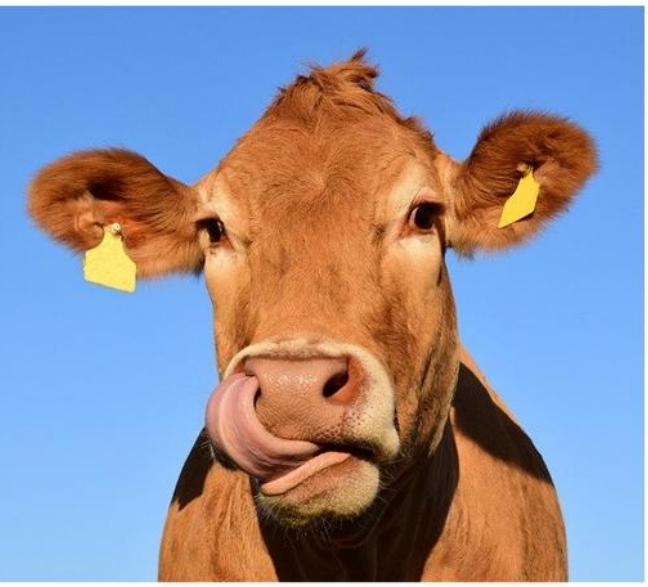
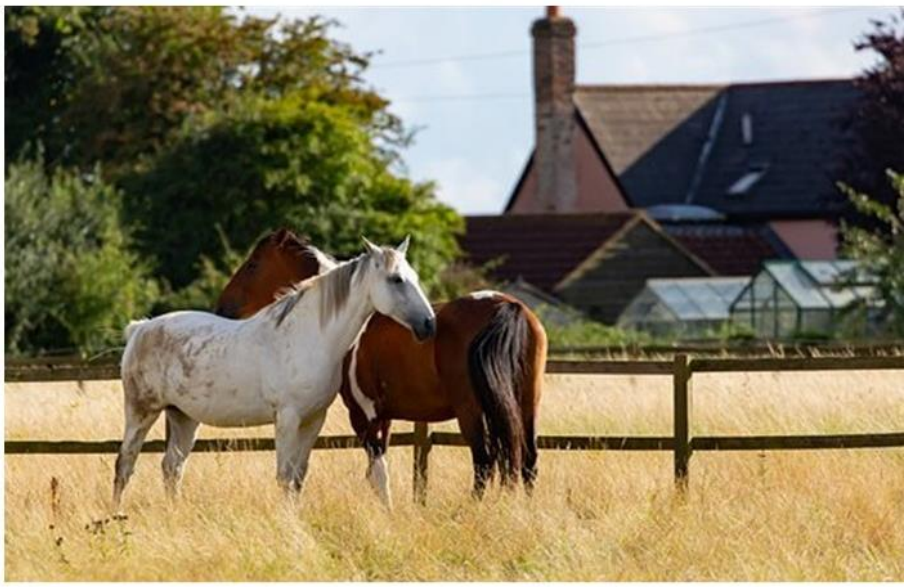
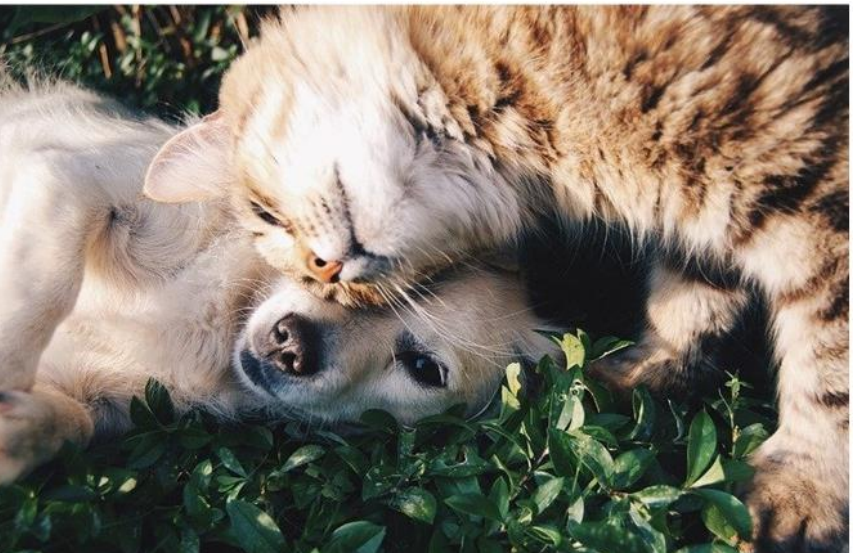
Veterinary Medicines Directorate

Regulatory Science Strategy 2021 - 2026





Creating a modernised and responsive scientific basis for regulating veterinary medicines



Introduction

Our Regulatory Science Strategy 2021-2026 underpins our mission to protect animal health, public health and the environment and promote animal welfare by assuring the quality, safety and efficacy of veterinary medicines.

By keeping abreast of and anticipating future, technological advances and novel approaches, we will ensure that we are well equipped to address scientific and regulatory challenges and advance the scientific basis underlying the authorisation and regulation of veterinary medicines.

This strategy complements our leading role on antimicrobial resistance (AMR) which is pivotal to inform policy decisions and delivery of the UK's AMR National Action Plan goals.

In November 2020, we consulted on our thinking, background and drivers for the proposals which formed this strategy and our priorities for the next 5 years.

See our consultation paper and introduction video.

Our science

Our strong scientific expertise is recognised in our robust assessment of marketing applications. We have held a leading role in Europe and made significant contributions to the scientific guidelines published by the European Medicines Agency. We now have a more global focus, building partnerships for joint international marketing authorisation assessments and developing medicines regulation capability in less developed countries.

Science driven, market-oriented

The rapid developments in science and technology in recent years have resulted in innovative medicines and novel scientific models and tools. The UK regulatory framework must continue to enable the assessment and acceptance of new and innovative technologies and ensure that these assessments are based on scientific, evidence-based decisions.

There is also an increasing awareness internationally of the impact of medicines on the environment and the public health consequences of antimicrobial resistance.

In parallel, there is a growing demand for products that fall on the borderline between veterinary medicines, biocides and feed additives, which are administered with a view to, not only support a reduction in antimicrobial use, but also control emerging diseases and maintain efficiency of livestock production.

The continued drive to improve animal welfare in testing through 3Rs methodologies is progressively leading to the replacement of some animal studies with *in vitro* and *in silico* tests.

Throughout the product life cycle, the approach to pharmacovigilance is changing to take advantage of modern methods to improve data collection and analysis. We are ready to embrace these challenges and form collaborative partnerships with stakeholders to develop these areas.

Strategic goals

1. Enabling access to novel therapies and technologies
2. Addressing emerging health threats
3. Enabling availability of veterinary medicines
4. Strengthening a life cycle approach to benefit-risk
5. Facilitating the use of novel scientific models and tools
6. Ensuring access to high quality regulatory scientific expertise

Objectives

- ensure that we maintain a modern regulatory framework for veterinary medicines, underpinned by good science
- support a flexible regulatory environment to enable us to respond rapidly in emergency situations, with a proportionate approach to managing risks
- ensure that assessment approaches can be adapted to take advantage of scientific developments
- ensure that our scientists have the knowledge and skills to deal with current and future challenges and innovations
- encourage knowledge exchange with other regulatory bodies (national and international), research communities, pharma partners, Defra and other government departments and with the Devolved Administrations
- develop a network of external specialists to provide advice and training
- identify research needs

1

Enabling Access to Novel Therapies and Technologies

Our strategy

To be best prepared to evaluate the quality, safety and efficacy of novel therapy veterinary medicinal products (NT-VMPs) and to conduct appropriate benefit-risk assessments, we will continue to expand our access to the necessary expertise to conduct scientific assessments and support decision making. Furthermore, to facilitate the development of NT-VMPs and promote innovation, we will ensure that there is a clear regulatory path to market.

We will:

- develop a fit-for-purpose UK regulatory framework and continually review the framework for emerging novel therapies including allergen immunotherapies
- support companies in better understanding data requirements, provide guidance and access to advice services
- coordinate horizon scanning activities to prioritise areas where significant activity is taking place and scientific guideline development is most urgent
- identify our skills gaps and achieve the required expertise through training, recruitment and continuing to build a network of independent advisors
- explore the advancement of knowledge/research in the human field for potential application to veterinary medicine

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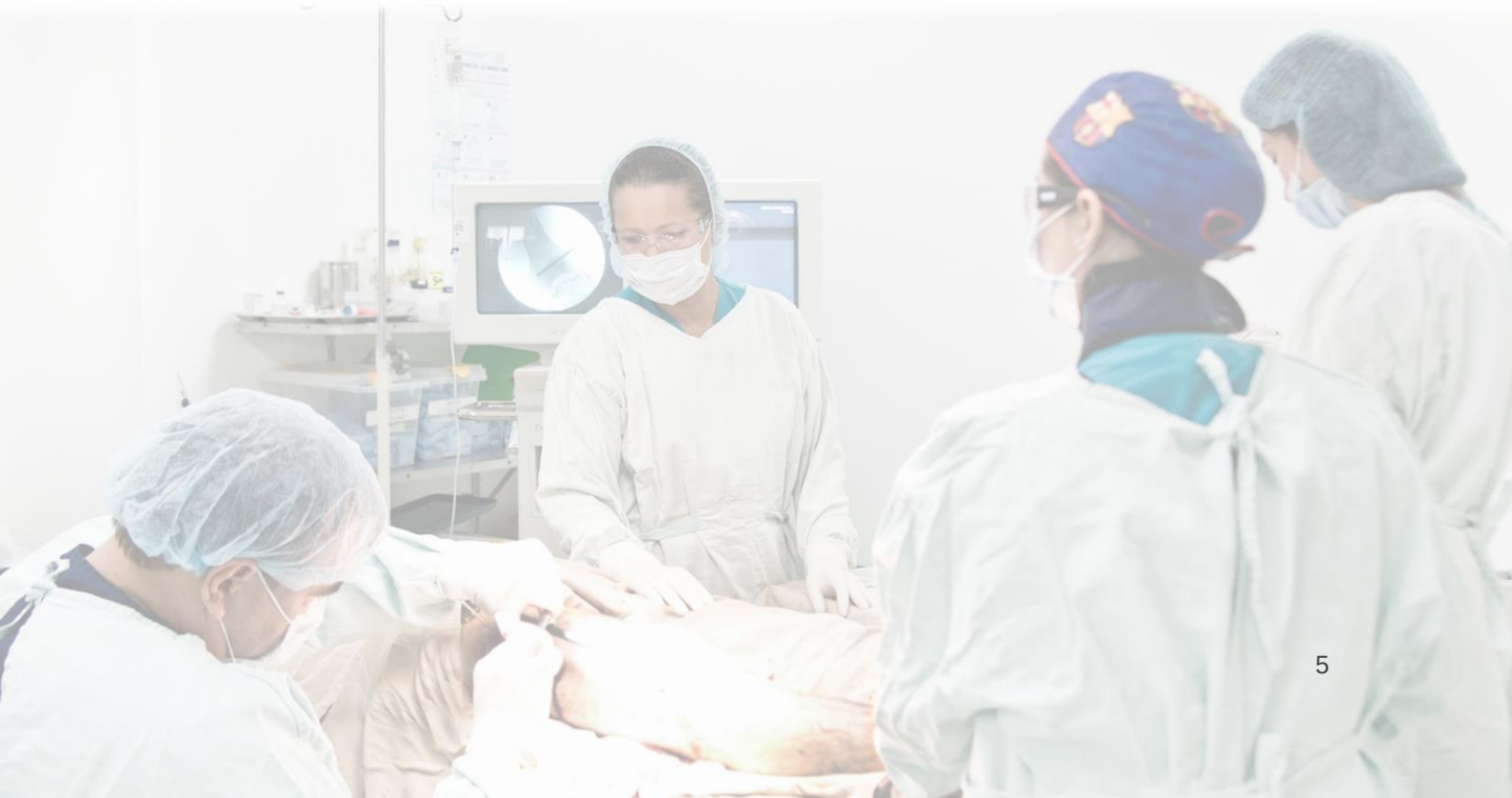
Addressing Emerging Health Threats

Our strategy

It is essential that we continue to work closely with surveillance groups to maintain an awareness of emerging diseases, consider the potential impact of global diseases on the veterinary industry in the UK and react in a timely manner to provide clear guidance and appropriate support to stakeholders.

We will:

- review the effectiveness of previous ‘exceptional’ marketing authorisation applications for therapies for emerging diseases
- consult with stakeholders about the difficulties developing or accessing veterinary medicines to prevent, treat and control emerging diseases
- establish a risk rating system for new diseases which will be linked to guidance on reduced data requirements
- review existing legislation to identify areas where changes to the existing legislation may be required
- review current guidance on the ‘exceptional circumstances’ provision and consider how this can be improved



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Enabling Availability of Veterinary Medicines

Our strategy

It is important that we have an appropriate range of medicines to prevent and treat diseases in animals and so ensure animal health and welfare and protect human health. In order to improve availability of medicines in some areas, we will review the regulatory framework to see whether progression to market of additional and/or alternative veterinary medicinal products can be encouraged.

Certain **veterinary healthcare products** fall outside both the strict definition of a veterinary medicine or classification as a biocide or feed additive. As a consequence, these products may be marketed in the UK without regulation. On the other hand, other useful products might fulfil the strict definition of a veterinary medicine by means of their label claims and/or how they work, but not fulfil the usual requirements for a marketing authorisation.

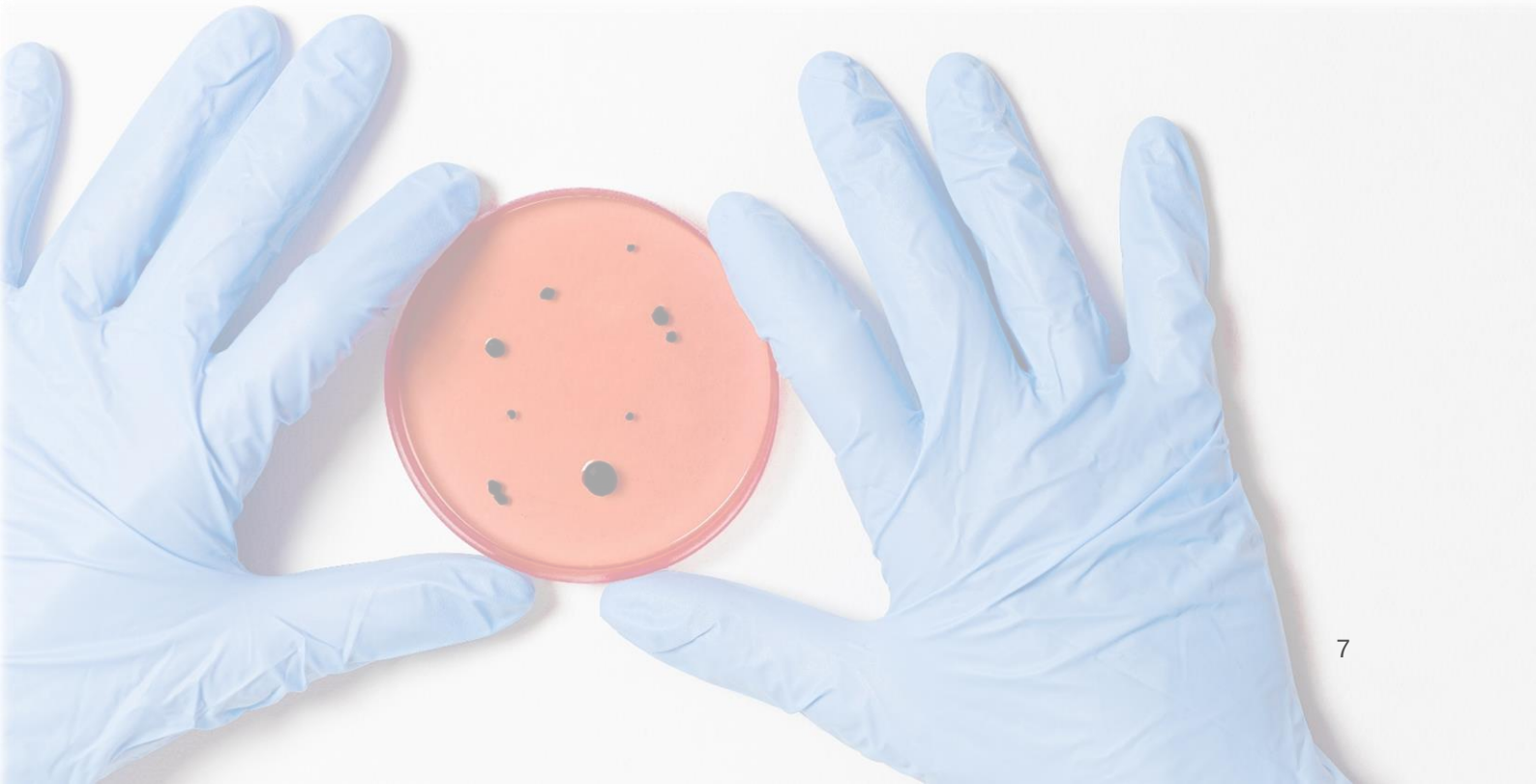
We will:

- conduct a review of queries about veterinary healthcare products and consider the need to regulate certain types of product, taking into account legal and scientific aspects and consultation with other interested parties. The overall aim will be to improve availability of beneficial products while ensuring their quality, safety and efficacy

The UK’s five-year AMR national action plan highlights plans to deliver a sustainable supply of **vaccines and alternatives to antimicrobials** to reduce the need for existing antimicrobials which, combined with optimised antimicrobial use, will slow the rise and spread of AMR. Alternatives might reduce antimicrobial consumption by either preventing, treating or reducing the risk of bacterial infection, or by increasing resilience to disease. In addition, the action plan highlights the importance of improving the development of, and access to, good quality new antimicrobials.

We will:

- define the key regulatory terms (*alternatives to antimicrobials* and *novel antimicrobials*) and consider the need for any additional terms
- identify regulatory strategies that will increase the development, availability, and use of alternatives to antimicrobials
- consider when alternatives to antimicrobials may be eligible for a limited marketing authorisation and ensure this is reflected in our guidance
- establish a clear picture of the pathway(s) to market for the major classes of product currently falling under the classification 'alternatives to antimicrobials'
- where appropriate, clarify the data required to confirm the safety and efficacy of a veterinary medicine and the product claims that might be acceptable



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Strengthening a Life Cycle Approach to Benefit-Risk

Our strategy

Benefit-risk assessment is an important tool to support the regulator's decision making. However, the validity of the benefit-risk assessment is dependent on the quality and quantity of the data available.

Benefit-risk assessments are usually performed on the basis of a qualitative approach that relies on expert judgement. The use of a more structured and/or a quantitative framework would improve the consistency and transparency of decision-making. A **review of benefit-risk methodology** is important to ensure that the approach is fit for purpose, is flexible, and to identify whether improvements can be made, either through new approaches or refinement of existing ones.

We will:

- review our current benefit-risk methodology to evaluate whether the approach is fit for purpose, and whether any improvements can be made
- investigate the suitability of alternative benefit-risk methods, including quantitative/semi-quantitative approaches and targeted approaches
- investigate whether a broader range of benefits may be incorporated into the benefit-risk assessment
- consider appropriate methodologies for 'exceptional' MAs, given the reduced data and potentially less certainty with regard to safety and efficacy
- investigate potential for improvement of communication of risks and risk mitigation strategies
- consult and provide guidance to industry on any new approaches or changes to benefit-risk assessment

The **signal management process in pharmacovigilance** analyses large volumes of data to provide assurance on the safety and efficacy of veterinary medicines and contributes to the ongoing benefit-risk evaluation. We must keep pace with developments in this field and continue to provide a robust safety net of efficient and effective pharmacovigilance and reassurance to the end user and general public.

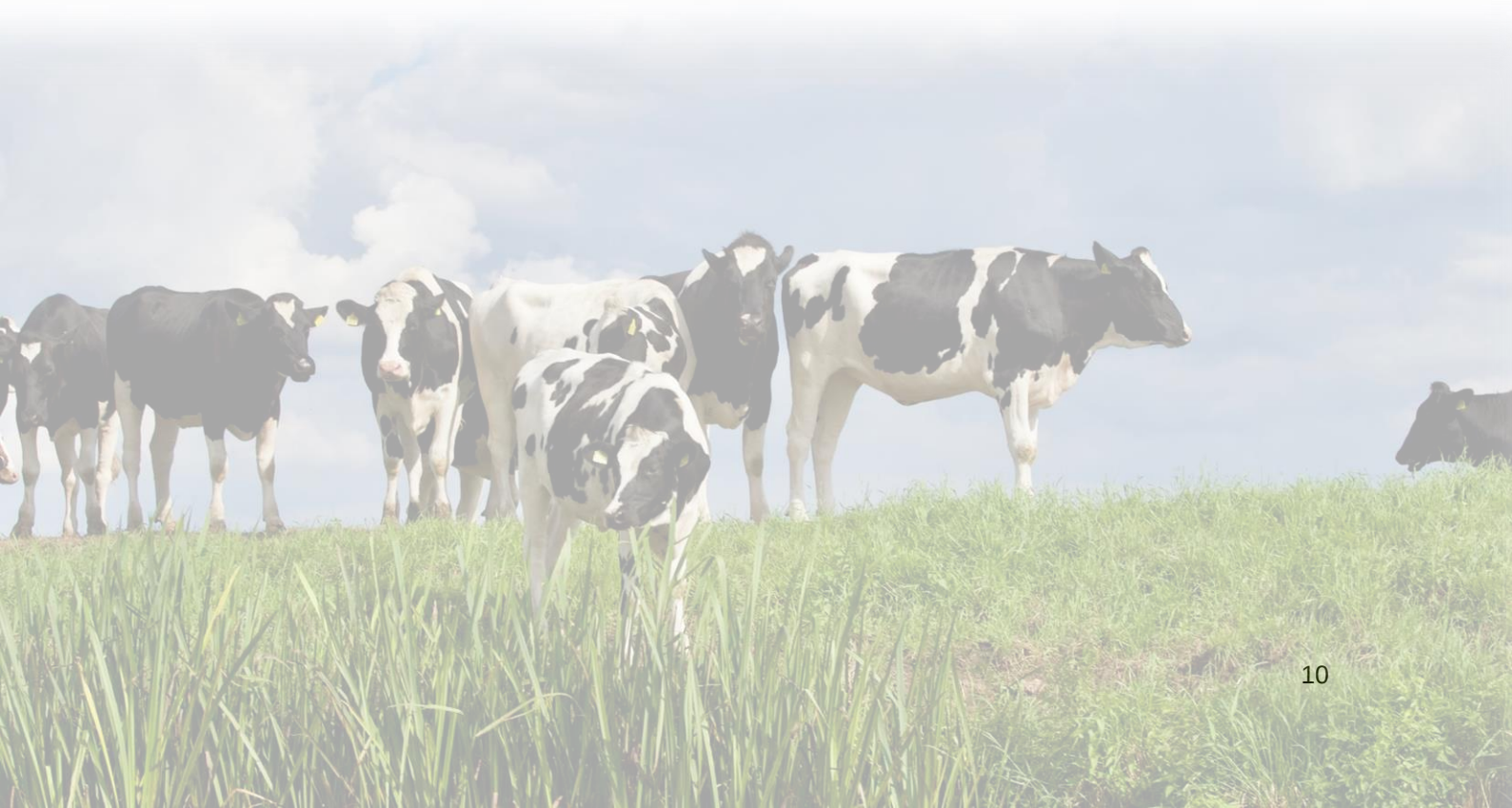
We will:

- develop working relationships with other regulatory agencies worldwide, and evaluate the methods and processes used for signal management
- establish an international regulatory forum to discuss signals and determine regulatory actions
- research and develop expertise to validate different statistical data mining methods for analysis of data
- advance our knowledge of pharmacology and pharmacoepidemiology
- enhance in-house pharmacovigilance IT capability, developing and implementing IT solutions for data analysis
- develop best practice guidance and criteria for signal management and interact collaboratively with industry to share methodology where appropriate

There is growing concern regarding the **impact of pharmaceuticals in the environment**, both in relation to their potential effects on ecosystems and effects on human safety. There is the need to better understand the fate and potential impacts of chemical contaminants in the environment on biological organisms.

We will:

- develop and/or extend working relationships with other government agencies and determine how they deal with environmental infringements
- investigate the benefit-risk balance for compounds of environmental concern, e.g. endocrine disruptors and PBTs
- understand the existing systems of environmental monitoring (of terrestrial and aquatic systems), for chemicals used as veterinary medicines in the UK
- research and develop appropriate guidance on the risks of secondary exposure from topically administered veterinary medicines for pets
- evaluate the need for post authorisation environmental monitoring programmes for those compounds considered to be a high risk to ecosystems



Risk Management Plans (RMPs) describe what is known, and not known, about the safety profile of a medicine and describe measures to minimise and mitigate the risks where possible. RMPs are a potentially valuable tool, especially for novel products and those authorised under 'exceptional circumstances', allowing them to gain market access in a controlled manner. However, although routinely implemented for human medicines, more experience needs to be gained in the veterinary field.

We will:

- review how RMPs and risk minimisation measures are planned, implemented, and regulated in other agencies
- build relationships with experts in the relevant fields and identify and fill any gaps in our scientific knowledge
- further investigate the potential for RMPs in the veterinary field, with a particular focus on innovative products and areas of unmet clinical need
- provide guidance and standards for post-authorisation data collection and analysis within the context of a RMP
- promote a regulated approach to marketing authorisation holder risk minimisation measures implemented during the post-authorisation phase
- request feedback from stakeholders on the proposals

On-going benefit-risk evaluation is a core activity of pharmacovigilance and is based on accumulating evidence during the life cycle of a product. Assessing the causality of the risk depends upon the nature and the amount of evidence. New strategies to link different data sources will help us **transform post-authorisation big data into knowledge and regulatory action**. In recent years, substantial advancements have occurred in the use of digital technologies in regulating medicines for human use. Such solutions in the veterinary regulatory domain are an unexplored yet potentially new territory.

We will:

- develop an integrated IT solution that joins-up relevant data (product information, historical and new pharmacovigilance and AMR data)
- conduct an analysis of available and potential new data sources suitable for supporting our pharmacovigilance regulatory activities
- undertake work-sharing assessments and utilise expertise in other fields, such as pharmacology, pharmacoepidemiology and statistics
- establish a cooperation forum on veterinary data across agency disciplines

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Facilitating the use of Novel Scientific Models and Tools

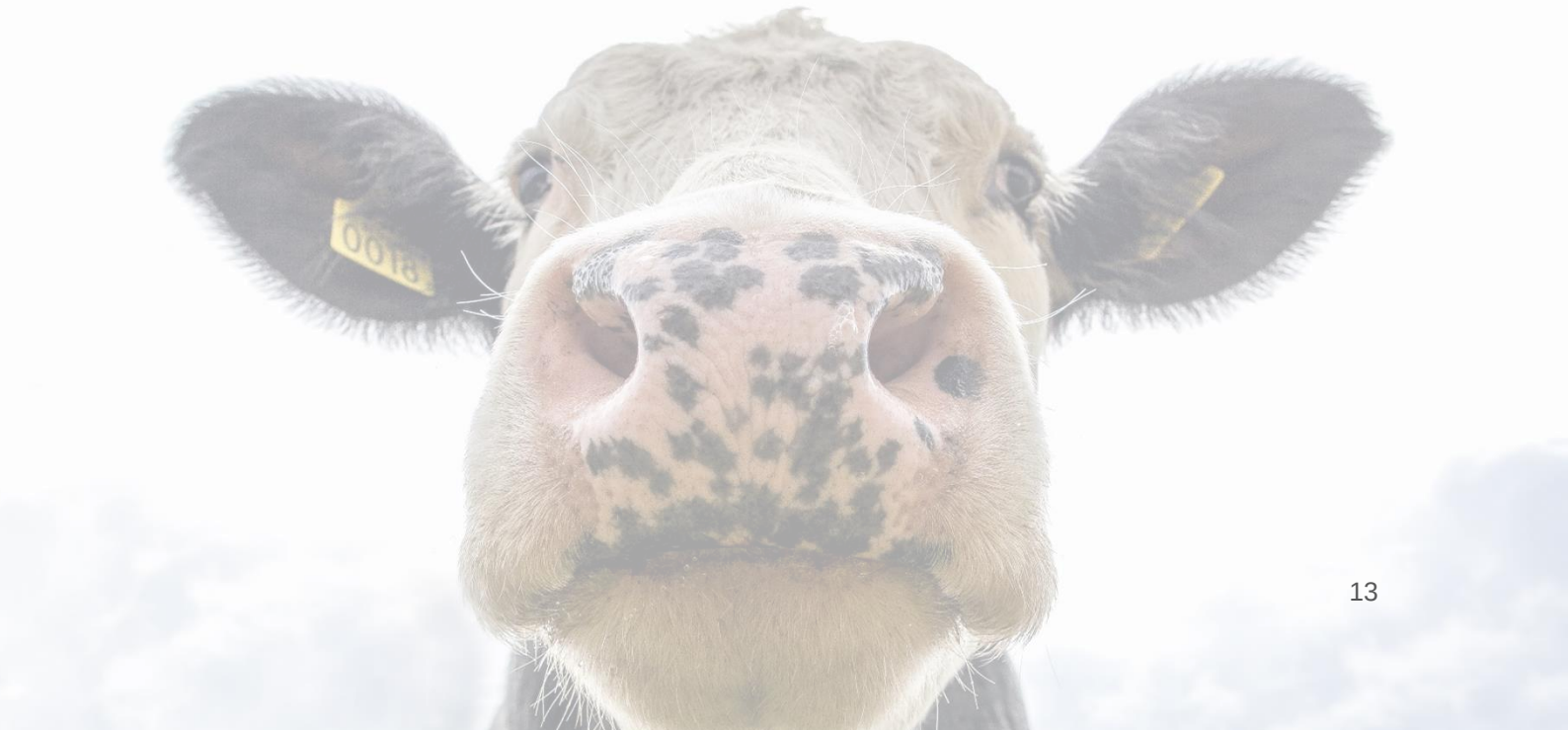
Our strategy

The emergence of novel scientific models and tools is leading to more efficient active substance and medicine development, as well as helping to replace and reduce the use of animals in experimental studies.

Pharmacological methods are increasingly being used in studies submitted in support of applications for marketing authorisation and should be encouraged. However, it must be ensured that use of 3Rs methodology will provide equivalent assurance of quality, safety and efficacy as the current widely accepted methodology.

We will:

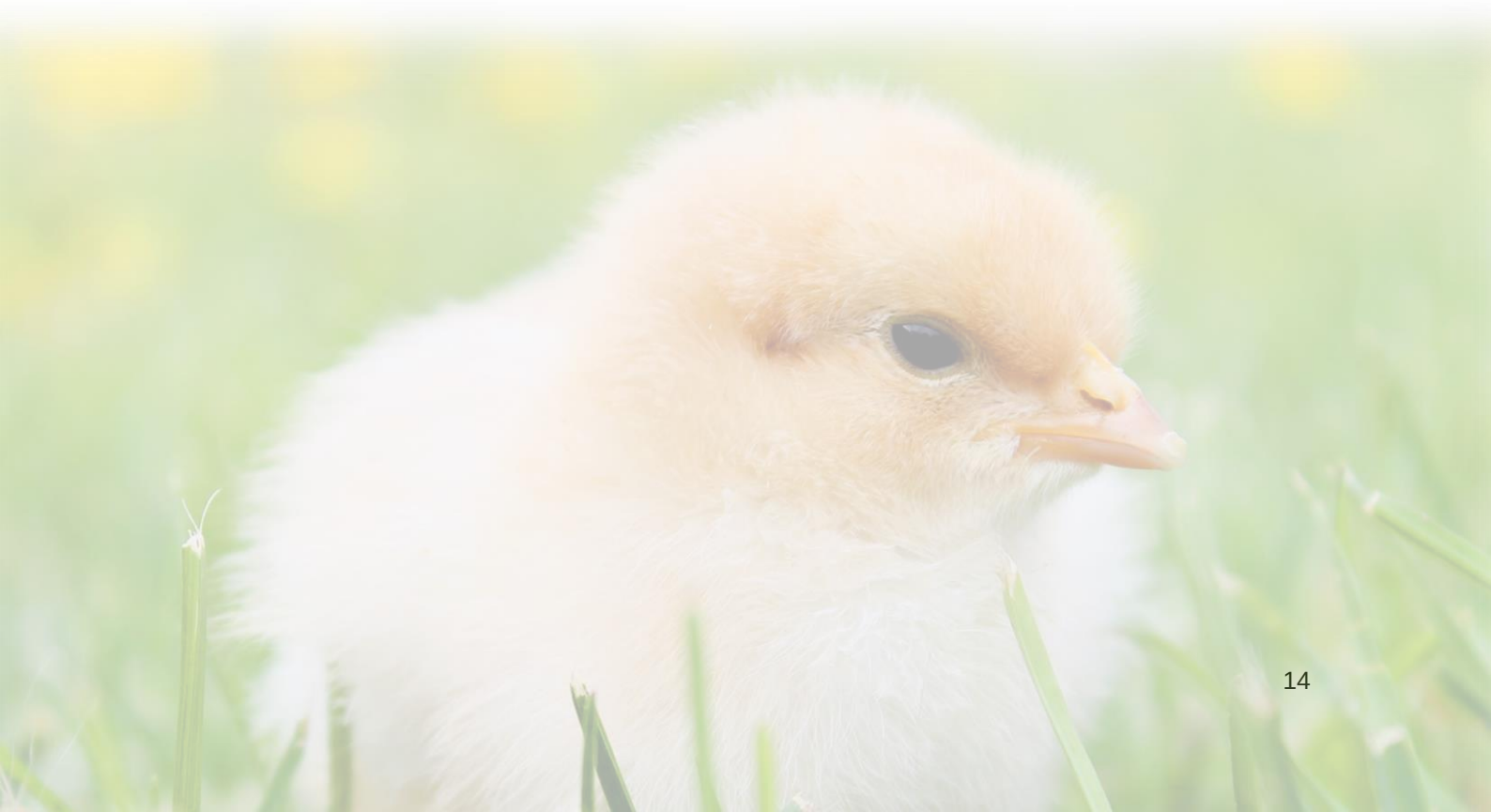
- review current scientific guidelines and identify opportunities for 3Rs implementation
- invite industry to share areas of development for 3Rs and build relationships with experts in the relevant fields
- promote the use of new 3Rs methodologies by updating current guidance and offering scientific advice for applicants
- explore opportunities for funding R&D projects related to the development of 3Rs methodologies



Various modelling techniques are used as part of the decision-making process in the authorisation of veterinary medicines. In particular, **modelling and simulation approaches** can make efficient use of imperfect empirical datasets. Although the potential benefit of using models is clear, it is important that regulators and stakeholders have a good understanding of how they are developed and validated if they are to be more widely used and accepted in the regulatory arena.

We will:

- identify and evaluate the merit of appropriate simulation and modelling techniques and see if they can be made more accessible
- as appropriate, interact with industry to encourage the use of new modelling techniques to reduce the number of animals used in testing
- investigate the potential to use other sources of data and analytical approaches within the environmental risk assessment
- ensure that appropriate guidance is provided for both regulators and industry



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Ensuring Access to High Quality Regulatory Scientific Expertise

Our strategy

We are determined to ensure we **maintain our scientific expertise and capability** and have ready access to specialised skills and competencies. This will enable us to continue to provide high quality scientific advice and undertake appropriate critical review and benefit-risk assessment of applications for new veterinary medicines.

We will:

- strengthen existing links between ourselves and other regulators and leverage collaborative links with new global/international regulatory partners
- develop a network of independent scientific experts
- provide professional development opportunities, secondments and experience postings to attract and retain highly qualified and skilled staff
- ensure the focus of our R&D programme remains current and is used to commission work on scientific questions of greatest importance and relevance