the market for Dutch patients. The MEB does this in consultation with the marketing authorisation holder.

2024 showed an increase in the number of marketing authorisation withdrawals. This may be related to developments in society, such as economic considerations.

See Tables 1.6a and 1.6b in the appendix for an overview of registered and withdrawn marketing authorisations.



### Scientific advice

By providing scientific advice, the MEB contributes to responsible medicinal product development, innovation and early patient access.

Scientific advice can cover various aspects, such as clinical or toxicological product development, but also regulatory aspects. This advice allows manufacturers to develop their products efficiently and prepare for (future) registration of a product. Partly because of this, issuing scientific advice is a statutory duty.

There are both national and centralised (European) procedures for issuing scientific advice. As a statutory duty, national scientific advice falls under the direct responsibility of the MEB. Centralised scientific advice is prepared by the European Scientific Advice Working Party (SAWP). This concerns a European consensus under the responsibility of the CHMP. The MEB issues both European and national scientific advice. Incidentally, it is not compulsory to request scientific advice.

In 2024, 137 scientific opinions were assigned to the Netherlands via the SAWP. This was similar to the number in 2020-2022. See Table 1.7 in the appendix. The decrease in the number in 2023 was related to fewer applications for scientific advice at the European level.

The MEB has participated in the Simultaneous National Scientific Advice (SNSA) pilot since 2022. This type of advice focuses on clinical trials, but other topics are also covered. Applicants can request scientific advice from several EU countries at the same time. This pilot has since been consolidated into a regular form of advice in which ethical committees often play a large role.

### Number of instances of national scientific advice

In 2024, the MEB provided national scientific advice 104 times. This number has remained stable over the years.



The MEB also issues tailored advice, allowing start-ups and academic groups to seek advice at a reduced rate. This encourages innovation at universities and in small businesses. See Table 1.8 in the appendix for figures on national scientific opinions.

As in previous years, the MEB was actively involved in drug rediscovery projects set up by ZonMw. ZonMw is the Dutch body that promotes and funds health research and innovation. By assessing project applications for research into medicinal products, which are sometimes already used off-label in practice, the MEB contributes to a possible on-label application. There are significant benefits to this for prescribers and patients, but also for pharmacovigilance. This is because the registered application is mentioned in the product information, including in the patient information leaflet.

In addition, the MEB provides comments concerning oncological research proposals at the request of the Dutch Cancer Society (KWF).

### **Adverse reactions**

Identifying and assessing adverse reactions to medicinal products is a core task of the MEB. On behalf of the MEB, the Netherlands pharmacovigilance centre Lareb collects, manages and analyses reports of suspected adverse reactions from healthcare providers and patients. Lareb sends relevant findings from these analyses to the MEB.

In 2024, Lareb and the MEB discussed 48 analyses of reports of suspected adverse reactions. Of the 48 analyses, one was developed for discussion in the MEB meeting and three for discussion in the meeting of the MEB Agency's Medical Practice Committee. The remaining analyses have found their way into ongoing proceedings at the MEB or are being monitored closely.

### **Signal detection**

In 2024, the MEB was responsible in the European context for the signal detection of 100 active ingredients, or combinations of active ingredients. This means that, for these ingredients, the MEB is responsible for analysing data in the European database of suspected adverse reactions (Eudravigilance) and for identifying signals of possible new or changed risks.

In 2024, the MEB assessed 17 signals as PRAC Rapporteur in the European context. The MEB was involved as Concerned Member State in 76 signals.

### **Periodic Safety Update Reports (PSURs)**

As part of the PSUR Single Assessment (PSUSA) procedure, the MEB assesses Periodic Safety Update Reports (PSUR) for 100 active ingredients with national registration. The MEB also acts as PRAC rapporteur for 193 products registered centrally, for which PSUSAs are also assessed.

A PSUR is a comprehensive and critical analysis of a product's risk-benefit balance. It gives medicinal products authorities updates on global safety experiences with a product at set intervals after registration. The need to submit PSURs is determined using a risk-based approach. The frequency



with which PSURs are submitted varies. A PSUR also assesses whether the identified signals from possible new and/or changed risks result in adjustment of the product information.

In 2024, the MEB conducted 138 PSUSA assessments in the European context.

### **PASS protocols and study results**

If there are any remaining uncertainties about the safety of a medicinal product, a company may be asked to conduct additional safety studies, called Post Authorisation Safety Studies (PASS). Over the past year, the MEB assessed 82 protocols and study results as PRAC rapporteur and it was involved as Concerned Member State in 169 cases.

### **Direct Healthcare Professional Communication**

In case of urgent or important safety issues, medical professionals are notified with a letter, called a Direct Healthcare Professional Communication (DHPC). In 2024, 12 DHPCs were sent. See Table 1.9 in the appendix.

As from 1 October 2024, Marketing Authorisation Holders have been sending risk communication, including the DHPC and recall letter, digitally. This was previously done by post. This policy change ensures that healthcare providers receive important risk communication sooner.



### **Additional Risk Minimisation Measures**

Sometimes, additional risk minimisation measures (such as the SmPC) are imposed in addition to the routine risk minimisation measures in order to limit the risks of a medicinal product, such as information concerning correct use of the product. In 2024, the MEB assessed 112 such additional measures or updates of these additional measures.

Another example would be pregnancy prevention programmes for medicinal products that increase the risk of congenital anomalies in babies when used by pregnant women, women who want to become pregnant or men who want to have children.

### **Medicine shortages**

The availability of medicinal products for the Dutch market is very important to public health, but has been under pressure for considerable time. This was also the case in 2024.



The MEB coordinates the Medicine Shortages and Defects Notification Centre together with the Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*). The MEB checks for each report of an anticipated supply interruption whether there are sufficient alternatives available in the Netherlands if a medicinal product is temporarily unavailable. In case of a life-threatening or very serious affliction or when the shortage has a major impact on patient and there are insufficient alternatives for the patient to deal with a supply interruption, the MEB will consider this to be a critical shortage. The MEB and the IGJ will then investigate together which measures can be taken to limit the adverse consequences of shortages for patients as much as possible.

Since 2024, the IGJ and the MEB have been participating in the Medicines Shortages Operational Team (OTG) together with the KNMP, the National Coordination Center for Prescription Drugs (LCG)

and the wholesale supplier umbrella organisation (BG Pharma). The OTG contributes to the early identification of imminent shortages and supports the Notification Centre when a critical shortage arises. Moreover, the OTG makes it possible to formulate custom treatment and dispensing advice and spread this among healthcare providers more effectively.

The total number of reports of anticipated supply interruptions (4,770) received by the Notification Centre in 2024 is lower than in the previous year. However, this number does not provide an accurate picture of the supply problems that will actually occur in practice. Companies are obliged to report anticipated supply problems. They also report risks of supply problems as a precaution.

In 2024, the Notification Centre [used measures against shortages more often than in previous years](#). One measure the MEB can implement is authorising ‘Temporarily Different Packaging’ (TAV), meaning foreign packaging of the same medicinal product. In 2024, the MEB issued 117 TAV authorisations (including renewals). A considerable increase over previous years.

Up to and including 18 November 2024, the IGJ authorised manufacturers, wholesale suppliers and pharmacists on 126 occasions to import an alternative medicinal product from abroad based on a shortage declaration. No shortage declarations were issued after 20 November because of a decision from the Council of State.

Between 28 November 2024 and 23 December 2024, the Minister of VWS decided with respect to 9 shortages that they come under the scope of application of the Instruction issued to the IGJ not to take enforcement action concerning the import of comparable medicinal products from abroad on a temporary basis.

The number of shortages where a shortage declaration was issued or that come under the Minister’s Instruction is therefore similar to 2023.

There were more occasions in 2024 than in previous years that no or insufficient alternatives were available in the Netherlands and also that there were insufficient possibilities to import from abroad in case of a critical shortage. In such cases, the MEB and the IGJ consider in consultation with healthcare professionals whether additional measures are necessary, such as adjusted treatment and dispensing advice. This was the case with 7 medicinal products in 2023 and 12 medicinal products in 2024.

Medicines shortages are not just a problem in the Netherlands. That is why the MEB also works to combat medicine shortages at the European level. For example, the MEB participates in the Single Point of Contact (SPOC) Working Party and the EMA’s Medicine Shortage Steering Group (MSSG). The revision of European pharmaceutical legislation also devotes a great deal of attention to measures against shortages.

The MEB’s policy-related and operational work on medicine shortages has increased over the past years. In order to increase the capacity and responsiveness with respect to the prevention and mitigation of medicine shortages, the MEB set up an internal Medicines Availability Programme in 2024 for the purpose of embedding work on medicine availability in a structural manner.

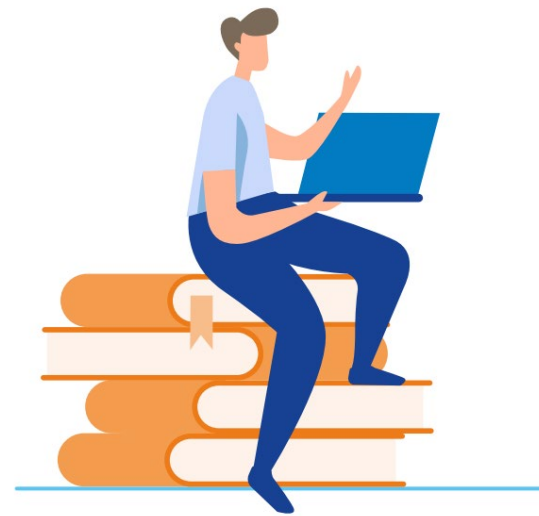


## Regulatory research

In 2024, the MEB was involved in 25 PhD tracks. Two PhD students completed their research and received their doctorate. Four new PhD students started their doctoral research in 2024.

In addition to the PhD research, the MEB was actively involved in student research. Eleven students followed a short research traineeship (5 to 10 weeks) and 19 students followed a research traineeship at the MEB for more than 10 weeks (up to at most 9 months).

In 2024, the regulatory research resulted in 57 peer-reviewed publications with MEB involvement. This constitutes a slight increase when compared to 2023 when the MEB was involved in 49 publications.



## Patient Information Network (NPI)

The Patient Information Network (NPI) was formed in 2018 in order to make reliable, understandable and accessible information available to patients in a simple manner. The MEB coordinates this network. The participants are the MEB with [geneesmiddeleninformatiebank.nl](https://www.geneesmiddeleninformatiebank.nl), [Thuisarts.nl](https://www.thuisarts.nl) (NHG, FMS, Netherlands Patients Federation), [apotheek.nl](https://www.apotheek.nl) of the Royal Dutch Society for the Advancement of Pharmacy (KNMP), Stichting Kijksluiter and Pharmacovigilance Centre Lareb. The members of this network meet regularly.

The NPI carries out activities to make information on medicines more understandable and more accessible while being mindful of reliable and independent information concerning medicinal products. The NPI receives advice from the Netherlands Patients Federation, NIVEL and Pharos. In 2024, the NPI also worked on various communications, such as the Style Guide for comprehensive writing about medicinal products, short summaries of vaccine information (Vaccin in het kort) for the National Immunisation Programme and informative materials for the vaccination campaign. A start had been made in 2024 with drawing up a new long-term work plan for the period 2025 up to and including 2027.

Furthermore, 17 parties from the medicinal product information landscape signed a letter of intent on 8 December 2022. These include BOGIN, VIG, VES, Nprofarm, CBD, KNMP, the MEB and the Ministry of Health, Welfare and Sport. The aim of this partnership is to develop a new, uniform set of icons.

The use of uniform icons in medicinal product information contributes to greater understanding, better and safer use of medicinal products and greater compliance. This resulted late 2024 in a final and uniform set of medicine pictograms. This set will be made available to the providers of medicine and vaccine information early 2025.

## Botanicals and novel foods



**The Botanicals and Novel Foods (BNV) team has two tasks. The first is the assessment of herbal medicinal products and homeopathic products. The MEB makes marketing authorisation decisions for these groups of products as well.**

In addition, the team provides policy support to the Ministry of Health, Welfare and Sport (VWS) in the authorisation of novel foods, pursuant to the EU Novel Foods Regulation. Since 2018, this has been done within a European system based on assessments by the European Food Safety Authority (EFSA). The Ministry of Health, Welfare and Sport decides on authorisation for the Netherlands.

The BNV team also represents the Netherlands on the EMA's Herbal Medicinal Products Committee (HMPC). The HMPC reviews scientific data on herbal medicinal products and compiles European herbal monographs.

### **Number of marketing authorisations for herbal and homeopathic medicinal products**

The number of herbal medicinal products with a marketing authorisation on the Dutch market is fairly stable, with a slight decrease over the years. See Table 2.1 in the appendix.

The total number of marketing authorisations for homeopathic medicinal products had remained stable over the years, but decreased strongly in 2024. See Table 2.2 in the appendix.

# Veterinary medicinal products

**The MEB Agency's Veterinary Medicinal Products Unit (VMPU) handles and assesses applications and issues production, distribution and marketing authorisations for veterinary medicinal products.**

The VMPU advises the Ministry of Agriculture, Fisheries, Food Security and Nature (LVVN) on this matter through the Committee for the Authorisation of Veterinary Medicines (Ctd). In the Netherlands, the Minister of LVVN is responsible for the marketing authorisation of veterinary medicinal products.

The VMPU is also tasked with monitoring the adverse reactions to veterinary medicinal products, granting trial exemptions for veterinary medicinal products and feed additives, and issuing batch approvals for veterinary vaccines, export certificates and licences for wholesale and retail trade.



## **New chair**

The chair of the Ctd, Dr Henk Vijverberg, retired in March 2024. His duties as chair were taken over by Ctd member Aldo Dekker.

## **Inspections**

Since January 2019, the MEB Agency has taken over veterinary pharmacovigilance inspections from the IGJ. In 2024, the VMPU conducted one pharmacovigilance inspection.

## **Assigned centralised CVMP rapporteurships and co-rapporteurships**

In 2024, the MEB Agency was assigned 8 rapporteurships and co-rapporteurships within the Committee for Veterinary Medicinal Products (CVMP). A significant increase over the year before, when this number was one. The number of rapporteurships and co-rapporteurships has been stable over the years, 2021 was an outlier. See Table 3.1 in the appendix.

## **Assigned centralised MRL rapporteurships and co-rapporteurships**

For substances used as medicinal products for food-producing animals, a maximum residue limit (MRL) must be set. The rapporteur for an MRL application assesses the maximum safe concentration of the residue of an active ingredient in the various consumable products of animal origin. In 2024, the MEB Agency was assigned one MRL rapporteurship or co-rapporteurship. See Table 3.2 in the appendix.

## **Closed RMS applications through the mutual recognition and decentralised procedure**

In 2024, the Netherlands closed 29 DCP applications as a leading Member State (RMS). The share of the European work carried out by the Netherlands is large. In 2024, Ireland closed the highest number of DCP applications, followed by the Netherlands. The Netherlands closed 30 RMS applications in 2024. See Tables 3.3a and 3.3b in the appendix.

### **Number of marketing authorisations and number of withdrawals of marketing authorisations**

Last year saw a very slight decrease in the number of marketing authorisations for veterinary medicinal products registered in the Netherlands – 2,220 in 2024 compared to 2,246 in the previous year.

In addition, 2024 saw a decrease in the number of withdrawals of marketing authorisations for veterinary medicinal products at the request of the marketing authorisation holder: 103 (compared to 153 in 2023).

See Tables 3.4a and 3.4b in the appendix for the number of marketing authorisations and withdrawals.



# Governance and organisation

## Organisational structure

The Medicines Evaluation Board is an autonomous administrative authority (ZBO) within the Central Government. The MEB takes decisions on the authorisation of medicinal products on the Dutch market. As an independent authority, the MEB regulates the quality, effects and safety of medicinal products and promotes the proper use of medicinal products for the right patient.

The MEB provides scientific advice and is responsible for the classification of medicinal products (legal status of supply) and pharmacovigilance. The MEB also assesses medical devices incorporating a medicinal product and advises the notified bodies on such devices. The MEB also checks whether (possible) supply problems constitute a critical shortage.

The preparation and implementation of decisions of the MEB are carried out by the MEB Agency, which is headed by the MEB Agency director/MEB secretary.

## The Board

The MEB has a maximum of 17 members, including the chair. The members are medical specialists, hospital pharmacists, professors and other experts. MEB members are appointed by the Minister of Health, Welfare and Sport for a period of four years. Members can be reappointed twice. In 2024, one member of the Medicines Evaluation Board left and two members joined the Board (see above in this annual report in the chapter entitled 'The year in a nutshell').

In principle, a meeting attended by all MEB members takes place once a month, while another monthly meeting is attended by a smaller group of members. In addition, a rotating group of MEB members meets once a month to discuss dossiers specifically related to pharmacovigilance. The chair and vice-chairs also meet with agency employees once a week to discuss specific questions about medicinal product dossiers. Furthermore, MEB members are regularly consulted in assessment work on an ad hoc basis. For the MEB's statutory duty with regard to issuing scientific advice, a coordination meeting takes place in the presence of the chair of the MEB every two weeks.

## The Agency

The MEB Agency supports the MEB. Administratively, the agency falls under the Ministry of Health, Welfare and Sport. Substantively, it falls under the authority of the MEB as far as tasks for which the MEB is responsible are concerned. The agency is responsible for preparing and implementing decisions by the MEB. The agency handles some 20,000 cases annually. Those cases range from administrative changes to reviews of medicinal product dossiers with new active ingredients.

The agency introduced a divisional structure with three department heads and a general manager in February 2023. The departments fall under three divisions:



- 1) Assessments & Marketing Authorisation
- 2) Europe, Medicine Use & Veterinary Medicinal Products
- 3) Business Operations, Legal Affairs & Communications

### European representation

The Netherlands is represented in the EMA's European scientific committees. The Dutch committee members are part of the agency.

At the CHMP and the PRAC, the lines for the assessment of medicinal products for human use under the European centralised procedure converge. These committees include representatives from all EU countries. The committees meet monthly at the EMA in Amsterdam.

If the Netherlands is rapporteur, a team of MEB Agency employees assesses the dossier. The composition of the team depends on the medicinal product and the topics to be answered in the assessment. The team then submits the results of the assessment to the MEB. The MEB, together with the European committee members, will recommend a proposal that the Dutch CHMP or PRAC members can take into the discussion with the committees.

For the allocation of rapporteurships and co-rapporteurships, the EMA uses criteria whereby allocation is based on the best available expertise in the Member States, while leaving room for countries that have been less frequent rapporteurs in the past.

The allocation of co-rapporteurships is different at the PRAC than at the CHMP: the country that is CHMP rapporteur automatically becomes PRAC co-rapporteur.

Besides the CHMP and the PRAC, the EMA has four other scientific committees to advise on the centralised procedure for medicinal products for human use:

- the Committee for Orphan Medicinal Products (COMP);
- the Paediatric Committee (PDCO);
- the Herbal Medicinal Products Committee (HMPC) and
- the Committee on Advanced Therapies (CAT).

Several working groups are active within each EMA scientific committee. An example of this is the SAWP.

The coordination of European work on decentralised and mutual recognition procedures has been assigned to the Coordination Group for Mutual Recognition and Decentralised Procedures human (CMDh). The CMDh is a committee of the Member States, but like the other committees, it meets at the EMA and is also supported by the EMA.

The EMA's HMPC reviews scientific data on herbal medicinal products and produces European herbal monographs.

The CVMP is the EMA's scientific committee for veterinary medicinal products. All EU Member States have representatives on this committee.

Analogous to the CMDh for human medicinal products, there is also a group coordinating European work on DCP and MRP procedures for veterinary medicinal products: the Coordination Group for Mutual Recognition and Decentralised Procedures veterinary (CMDv). The Dutch representatives on both the CVMP and the CMDv work at the VMPU.

## The Advisory Board

The task of the Advisory Board is to advise the MEB independently and critically about the major policy themes and other aspects of our tasks. It provides advice by focusing strategically on the environment in which the MEB operates.

In 2024, the Advisory Board issued advice on the Strategic Business Plan and the Science Policy.

## Transparency, independence and integrity

As an autonomous administrative authority, the MEB aims to make independent, reasoned and insightful decisions. That is why the MEB, when it makes a decision, provides an opportunity to submit opinions and be heard. A person can also object to an MEB decision and then appeal to the courts.

Independence demands integrity. The MEB safeguards integrity with a [Code of Conduct](#) and an integrity policy. MEB members, MEB Agency employees and external experts complete a 'declaration of interests'. This is done prior to employment or when entering into a contract. After the first time, this happens annually. New interests should be reported in the interim.

## Objection and appeal procedures

In 2024, 11 different objection and (higher) appeal procedures were pending. See Table 4.1 in the appendix. The procedures could be broadly divided into two main categories. The first category includes procedures in which decisions to grant or refuse a marketing authorisation were at issue. The other category covers procedures on disclosure decisions under the Open Government Act (Wet open Overheid, Woo). In both types of procedures, competitive interests of pharmaceutical companies play an important role.

## Requests under the Open Government Act (Woo)

In 2024, the MEB received a total of 29 disclosure requests under the Woo. In most cases, such requests are made by competing pharmaceutical companies. The vast majority of requests were about pending applications for marketing authorisations before the MEB.

The MEB Agency also handles Woo requests concerning veterinary medicines. We do this on behalf of the Minister of Agriculture, Nature and Food Quality. No Woo requests concerning veterinary medicines were received in 2024.

The MEB actively publishes Public Assessment Reports (PARs) (humane) on its website. The MEB published 125 PARs in 2024. A PAR provides the public with structured information concerning the assessment process of a certain medicinal product. Striking the balance between confidential information and transparency is important in this regard. There is close collaboration between the employees who handle Woo requests and the employees who draw up PARs.

## Opinion procedure

If the MEB intends to take a negative decision, interested companies (such as the applicant or competitors) have the opportunity to submit an opinion. An opinion procedure can be either written or oral. In 2024, the MEB processed 22 opinions. See Table 4.2 in the appendix.

## Quality management

The MEB has been ISO-9001 certified since 2006. With this certificate, the MEB shows that it complies with this international standard in the field of quality management for the performance of its statutory duties.

For its statutory pharmacovigilance duties, the MEB is required by European regulations to operate a quality system. Although external certification is not, strictly speaking, mandatory from a regulatory perspective, the MEB Agency considers it important to adopt a transparent and, where possible, verifiable approach. That creates confidence. External certification helps with this. The 2024 audit certification shows that the MEB continues to meet the standard.

The European network of medicine authorities applies a benchmark cycle. The MEB was benchmarked in 2024 and obtained sound results.

### Complaints

In 2024, 29 complaints were received from external parties. Of these, 9 were upheld, 3 were partially upheld, 8 were unfounded and 9 were inadmissible. The (partly) well-founded complaints mainly concern communication and processing times.

### Employees

At the end of December 2024, the MEB Agency had 522 employees. Together, they accounted for 479.7 FTEs on average. See Table 4.3 in the appendix. The average MEB Agency employee is 43.7 years old and works at a part-time rate of 91.9%. The average MEB Agency employee has 8.1 years of service.

The average sickness absence rate for 2024 was 4.9%. A minor increase compared to the previous year.

### Diversity & inclusion

In 2024, the MEB Agency's Diversity & Inclusion working group consisted of five employees, one of whom was an HR adviser and four were employees from within the organisation. There were various initiatives to draw attention to D&I-related subjects. A mini library was formed where employees can borrow books and there is also an D&I suggestion box. D&I tips on what watch and listen to were shared on intranet. D&I group members also participate in VWS-wide initiatives and attend lectures, for example.

As regards the implementation of the Job Agreement (more jobs for people with an occupational impairment), as laid down in law, the MEB Agency nearly complied with the quota in 2024. This was set at 18.23 jobs late 2024, and 0.8 jobs to be filled are still outstanding. Retention of staff from the Job Agreement is going well. Furthermore, jobs were spread wider over the departments that employ someone from the Job Agreement when compared to previous years.

### Information provision

In 2024, preparations for a new medicinal product assessment system were the key issue in ICT/Information provision. The tender process for this new system was completed in 2024. The contract was awarded to Netcompany. During the tender process, both a CIO test and a test by the ICT Advisory Board were performed in respect of the programme that carries out the tender process. Both tests were completed successfully. The realisation and implementation of the new assessment system will start in February 2025.



Another important development is the process of strengthening the MEB’s Information provision (IV) organisation. Started late 2024, this process will continue throughout 2025 and 2026. Setting up a professional management organisation will further improve the intensive use of ICT. In doing so, the MEB also anticipates rapid ICT developments and the strategic objectives of the MEB.

## Finances

The MEB Agency posted a positive result of €1.8 million in 2024. This can be explained by a €5.1 million lower income than budgeted and €3.3 million higher costs. The balance of €1.8 million was added to the equity.

### Income

The income that exceeds the budget by €5.1 million can be explained by income from procedures that are €2.6 million higher and €0.6 million from annual fees (third-party turnover). The contributions from the Ministry of VWS and LVVN were €1.0 million and €0.1 million higher than budgeted. Subsidies from other sources, such as the European Commission, are down by €0.1 million. The interest income of €0.9 million was not budgeted.

On balance, the increased revenue from procedures and annual fees of €3.2 million is due to lower revenue than budgeted for national (€0.3 million) and central procedures (€0.5 million). This is offset by higher revenue from mutual recognition procedures/MRP (€0.1 million), decentralised procedures (€2.9 million), veterinary medicines (€0.4 million) and annual fees (€0.6 million). Income from procedures and annual fees increased by €7.7 million when compared to 2023.

The reason for the increased contribution of €0.1 million from the Ministry of VWS is the compensation for the increased costs resulting from the CLA (€3.5 million) and the contribution for the efforts made for the European Pharmaceutical Legislation (€0.4 million) on the one hand, and the lower subsidy revenue for other project-based activities on the other hand. Part of these activities and budget are carried over to 2025.

The contribution for the Information Management in Order programme, including the implementation of the Open Government Act, was €1.1 million lower than budgeted. Within the MEB Agency, the Open Government coordinator has now set up a solid programme and line organisation.

Several subprojects financed with WaU (Work on Implementation) funds were carried over to 2025 due to the delay that occurred in the Core System Replacement project. This resulted in a decrease in income of €1.3 million. The Core System Replacement project passed the additional AC ICT test. The contract was awarded to the supplier late 2024. This delayed other projects with an ICT component, as a result of which the income realised was €0.5 million lower than budgeted.

### Expenditure

The new CLA agreements that apply since 1 July 2024 and the expansion of the option of saving IKB hours effective as from 2023 mean that the own personnel expenses were €4.1 million higher than budgeted. By extension, the other personnel expenses were also €0.4 million higher than budgeted. The costs of external temporary workers remained at the same level as in 2023 and in line with the budget. It proved possible to fill some of the difficult to fill vacancies by recruiting administrative staff in the course of 2024. However, the deployment of external workers remains necessary and



desirable for temporary and specialist activities (such as in ICT) for the various programmes and projects.

The other tangible expenses were €1.1 million lower than budgeted. This is caused by postponed scheduled activities (on the one hand due to the delay that occurred within the Core System Replacement project and on the other hand due to the measures to limit expenditure implemented by the MEB Agency in Q4) and the lower accommodation costs. The replacement of the laptops was postponed, lowering the depreciation costs by €0.2 million.

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**Telephone:** +31 (0) 88 224 80 00  
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### Disclaimer:

*Due to retrospective adjustments to the MEB database, some figures from previous years in this edition of the annual report may differ from the figures as published in the annual reports of previous years.*

## List of abbreviations

|               |   |
|---------------|---|
| <b>ATMP's</b> | Advanced Therapy Medicinal Products   |
| <b>BEMA</b>   | Benchmarking of European Medicines Agencies   |
| <b>BOGIN</b>  | Dutch generic and Biosimilar medicines association (Dutch: Biosimilars en generieke geneesmiddelenindustrie Nederland)              |
| <b>BNV</b>    | Botanicals and Novel Foods (Dutch: Botanicals en Nieuwe Voedingsmiddelen)   |
| <b>CAT</b>    | Committee for Advanced Therapies  |
| <b>CBD</b>    | Central Office of Drugstore Companies (Dutch: Centraal Bureau Drogisterijbedrijven)   |
| <b>CCMO</b>   | Committee for Research Involving Human Subjects (Dutch: Centrale Commissie Mensgebonden Onderzoek)                                  |
| <b>CHMP</b>   | Committee for Medicinal Products for Human Use  |
| <b>CLA</b>    | Collective Labour Agreement   |
| <b>CMDh</b>   | Coordination group for Mutual recognition and Decentralised procedures  |
| <b>CMDv</b>   | Coordination group for Mutual recognition and Decentralised procedures for veterinary medicinal products                            |
| <b>CMS</b>    | Concerned Member State  |
| <b>COMP</b>   | Committee for Orphan Medicinal Products   |
| <b>Ctd</b>    | Committee for the Authorisation of Veterinary Medicines (Dutch: Commissie toelating diergeneesmiddelen)                             |
| <b>CUP</b>    | Compassionate Use Programma   |
| <b>CVMP</b>   | Committee for Medicinal Products for Veterinary Use   |
| <b>DCP</b>    | Decentralised procedure   |
| <b>DHPC</b>   | Direct Healthcare Professional Communication  |
| <b>EFSA</b>   | European Food Safety Authority  |
| <b>EMA</b>    | European Medicines Agency   |
| <b>FMS</b>    | Dutch Federation of Medical Specialists (Dutch: Federatie Medisch Specialisten)   |
| <b>HMA</b>    | Heads of Medicines Agencies   |
| <b>HMPC</b>   | Committee on Herbal Medicinal Products  |
| <b>IGJ</b>    | Health and Youth Inspectorate (Dutch: Inspectie Gezondheidszorg en Jeugd)   |
| <b>IKB</b>    | Individual choice budget (Dutch: Individueel Keuze Budget)  |
| <b>IV</b>     | Information provision (Dutch: Informatievoorziening)  |
| <b>KNMP</b>   | The Royal Dutch Pharmacists Association (Dutch: Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie)                 |
| <b>LCG</b>    | National Coordination Center for Medicines (Dutch: Landelijk Coördinatiecentrum Geneesmiddelen)                                     |
| <b>LVVN</b>   | Ministry of Agriculture, Fisheries, Food Security and Nature (Dutch: Ministerie van Landbouw, Visserij, Voedselzekerheid en Natuur) |
| <b>MEB</b>    | Medicines Evaluation Board  |
| <b>MNAT</b>   | Multi-National Assessment Team  |
| <b>MRL</b>    | Maximum Residue Limit   |
| <b>MRP</b>    | Mutual Recognition Procedure  |
| <b>MSSG</b>   | Executive Steering Group on Shortages and Safety of Medicinal Products  |
| <b>NHG</b>    | Dutch General Practitioners Society (Dutch: Nederlands Huisartsen Genootschap)  |
| <b>NPI</b>    | Patient Information Network (Dutch: Netwerk Patiënten Informatie)   |
| <b>NVWA</b>   | Netherlands Food and Consumer Product Safety Authority (Dutch: Nederlandse Voedsel- en Waren Autoriteit)                            |
| <b>OTG</b>    | Medical Shortages Operational Team (Dutch: Operationeel Team Geneesmiddelentekorten)  |
| <b>PAR</b>    | Public Assessment Report  |
| <b>PASS</b>   | Post Authorisation Safety Studies   |

|              |   |
|--------------|---|
| <b>PDCO</b>  | Pediatric Committee   |
| <b>PRAC</b>  | Pharmacovigilance Risk Assessment Committee   |
| <b>PSUR</b>  | Periodic Safety Update Report   |
| <b>PSUSA</b> | PSUR Single Assessment  |
| <b>RMS</b>   | Reporting Member State  |
| <b>SAWP</b>  | Scientific Advice Working Party   |
| <b>SBP</b>   | Strategic Business Plan   |
| <b>SmPC</b>  | Summary of Product Characteristics  |
| <b>SNSA</b>  | Simultaneous National Scientific Advice   |
| <b>SPOC</b>  | Single Point of Contact   |
| <b>TAV</b>   | Temporarily Different Packaging (Dutch: Tijdelijk Afwijkende Verpakking)                        |
| <b>TOPRA</b> | The Organisation for Professionals in Regulatory Affairs  |
| <b>VES</b>   | Association of Euro Specialités (Dutch: Vereniging Eurospecialité's)                            |
| <b>VIG</b>   | Dutch Association Innovative Medicines (Dutch: Vereniging Innovatieve Geneesmiddelen)           |
| <b>VMPU</b>  | Veterinary Medicinap Product Unit (Dutch: Bureau Diergeneesmiddelen)                            |
| <b>VWS</b>   | Ministry of Health, Welfare and Sport (Dutch: Ministerie van Volksgezondheid, Welzijn en Sport) |
| <b>WaU</b>   | Work on Implementation (Werk aan Uitvoering)  |
| <b>Woo</b>   | Open Government Act (Dutch: Wet open overheid)  |
| <b>ZBO</b>   | Autonomous administrative authority (Dutch: Zelfstandig bestuursorgaan)                         |

# Appendices

## Human medicinal products and vaccines

Table 1.1a Rapporteurships and co-rapporteurships assigned to the Netherlands through the centralised procedure (CHMP)

| Years | Co-rapporteurships | Rapporteurships |
|-------|--------------------|-----------------|
| 2020  | 10                 | 19              |
| 2021  | 2                  | 21              |
| 2022  | 5                  | 17              |
| 2023  | 8                  | 10              |
| 2024  | 11                 | 12              |

Table 1.1b Assigned rapporteurships and co-rapporteurships through the centralised procedure (CHMP) per country

| Country         | Rapporteurships/co-rapporteurships |
|-----------------|------------------------------------|
| Germany         | 30                                 |
| Austria         | 23                                 |
| The Netherlands | 23                                 |
| Poland          | 23                                 |
| Sweden          | 23                                 |
| France          | 22                                 |
| Denmark         | 13                                 |
| Spain           | 10                                 |
| Ireland         | 10                                 |
| Czech Republic  | 8                                  |
| Croatia         | 8                                  |
| Finland         | 7                                  |
| Norway          | 7                                  |
| Belgium         | 6                                  |
| Italy           | 6                                  |
| Romania         | 6                                  |
| Slovakia        | 6                                  |
| Slovenia        | 5                                  |
| Estonia         | 4                                  |
| Portugal        | 4                                  |
| Hungary         | 3                                  |
| Iceland         | 2                                  |
| Lithuania       | 2                                  |
| Latvia          | 2                                  |
| Malta           | 2                                  |
| Bulgaria        | 0                                  |
| Cyprus          | 0                                  |
| Greece          | 0                                  |
| Luxemburg       | 0                                  |

Table 1.2a Pharmacovigilance (PRAC) rapporteurships assigned to the Netherlands)

| Years | Other substances | New substances |
|-------|------------------|----------------|
| 2020  | 9                | 11             |
| 2021  | 5                | 17             |
| 2022  | 8                | 16             |
| 2023  | 3                | 11             |
| 2024  | 2                | 7              |

Table 1.2b Assigned pharmacovigilance rapporteurships (PRAC) by country

| Country         | Number of rapporteurships |
|-----------------|---------------------------|
| Sweden          | 31                        |
| Germany         | 12                        |
| Danmark         | 10                        |
| The Netherlands | 9                         |
| Belgium         | 8                         |
| Portugal        | 8                         |
| France          | 7                         |
| Croatia         | 7                         |
| Ireland         | 5                         |
| Italy           | 5                         |
| Poland          | 5                         |
| Finland         | 4                         |
| Iceland         | 4                         |
| Czech Republic  | 3                         |
| Spain           | 3                         |
| Austria         | 2                         |
| Greece          | 2                         |
| Lithuania       | 2                         |
| Hungary         | 1                         |
| Latvia          | 1                         |
| Malta           | 1                         |
| Norway          | 1                         |
| Bulgaria        | 0                         |
| Cyprus          | 0                         |
| Estonia         | 0                         |
| Luxemburg       | 0                         |
| Romania         | 0                         |
| Slovenia        | 0                         |
| Slovakia        | 0                         |

Table 1.3a RMS applications started in the Netherlands via the decentralised procedure (DCP) and mutual recognition procedure (MRP)

| Year | MRP | DCP |
|------|-----|-----|
| 2020 | 85  | 174 |
| 2021 | 93  | 162 |
| 2022 | 69  | 111 |
| 2023 | 56  | 180 |
| 2024 | 67  | 213 |

Table 1.3b RMS applications initiated through the decentralised procedure (DCP) and mutual recognition procedure (MRP) per country

| Country         | MRP | DCP |
|-----------------|-----|-----|
| The Netherlands | 67  | 213 |
| Germany         | 44  | 227 |
| Sweden          | 36  | 165 |
| Portugal        | 26  | 87  |
| Danmark         | 25  | 70  |
| Czech Republic  | 14  | 71  |
| Iceland         | 9   | 60  |
| Hungary         | 17  | 49  |
| Austria         | 22  | 42  |
| Finland         | 8   | 50  |
| Ireland         | 19  | 37  |
| Poland          | 13  | 38  |
| Malta           | 5   | 43  |
| Spain           | 16  | 30  |
| Croatia         | 5   | 36  |
| Slovenia        | 6   | 30  |
| Latvia          | 5   | 25  |
| Estonia         | 6   | 11  |
| Slovakia        | 4   | 10  |
| Lithuania       | 0   | 8   |
| Norway          | 5   | 3   |
| Italy           | 4   | 3   |
| Cyprus          | 1   | 6   |
| Belgium         | 3   | 4   |
| France          | 6   | 0   |
| Bulgaria        | 0   | 3   |
| Greece          | 2   | 0   |
| Romania         | 0   | 1   |
| Luxemburg       | 0   | 0   |

Table 1.3c CMS applications initiated through the decentralised procedure (DCP) and mutual recognition procedure (MRP) per country

| Country             | MRP | DCP |
|---------------------|-----|-----|
| Germany             | 43  | 375 |
| Italy               | 61  | 356 |
| Spain               | 64  | 347 |
| Poland              | 48  | 275 |
| Norway              | 74  | 226 |
| Danmarke            | 69  | 220 |
| Sweden              | 58  | 227 |
| Czech Republic      | 39  | 235 |
| France              | 42  | 226 |
| Slovakia            | 42  | 222 |
| Austria             | 34  | 228 |
| Finland             | 61  | 183 |
| Portugal            | 46  | 187 |
| Romania             | 39  | 193 |
| Greece              | 26  | 179 |
| Hungary             | 30  | 173 |
| The Netherlands     | 44  | 157 |
| Bulgaria            | 22  | 146 |
| Lithuania           | 28  | 131 |
| Belgium             | 29  | 130 |
| Hungary             | 31  | 124 |
| Estonia             | 30  | 124 |
| Latvia              | 33  | 118 |
| Luxemburg           | 17  | 127 |
| Malta               | 30  | 112 |
| Ireland             | 25  | 114 |
| Slovenia            | 36  | 99  |
| Cyprus              | 29  | 97  |
| Iceland             | 37  | 61  |
| United Kingdom (NI) | 0   | 9   |
| Liechtenstein       | 0   | 2   |

Table 1.4 Applications submitted through the national procedure

| Year | Applications submitted |
|------|------------------------|
| 2020 | 87                     |
| 2021 | 59                     |
| 2022 | 80                     |
| 2023 | 63                     |
| 2024 | 61                     |

Table 1.5 Parallel import applications submitted

| Year | Applications submitted |
|------|------------------------|
| 2020 | 316                    |
| 2021 | 486                    |
| 2022 | 302                    |
| 2023 | 224                    |
| 2024 | 212                    |

Table 1.6a Number of registered marketing authorisations

| Years | Registered marketing authorisations |
|-------|-------------------------------------|
| 2020  | 13,565                              |
| 2021  | 13,452                              |
| 2022  | 13,577                              |
| 2023  | 13,774                              |
| 2024  | 13,455                              |

Table 1.6b Number of withdrawals after registration

| Years | Withdrawals |
|-------|-------------|
| 2020  | 1,649       |
| 2021  | 1,150       |
| 2022  | 859         |
| 2023  | 549         |
| 2024  | 1.185       |

Table 1.7 Number of scientific opinions assigned to the Netherlands through the SAWP

| Years | Number of scientific opinions assigned |
|-------|--|
| 2020  | 140                                    |
| 2021  | 146                                    |
| 2022  | 140                                    |
| 2023  | 106                                    |
| 2024  | 137                                    |

Table 1.8 Opened cases for national scientific opinions

| Years | Scientific opinions | Tailored scientific opinions |
|-------|---------------------|------------------------------|
| 2020  | 103                 | 10                           |
| 2021  | 95                  | 6                            |
| 2022  | 98                  | 12                           |
| 2023  | 105                 | 9                            |
| 2024  | 100                 | 4                            |

Table 1.9 Number of Direct Healthcare Professional Communications (DHPCs) sent in the Netherlands

| Years | Number of DHPC's |
|-------|------------------|
| 2020  | 22               |
| 2021  | 26               |
| 2022  | 20               |
| 2023  | 14               |
| 2024  | 12               |

## Botanicals and novel foods

Table 2.1 Number of registered marketing authorisations for herbal medicinal products

| Years | Based on a complete dossier | Based on traditional use |
|-------|-----------------------------|--------------------------|
| 2020  | 43                          | 55                       |
| 2021  | 37                          | 50                       |
| 2022  | 37                          | 48                       |
| 2023  | 35                          | 44                       |
| 2024  | 34                          | 47                       |

Table 2.2 Number of registered marketing authorisations for homeopathic medicinal products

| Years | Number of registered marketing authorisations |
|-------|---|
| 2020  | 2,034   |
| 2021  | 2,013   |
| 2022  | 2,041   |
| 2023  | 2,044   |
| 2024  | 1,414   |

## Veterinary medicinal products

Table 3.1 Initiated centralised CVMP rapporteurships and co-rapporteurships

| Years | Numer of assigned CVMP rapporteurships and co-rapporteurships |
|-------|---|
| 2020  | 1   |
| 2021  | 16  |
| 2022  | 7   |
| 2023  | 1   |
| 2024  | 8   |

Table 3.2 Initiated centralised MRL rapporteurships and co-rapporteurships

| Years | Number of assigned MRL rapporteurships and co-rapporteurships |
|-------|---|
| 2020  | 2   |
| 2021  | 0   |
| 2022  | 0   |
| 2023  | 1   |
| 2024  | 1   |

Table 3.3a RMS applications closed through the decentralised (DCP) and mutual recognition procedure (MRP)

| Years | MRP | DCP |
|-------|-----|-----|
| 2020  | 0   | 40  |
| 2021  | 0   | 30  |
| 2022  | 0   | 28  |
| 2023  | 2   | 50  |
| 2024  | 1   | 29  |

Table 3.3b RMS applications closed through the decentralised (DCP) and mutual recognition procedure (MRP) per country

| Country         | Number of MRP's and DCP's |
|-----------------|---------------------------|
| Ireland         | 45                        |
| The Netherlands | 30                        |
| France          | 21                        |
| Czech Republic  | 13                        |
| Germany         | 11                        |
| Spain           | 8                         |
| Estonia         | 2                         |
| Portugal        | 2                         |
| Hungary         | 1                         |
| Sweden          | 1                         |
| Italy           | 0                         |
| Austria         | 0                         |
| Norway          | 0                         |
| Poland          | 0                         |
| Danmark         | 0                         |
| Finland         | 0                         |
| Slovenia        | 0                         |
| Slovakia        | 0                         |
| Belgium         | 0                         |

Table 3.4a Number of registered marketing authorisations for veterinary medicinal products

| Years | Numer of registered marketing authorisations |
|-------|--|
| 2020  | 2,382  |
| 2021  | 2,349  |
| 2022  | 2,279  |
| 2023  | 2,246  |
| 2024  | 2,220  |

Table 3.4b Number of withdrawals of marketing authorisations after registration of veterinary medicinal products

| Years | Number of withdrawals after registration |
|-------|--|
| 2020  | 60                                       |
| 2021  | 139                                      |
| 2022  | 143                                      |
| 2023  | 153                                      |
| 2024  | 103                                      |

# Governance and organisation

Table 4.1 Objection and appeal procedures

| Years | Number of objection and appeal procedures |
|-------|---|
| 2020  | 30  |
| 2021  | 32  |
| 2022  | 30  |
| 2023  | 23  |
| 2024  | 11  |

Table 4.2 Number of hearings and opinions

| Years | Number of hearings and opinions |
|-------|---------------------------------|
| 2020  | 26                              |
| 2021  | 15                              |
| 2022  | 24                              |
| 2023  | 11                              |
| 2024  | 22                              |

Table 4.3 Number of employees and full-time equivalents (FTEs)

| Years | Employees | FTE   |
|-------|-----------|-------|
| 2020  | 408       | 374   |
| 2021  | 421       | 387   |
| 2022  | 460       | 423.5 |
| 2023  | 511       | 474.7 |
| 2024  | 522       | 479.7 |