CBG MEB

MEDICINES EVALUATION BOARD

Strategic Business Plan 2020–2024

Regulating in a future-proof and practice-based way

GOOD MEDICINES USED BETTER

Strategic Business Plan 2020 – 2024

Regulating in a future-proof and practice-based way

Medicines Evaluation Board

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Foreword

This Strategic Business Plan (SBP) describes the strategic direction of the Medicines Evaluation Board (MEB) in the coming period from 2020 to 2024. We used the previous SBP to plot a course to connect with medical practice, for example by improving the provision of information. We now wish to continue along that course in line with our core values – scientific, vigilant and connected – with the aim to improve confidence in medicines.

The availability of medicines and their proper use continue to be important themes. Better information on medicines for patients and healthcare providers encourages the proper use of medicines and therefore their safety and effectiveness as well. We however maintain our focus on the availability of medicines, because an efficient regulatory system facilitates rapid access to new medicines and a better insight into medicine shortages helps the medicines chain to minimise those shortages.

Of course, we are also looking to the future. The world of medicines is changing rapidly. Developments such as personalised medicine, biomarkers and real world data are also affecting our core tasks and that is why the MEB wants to operate in a future-proof way. This means more and improved collaboration at all kinds of levels, from patient organisations to the developers of medicines and scientists, so that we can apply new developments appropriate to our way of working.

Our activities in the veterinary domain are mainly portrayed in this SBP in terms of the implementation of the new European regulation for veterinary medicines. Among other things this will lead to less administrative burdens. However, it also means different ways of working, with a focus for the MEB on more efficient work processes.

Finally we would like to thank everyone who has contributed to the creation of this SBP. In particular, we would like to thank all our MEB colleagues, the MEB Board members and the members of the Veterinary Medicines Board (CRD), as well as the members of the Advisory Board and the employees at the ministries of Health, Welfare and Sport (VWS) and Agriculture, Nature and Food Quality (LNV), as well as the various other chain parties and stakeholders who shared their insights and knowledge. All this has enabled us to realise our ambition and to ensure that the MEB continues to be one of the leading European medicines authorities.

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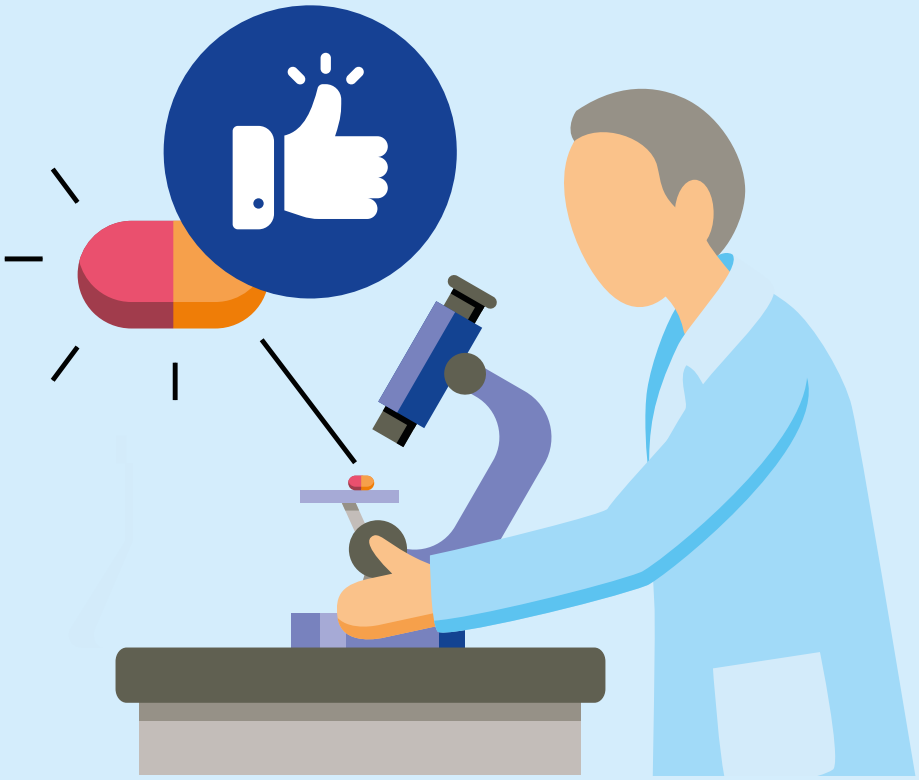

1 Introduction

The MEB is the Netherlands medicines authority. It assesses the quality, efficacy and safety of medicines and focuses on the whole life cycle of medicines for people. This covers the entire process from the development of medicines to their authorisation and the monitoring of medicines which are on the market. Commissioned by the Minister of VWS, the MEB also performs these tasks for novel foods. The Veterinary Medicinal Products Unit carries out the same tasks for veterinary medicines as commissioned by the Minister of LNV (see also chapter 3).

The MEB stands for efficient execution of our statutory tasks for people and animals. We fulfil our roll independently and on the basis of three core values, namely scientific, vigilant and connected. The scientific analysis of data forms the basis for our medicine assessments. Innovation in the way in which the MEB assesses and regulates medicines is also based largely on science. We fulfil our role vigilantly and are always alert and looking actively at what is going on in practice so that we can respond accordingly. We perform our work in the field of medicines for people in connection with healthcare providers, patients and consumers in the field. In the process, we collaborate with other parties at both national and international level, within government, industry and the academic world. In this way we can work on increasing people's confidence in good medicines used better.

1.1 Good medicines used better

The MEB is responsible for the authorisation and monitoring of medicines on the market. Patients and healthcare providers must be able to rely on the available medicines and corresponding product information. With that in mind, the MEB set itself the following mission in 2017:

> ANYONE WHO USES MEDICINES SHOULD BE ABLE TO TRUST THEM. THE MEB IS DEDICATED TO FULFILLING THIS MISSION EVERY SINGLE DAY, IN THE NETHERLANDS AND INTERNATIONALLY.'

This mission forms the source of inspiration for the SBP 2020-2024. We stand for good medicines used better and users must be able to have confidence in medicines.

1.2 Regulating in a future-proof and practice-based way

The assessment of the quality, safety and efficacy of medicines, our statutory task, continues to be essential for people and animal health. The proper use of medicines is important for the safety of people, animals and the environment. Interdisciplinary cooperation and a 'one health' approach is needed for people and animal health and to limit the environmental effects of medicines. Based on that framework, the MEB is focusing on key social themes, such as antimicrobial resistance, animal testing and the environmental effects of medicines.

Throughout the world bacteria are increasingly becoming resistant to antibiotics. Antimicrobial resistance is an urgent, growing and global problem. The MEB supports the Dutch policy of working with others in Europe in the coming years in order to realise a further reduction in the risks of anti-microbial resistance. During the term of this SBP the MEB is going to continue to work on reducing animal testing. The MEB's aim is to not use test animals when this is not necessary. An important first step was recently taken in the form of an international guideline on clinical trials. As a result, the number of test animals needed may be reduced by hundreds of thousands than is currently the case. The MEB was closely involved in amending this guideline and is continuing to focus on reducing animal use when providing scientific advice.

Proper care for people and animals goes hand-in-hand with proper care for the environment. We underscore the fact that we have a role to play in encouraging the proper use of medicines and in reducing their unnecessary or harmful use. The MEB contributes to government policy aimed at the sensible use of medicines and the continued development of an environmentally friendly production chain. The MEB's know-how and information is also particularly important in this respect.

As an organisation we are also paying specific attention to developments which may have consequences for the system of assessing and regulating medicines. After all, developments such as personalised medicines, gene therapy, biomarkers, big and real world data and artificial intelligence are affecting the

essence of our work. They may lead to changes in policy or legislation and must be given a place in our assessment methods. In order to make sure that we, as an organisation, are sufficiently equipped, we are investing in our employees, education and research and we are translating these developments into our daily practice. As a result we continue to have the capacity to assess medicines adequately in a rapidly changing world and to monitor them in daily practice. That is what future-proof regulation and working on people's confidence in medicines means.

We are doing this in connection with the world around us, for example by investing in the involvement of patients and healthcare providers (the field) in our work. We are also encouraging the proper use of medicines in practice, for people and animals, by improving information on medicines for healthcare providers, patients and animal owners, partly in response to their suggestions. Via this practice-based regulation, the MEB wants to continue to add value to the medicines chain and the medicine users. We are going to continue building on this role in the coming years.

We will be doing all this from a position on an international playing field. The MEB has an excellent reputation internationally and plays a leading role within the European network. This position is important in order to ensure that Dutch patients have access to high-quality medicines. In the coming years we are going to consolidate this position and continue to work on an innovative regulatory environment in the Netherlands and Europe in order to safeguard access to medicines in the future. The MEB has formulated the following objective for this SBP 2020 – 2024:

> THE MEB WILL CONTINUE TO BE A TOP 5 MEDICINES AUTHORITY IN EUROPE THROUGH FUTURE-PROOF AND PRACTICE-BASED REGULATION.

1.3 Key principles

With almost 400 dedicated employees we will be working in the coming years on realising the ambitions as stated in this SBP. To guide us we have formulated key principles which form the basis for all the activities the MEB is going to carry out in relation to medicines for people and animals in the coming years.

What we do, we do together

Regulation and assessment have to be done internationally and the MEB is therefore part of a(n) (inter)national network for the development, authorisation, monitoring and reimbursement of (veterinary) medicines. This network consists of commissioning parties, chain partners, fellow authorities, other government institutions, pharmaceutical companies and those in the field (healthcare providers, patients, vets and animal owners). Every member of this network is facing similar challenges, such as social and technological developments, the consequences of globalisation, changing regulations and pressure on budgets. Continuous cooperation with, and knowledge sharing within this network are essential in order to find and implement solutions which make medicines regulation faster, more efficient and more flexible. For that reason, the MEB is proactively looking for partnerships at both the national and international level.

That is also why we are carrying out our activities based on the principle of our position in a(n) (inter) national network. What we do, we do together, wherever necessary and possible. We are collaborating with our commissioning parties, the Ministry of VWS and the Ministry of LNV and at national level we are working as part of a Dutch medicines chain. We are connected to our stakeholders, which are pharmaceutical companies, applicants and holders of marketing authorisations – in other words, the start of the chain. We cooperate with, for example, the Central Committee on Research Involving Human Subjects (CCMO), the Healthcare and Youth Care Inspectorate (IGJ), the National Institute for Public Health and the Environment (RIVM), the Netherlands Pharmacovigilance Centre Lareb (Lareb), the Patient Safety Portal (PvP), the National Health Care Institute (ZIN) and the Netherlands Food and Consumer Product Safety Authority (NVWA). We maintain intensive alliances with various Dutch universities, professional organisations, patient organisations and umbrella organisations. In addition, at the international level we have good relationships with other medicines authorities and the European Medicines Agency (EMA). Above all, we stay connected with the field, patients and healthcare providers during all our activities. In some cases we are in direct contact and in other cases through umbrella organisations.

Suitable financing

Whenever the MEB carries out activities it has to be clear in advance how these activities can be structurally financed. Some of the activities are (partly) financed structurally by the MEB using the rates and annual fees because they are part of the statutory task.

In the case of new activities or extra tasks, which are not part of the direct statutory task, the MEB draws up a financing plan (before the start) so that it is clear how these activities can be structurally paid for. The MEB will also engage in discussions with the commissioning party in order to determine the need and necessity of any structural activities which do not have a statutory basis and which the MEB carries out on the basis of social importance. These discussions also cover appropriate financing to make sure that all our activities are not just properly embedded, but also properly financed. If it transpires that the activity in question cannot be financed, the MEB will not initiate the activity in question.

Lastly, during the term of this SBP, a new European financing model will be put in place, which is referred to as the EMA Fee Regulation. The MEB has a considerable interest in improvements in this financing model, for example in terms of obtaining a reimbursement for European activities on behalf of people and animals for which a statutory basis exists[1], but for which there is no suitable financing. In order to achieve the necessary improvements, the MEB is investing in the collaboration with the ministries of VWS and LNV and is supporting them where necessary in the discussions in EU Council working groups. From our position in the Heads of Medicines Agencies (HMA) we are working with the European Commission, our partners in the network and the EMA.

Implementation

The SBP 2020 – 2024 is a multi-year plan with broad activities and issues. In order to interpret these specifically the SBP will therefore be developed in more detail each year in the MEB's annual plan. In that way activities can be made more specific and can be backed up by an action plan and, if necessary, a financing plan. Doing this will ensure that the monitoring work relating to the implementation of the SBP and any interim adjustments are linked to the annual cycle.

1 Examples in the case of medicines for people are orphan medicines, paediatric indications and contributions to guideline development. Examples in the case of medicines for animals are referrals, (centralised) pharmacovigilance and new activities which follow from the regulation.

2 Medicines for human use

In the case of medicines for human use, we are going to implement our ambition specifically on the basis of three strategic main themes, by consolidating, improving or innovating on a number of issues. The strategic lines are described in more detail below, along with the activities the MEB wants to focus on in the coming years. The above-mentioned key principles provide the basis in this respect.
The activities relating to medicines for animals are dealt with in chapter 3.

2.1 Future and goal-oriented

The assessment of the quality, safety and efficacy of medicines, our statutory task, continues to be essential for the health of humans and animals and is therefore at the heart of our work. Within that framework we are focusing continuously on the patient and healthcare providers and we are also constantly developing our work (both the primary processes and operations), as well as our organisation. By consolidating existing activities which are part of our working method and by improving that working method (where necessary), we can ensure that we can continue to perform our work properly in the future as well. One of the ways we are doing this is in close cooperation with various parties in the medicines chain (see also strategy 3). The aim of this strategy is:

EQUIPPED FOR THE FUTURE THROUGH OPTIMAL ORGANISATION AND HIGH-QUALITY SERVICES.

The MEB will structurally finance (some of) the activities set up on the basis of this strategy itself using the annual fees and rates, because these are part of the statutory task.

In connection with practice

In the previous SBP we focused on patient-oriented assessment. In the case of medicines for people we have involved patients and healthcare providers more directly in the MEB's assessment work. During the coming period we will have to make sure that our internal organisation links up with this optimally by continuing to embed the involvement of patients and healthcare providers in the regular work. We will do this by, for example, starting to work with fixed contact persons for the various patient and professional organisations. The assessment work will also be supported by a core group of professional and patient organisations. There will also be a specific focus on involving patients and patient organisations in the early phase of medicines development, for example through participation in scientific advice.

Information about the effectiveness, effect and adverse reactions of (new) medicines in practice can be collected and monitored via patient or disease registers. This information about how medicines are used in practice is becoming increasingly important from both an authorisation and a reimbursement perspective. The information in these registers can, in fact, provide an insight into the added value of a medicine in practice, for example because innovative medicines are still often marketed on the basis of relatively unreliable evidence. The Dutch government's aim is to compile and maintain up-to-date registers with similar form and content for authorisation and reimbursement. The ZIN is carrying out a feasibility study entitled 'Control of Registers' [Regie op Registers] in order to create conditions and frameworks for registers. The MEB is contributing to this and is also highlighting the importance of collecting data for a proper assessment of quality, efficacy and safety and for the monitoring of effectiveness and safety after authorisation on the market.

The linking of education, science and regulation

The MEB is working on strengthening the relationship between scientific research, education and medicines regulation. Science and scientific data form the foundation for the assessment work at the MEB and are the basis for innovation. Within that framework, the MEB is working with a long-term science policy and budget.

The MEB is encouraging the relationship between science and regulation by reinforcing and deepening the scientific basis of regulation and by contributing to further innovations in terms of medicines development ('regulatory science'). Important related aspects are the PhD processes, whereby PhD students have one foot in scientific research and the other in our practical assessment work. In this way we can ensure, among other things, that our assessments are continuously improving. Via scientific advice we can also contribute to further innovations in the field of medicines development. By offering students the possibility of doing work placements, we can bring the MEB's work to the attention of the care providers of the future.

In addition to this, we are continuing to be actively involved in several ways in various forms of scientific education. We are investing in the cooperation with universities and research institutes and are monitoring scientific developments and innovations which we can use in our assessment and

advice work. The MEB is closely involved in training patient representatives. Through education we want to help train doctors, pharmacists and other care providers in the field of medicines regulation and the correct use of medicines.

The task of linking science and medicines regulation is something the MEB is unable and unwilling to do alone. Close cooperation with national and international partners and knowledge organisations is essential. With that in mind we are investing in the existing partnerships in the Netherlands, such as the Regulatory Science Network Netherlands, and in Europe (Regulatory Science to 2025 Strategy of the EMA).

Appropriate implementation of new developments

The MEB is focusing specifically on developments which may have consequences for the regulatory system or for medicines and their use. Social and ground-breaking technological developments, such as personalised medicines, gene therapy and big and real world data affect the essence of our work. These developments are leading to changes in policy or legislation and must be integrated in our assessment methods.

Medical science is making more and more personalised treatment possible, with major advantages for the individual patient. This, in turn, presents new challenges in terms of securing quality, efficacy and safety. The Ministry of VWS has an active role to play in the development of a (European) assessment framework for small groups of patients and personalised medicine. The MEB is monitoring this development and is advising the Ministry. The MEB is also taking the lead when it comes to innovating our assessment method within the current statutory frameworks. We are paying specific attention to the emergence of combinations of medicines, in vitro diagnostics and medical appliances. The ambition is to acquire a leading position in the assessment work in this field in Europe.

In the future, types of data other than those usually present in an authorisation dossier will start to become an increasingly important element of the MEB's assessment work, for both the authorisation and the usage phase. One example is data collected with *wearables* and *apps* in order to record the movements, activities and experiences of patients and new links between all the existing datasets. Together with other (European) authorities and knowledge institutes we are going to identify the influence and consequences of the emergence of big data and real world data and the opportunities for medicine authorisation and monitoring which arise as a result. This will involve collaboration between the MEB and the Ministry of VWS and other (European) authorities.

Modern organisation

In the coming years, we will continue to work in the Netherlands and Europe on regulatory optimisation and innovation in order to maintain our lead in the worldwide network of medicine authorities. With a view to keeping the European regulatory system future-proof and sufficiently innovative, we are going to focus on reducing administrative burdens, accurate and proportional pharmacovigilance and creating and having access to centralised European databases with medicine data as guiding principles. The new European regulation for veterinary medicines[2] provides a direction for the practical implementation of these principles. Elements of the new veterinary medicines regulation can serve as an example for the way we think about innovating the European regulatory system for human medicines.

This needs to be accompanied by an optimal internal organisation. The above-mentioned developments are not only having an impact on our primary work, but also on the structure of the organisation and the knowledge and expertise that we need. Given the changing world around us, there is a need to assess the way in which the MEB is currently organised, with the aim to create a future-proof organisation. Important

2 EU regulation 2019/4 and 2019/6

principles in this respect are increasing the organisation's agility and effectiveness by reducing complexity and encouraging flexibility. All this requires focus and clarity as regards roles in order to be able to direct the process properly and to ensure cohesion in terms of our activities.

One aspect of modernising the organisation involves providing high-quality, safe and efficient information which is available for the long term to all users, both our own employees and others who use our information. The MEB has drawn up a vision on how information should be[3] provided and this has been developed into a strategy[4] and a multi-year information provision plan[5]. Consequently, there is a clear vision of how the MEB believes information should be provided in the coming years which includes the specific issues that have to be improved in order to be able to provide our employees with optimal support for their work. We are, of course, doing this in cooperation with Dutch, European and international partners.

2.2 Better use of medicines

This strategy is a continuation of one of the pillars of the previous SBP, which focused on the patient. The MEB's objective to ensure that patients and consumers use good medicines as well as possible is also going to be developed in more detail. The MEB already developed a large number of activities during the period of applicability of the previous SBP and these were intended to improve information on medicines and make it more accessible and understandable. The result is that internal processes can be optimised but, above all, the proper use of medicines can be stimulated in practice and the information on medicines for care providers and patients can be improved. The next step in this process is to improve the information provided when medicines are issued. In the coming years we are going to continue extending this role in close cooperation with other parties involved. The aim of this strategy is:

> TO ENCOURAGE THE PROPER USE OF MEDICINES IN PRACTICE BY IMPROVING THE PROVISION OF INFORMATION TO PATIENTS AND HEALTHCARE PROVIDERS.

The MEB will structurally finance (some of) the activities set up on the basis of this strategy itself using the annual fees and rates, because these are part of the statutory task. In the case of some activities, a financing plan has to be drawn up (before the start) so that it is clear how these activities can be structurally paid for.

Improving information about medicines

The MEB wants to contribute to the general confidence that people have in medicines by sharing reliable information about medicines. The MEB will do this in close cooperation with the Ministry of VWS and chain partners, by participating more proactively and visibly in themes such as shortages, pharmaceutical compounding, off-label use, self-care, the quality of active substances, generic versus brand products and responsible switching. Patients are regularly concerned and dissatisfied about frequently having to switch medicines. Through scientific insights and by sharing knowledge and information, the MEB is contributing

3 MEB I-vision (2016)
4 MEB I-strategy (2017)
5 MEB I-multi-year plan 2018 – 2020 (2017)

to a broadly supported approach to generic medicines. MEB contributions are characterised by clear and factually correct information, well-considered viewpoints and the interpretation of relevant developments.

We are involving patients, patient organisations and healthcare providers more closely in our activities, based on the idea of openness and transparency about our medicine assessments and underlying data. In the process, we will also contribute to themes which affect the MEB, the proper use of medicines and confidence in medicines.

Improving information supplied with medicines

Together with patients and patient organisations, care providers, professional organisations for doctors, pharmacists and the pharmaceutical industry and chain partners, the MEB is going to improve the information supplied with medicines. We are going to do this by paying more attention to the legibility of the official package leaflet. We are also taking the lead with regard to compact information on medicines at the level of the active substance, based on our belief that the information in question has to be visually attractive and in understandable language. We are going to refer explicitly to the positive effects of the medicine and point out the most relevant adverse reactions and warnings. This improved and compact information on medicines can help patients and healthcare providers take joint decisions about how medicines should be used.

Via the Better Use programme, digital product information is to be enriched with updated information about the risks (including off-label use) and adverse reactions and tailor-made information for various target groups. Audiovisual information will also be made available by providing broad access to animated videos (via the ‘Kijksluiter’).

The importance of proper use and improving the information on medicines is an international issue and is therefore embedded in the Netherlands via the Patient Information Network [Netwerk Patiëntinformatie] and the cooperation in the G5 (MEB, ZIN, Lareb, the Dutch Institute for Rational Use of Medicine (IVM) and the Medicinal Products Bulletin Foundation (GeBu)), in Europe (HMA Support for Better Use of Medicines Working Group) and internationally (via the Council for International Organisations of Medical Sciences (CIOMS)).

A critical look at authorised medicines

The MEB believes there are various opportunities in the field of specific evaluation of medicines to improve people's confidence in medicines and high-quality and affordable pharmaceutical care. Both for the patient and from the point of view of cost control, we believe that people should stop using medicines if they – in whatever way – no longer have any added value. The MEB is helping to ensure appropriate use by permanently drawing people's attention towards stopping criteria in its assessment work and scientific advice.

During the period that this SBP covers, we are going to assess whether the latest insights from science and practice and new regulations for medical appliances ought to have consequences for medicines authorised in the past and their use. We are going to do this by systematically following a medicine that has been authorised for the Dutch market. After all, one of the MEB's tasks is to monitor the adverse reactions and risks associated with medicines. With regard to medicines, the MEB imposes, among other things, limits for dosages, packaging sizes and the length of time that they should be used. It is unclear, particularly for self-care medicines, how these limits relate to usage in daily practice. For that reason the MEB wants to monitor the use of self-care medicines in daily practice. Another example is the monitoring and recording of interactions in daily practice between herbal and regular medicines. This involves us looking, even more than we used to, at the entire life cycle of medicines – from research and development via market authorisation to use in practice – and, by doing so, helping to provide 'appropriate care'.

2.3 Cooperation in the medicines chain

Society increasingly expects new and advanced medicines to be available rapidly. The availability of new medicines for people is determined partly by the efficiency of the regulatory system. We are increasing the chance of rapid access to (new) medicines by reducing the space between the links in the chain, in other words between the start of the medical scientific research, the assessment process that leads to an judgment about the balance between the benefits and the risks and the process that leads to a decision about reimbursement. The aim of this strategy is:

> TO ENCOURAGE THE AVAILABILITY OF MEDICINES THROUGH REGULATORY OPTIMISATION AND INNOVATION.

The MEB will structurally finance (some of) the activities set up on the basis of this strategy itself using the annual fees and rates, because these are part of the statutory task. A financing plan will be drawn up for some activities (before they start).

Streamlining development, authorisation and reimbursement

In order to ensure rapid access to (new) medicines it is important that we work intensively in the medicines chain. Together with the CCMO we are working on the effective implementation of the European clinical trials regulation[6]. There are, for example, opportunities to cooperate on the assessment of Investigational medicinal products (IMPs), (European) IT and the streamlining of the requirements that apply to clinical trials, authorisation and assessments. We are cooperating intensively with the CCMO and the ZIN in the field of scientific advice and are going to continue building on this cooperation during the period that this SBP covers.

The MEB is going to continue working together with ZIN on the streamlining between authorisation and reimbursement. Until now, the ZIN has taken decisions regarding the reimbursement of new medicines after they have successfully completed the authorisation process. A project is being carried out in cooperation with the ZIN, which is intended to also create clarity about reimbursements when taking decisions regarding authorisation. This involves decision-making processes taking place both individually and in parallel, rather than successively. This can generate substantial time-saving in terms of the availability of medicines for patients. In the first instance, an approach is to be developed and pilot projects carried out at national level in cooperation with pharmaceutical companies. If this turns

6 EU regulation 536/2014

out to be successful, this approach may not only lead to structural changes in Dutch practices, but can also contribute to the debate at European level.

Insight into availability

The MEB is working together with chain partners to ensure that the Medicine shortages and defects notification centre expands to become a complete and up-to-date source of information about shortages in the Netherlands. In Europe, we are helping to formulate a clear EU-wide definition of shortages and we are also working on ways of exchanging information about shortages. In the process, the MEB is emphasising the importance of structured and reliable information systems and efficient organisation and execution.

The continued development of (customised) scientific advice

The MEB is becoming involved in development processes at an earlier stage through (customised) scientific advice. This is opening up possibilities for innovation at companies and in the regulatory system. The MEB regards (customised) scientific advice as the instrument for providing guidance, in contact with developers, during the preparation of an appropriate authorisation dossier at an early stage in the development (of, for example, personalised medicine). In the context of scientific advice, the MEB will continuously ask for attention to be paid not only to the unnecessary use of test animals, but also, when there is a basis for doing so, to research into stopping criteria. In the Netherlands, the MEB will actively look to establish contact with developers of new types of medicines and combinations with in vitro diagnostics and medical appliances. It will also contribute, by providing scientific advice, to further innovations related to the development of medicines (regulatory science). At European level, the MEB will retain its leading position in the Scientific Advice Working Party and expand on it where possible.

3 Veterinary medicines

The Veterinary Medicinal Products Unit (VMPU) handles and assesses applications for the market authorisation of veterinary medicines and issues production, distribution and marketing authorisations for veterinary medicines. The VMPU's work focuses on the availability of effective and safe veterinary medicines in order to promote animal health and welfare. The VMPU helps to ensure that good veterinary medicines are used better by assessing and authorising veterinary medicines, and by maintaining a veterinary medicines information bank[7] . The VMPU is commissioned by the Dutch Ministry of Agriculture, Nature and Food Quality (LNV) to carry out a number of tasks relating to animal feeds.

In line with the above-mentioned activities we are going to invest, in the coming years, in activities which will help us continue to perform our work to a high standard now and in the future. We are continuing to develop our work (both the primary processes and operations) and our organisation by consolidating existing activities in our working method and by improving or renewing that working method (where possible). One of the ways we are doing this is in close cooperation with various parties in our network, such as the Ministry of LNV, the NVWA and the customs authorities.
We are also working on strengthening the relationship between scientific research, medicines

7 The veterinary medicines information bank can be accessed via www.diergeneesmiddeleninformatiebank.nl

regulation and practice (animal owners and vets). Via scientific advice we are also contributing to further innovations in the field of medicines development. This continuous focus on animal owners and vets is essential in order to encourage the proper use of veterinary medicines. The VMPU is working on this by, for example, improving veterinary medicines information and by making this information more accessible and understandable for animal owners and vets.

3.1 Equipped for the future

During the period of applicability of this SBP, the veterinary domain will, alongside the regular activities, concentrate on the implementation of the new European regulation for veterinary medicines[8] and the regulation for medicated animal feeds[9], which will be applicable in Europe as from 28 January 2022. The objectives of these regulations are to encourage innovation, reduce administrative burdens, improve the internal market, increase the availability of veterinary medicines and prevent antibiotics resistance. The new regulations are also having a direct influence on the VMPU's working method. In light of this change and based on the future-proof regulation, there is a need to examine the way in which work processes and decision-making processes are organised. The VMPU's activities for the coming years are detailed below. The aim of this strategy is:

> TO BE EQUIPPED FOR THE FUTURE THANKS TO OPTIMAL IMPLEMENTATION OF THE NEW VETERINARY MEDICINES REGULATION.

The VMPU will partly be able to finance the activities which are to be initiated on the basis of this strategy itself, using the rates and annual fees, because these are part of the statutory task. In addition to that, an annual financing plan will be drawn up for a significant number of the activities in consultation with the Ministry of LNV. Structural financing has been made available by the Ministry of LNV for the implementation of the Regulations on veterinary medicines and medicated animal feeds.

Implementation of the European veterinary regulations

In the coming period we will contribute in the Netherlands to the implementation of the new European Regulations on veterinary medicines and medicated animal feeds. These regulations introduce a number of new principles into the European regulatory system which are to reduce administrative burdens by modernising and unifying the requirements for packaging and labelling, reduce the number of variations that have to be assessed, open up the centralised procedure for all types of applications, proportional pharmacovigilance and the development and use of European databases.

In order to ensure proper implementation, the VMPU is investing in the network at European and national levels. The VMPU is affiliated to European developments and contributes actively to European discussions. In consultation with the Ministry of LNV, we are providing a clear Dutch vision which can be used for discussions in Europe. In the context of changes to national legislation, the VMPU supports and advises the Ministry of LNV. In the period this SBP covers, the VMPU will ensure the implementation of the Regulations on veterinary medicines and medicated animal feeds via an implementation

8 EU regulation 2019/6
9 EU regulation 2019/4

project by the Ministry of LNV and in close cooperation with the Ministry. Using this project as a basis, we will focus on the development of Dutch systems, processes and procedures which meet the requirements of the regulation.

Harmonisation of product information

One important aspect of the Regulation is the harmonisation of virtually identical products.
All veterinary medicines which have been authorised in Europe are to be included in a yet to be developed European project database for veterinary medicines information. This database is the backbone of the regulation and is to be a source of information for all veterinary medicines for which a licence has been granted in the European Union. The information in the database can be used for granting a marketing authorisation, as well as for pharmacovigilance and the collection of data about the use and the sale of antibiotics. The database also has to ensure that veterinarians have easier access to veterinary medicines in Europe. This will help to improve the availability of veterinary medicines.

The VMPU is actively involved in the design and development of this database and is working closely in this context with the Ministry of LNV and with fellow authorities in Europe. In addition to the investment in the European network we are also establishing optimal links between the European database and our own systems and, by doing so, we are helping to achieve one of the objectives of the regulation, namely to reduce administrative burdens. For example, even minor changes to the marketing authorisation will, in the future, no longer be submitted and processed by the national authorities, but will be entered into the European project database by the applicants themselves. Authorities will also have a more controlling task. In addition to this, the requirements for packaging and labelling of veterinary medicines in Europe will, for example, have to be simplified. This will reduce administrative burdens for marketing authorisation holders and the VMPU and will help us to optimise our internal work processes.

Antimicrobial resistance

Throughout the world bacteria are increasingly becoming resistant to antibiotics. Antimicrobial resistance is an urgent, growing and global problem. This means that an integral approach (One Health) is essential, whereby measures will be taken in all relevant domains (the veterinary domain, healthcare, nutrition and the environment). The aim will be to prevent resistance and minimise the consequences of resistance. For example, the use of antibiotics on farmed animals has been reduced in the Netherlands by well over 60% (in 2018) since 2009. We support the Dutch policy of working with others in Europe in the coming years in order to realise a further reduction of the risks of antimicrobial resistance. With this in mind, the Veterinary Medicines Regulation includes a number of requirements which can have an effect on this, such as the setting up of a harmonised system to collect data on the sale and use of antibiotics in relation to animals. A list will also be drawn up of antibiotics which are reserved for human use and additional requirements will be imposed on their use.

Abbreviations and definitions

Abbreviations	Definitions
CCMO	Central Committee on Research Involving Human Subjects [Centrale Commissie Mensgebonden Onderzoek]
CIOMS	Council for International Organisations of Medical Sciences
CRD	Veterinary Medicines Board [Commissie Registratie Diergeneesmiddelen]
EMA	European Medicines Agency
GeBu	Medicines Bulletin [Geneesmiddelenbulletin]
HMA	Heads of Medicines Agencies
IGJ	Health and Youth Care Inspectorate [Inspectie Gezondheidszorg en Jeugd]
IVM	Dutch Institute for Rational Use of Medicine [Instituut Verantwoord Medicijngebruik]
Lareb	Netherlands Pharmacovigilance Centre Lareb
LNV	Ministry of Agriculture, Nature and Food Quality [Ministerie van Landbouw, Natuur en Voedselkwaliteit]
MEB	Medicines Evaluation Board
NVWA	Netherlands Food and Consumer Products Safety Authority [Nederlandse Voedsel en Waren Autoriteit]
PVP	Patient Safety Portal [Portaal voor Patiëntveiligheid]
RIVM	National Institute for Public Health and the Environment [Rijksinstituut voor Volksgezondheid en Milieu]
SBP	Strategic Business Plan
VMPU	Veterinary Medicinal Products Unit
VWS	Ministry of Health, Welfare and Sport [Ministerie van Volksgezondheid Welzijn en Sport]
ZIN	The National Health Care Institute [Zorginstituut Nederland]

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.

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