EMA
EUROPEAN MEDICINES AGENCY

Support to innovative veterinary medicines

Overview of regulatory tools available

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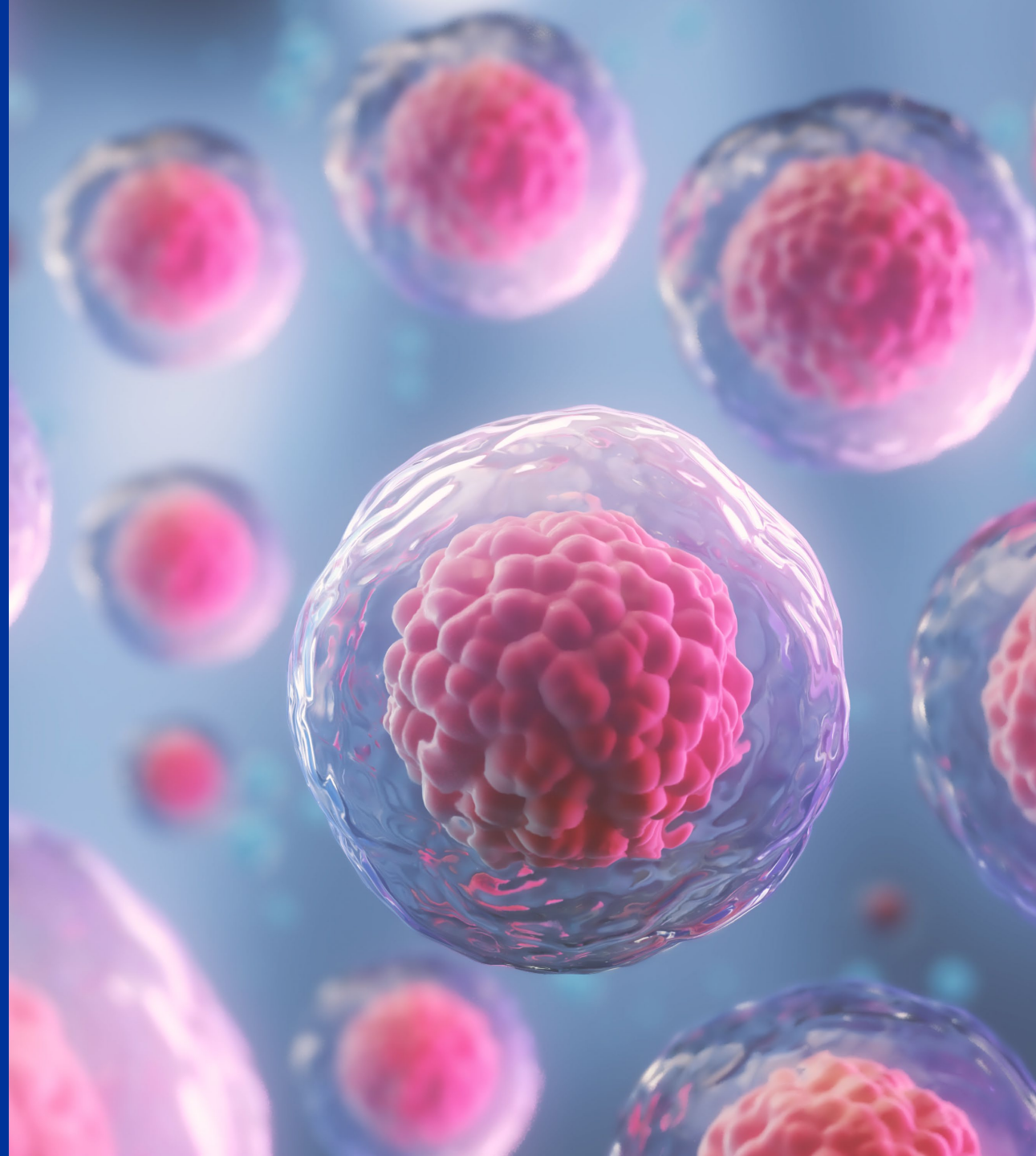
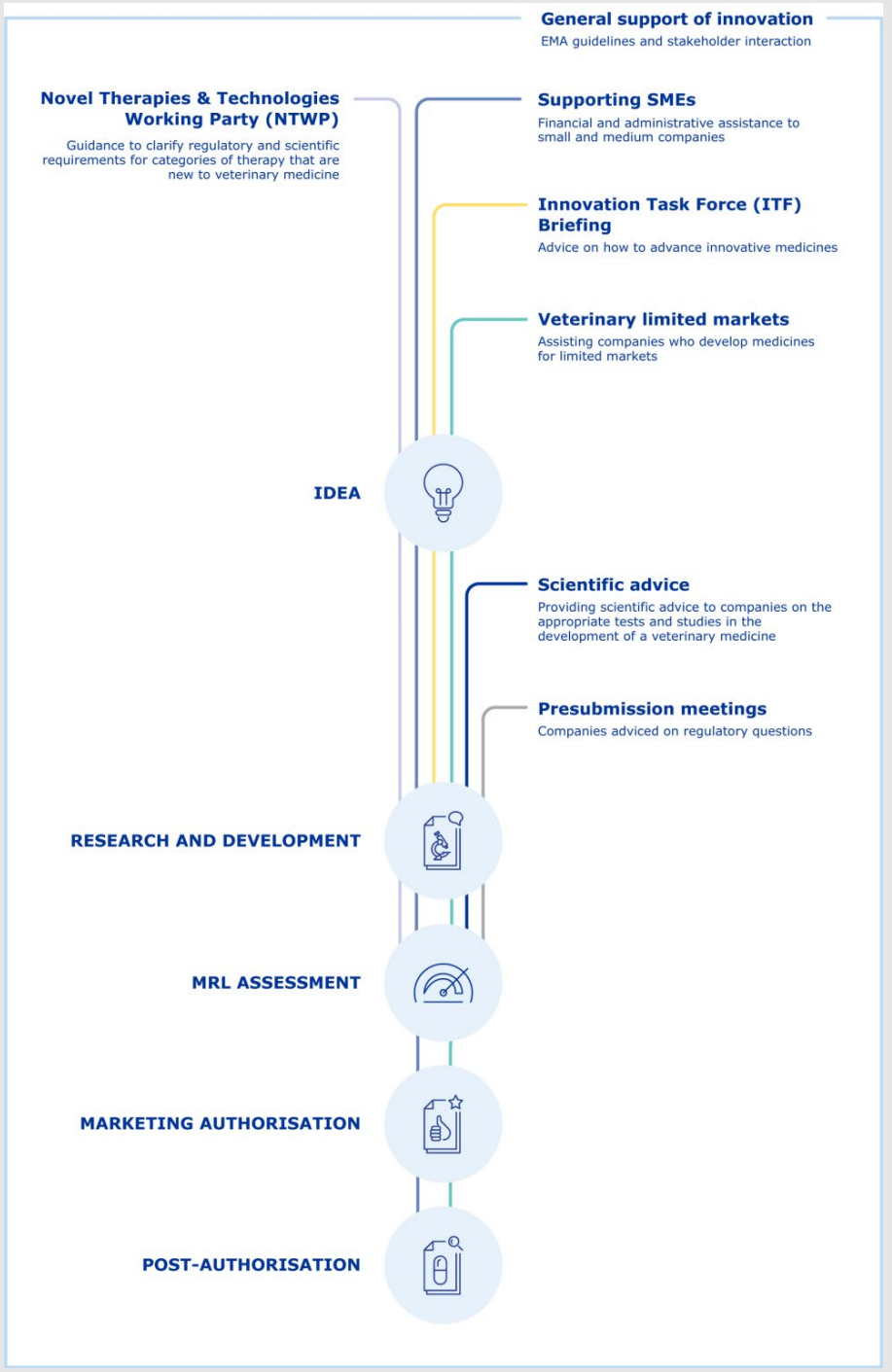


Support to innovation

Goal: create a regulatory framework that fosters innovation while ensuring veterinary medicines of adequate quality, safety and efficacy.

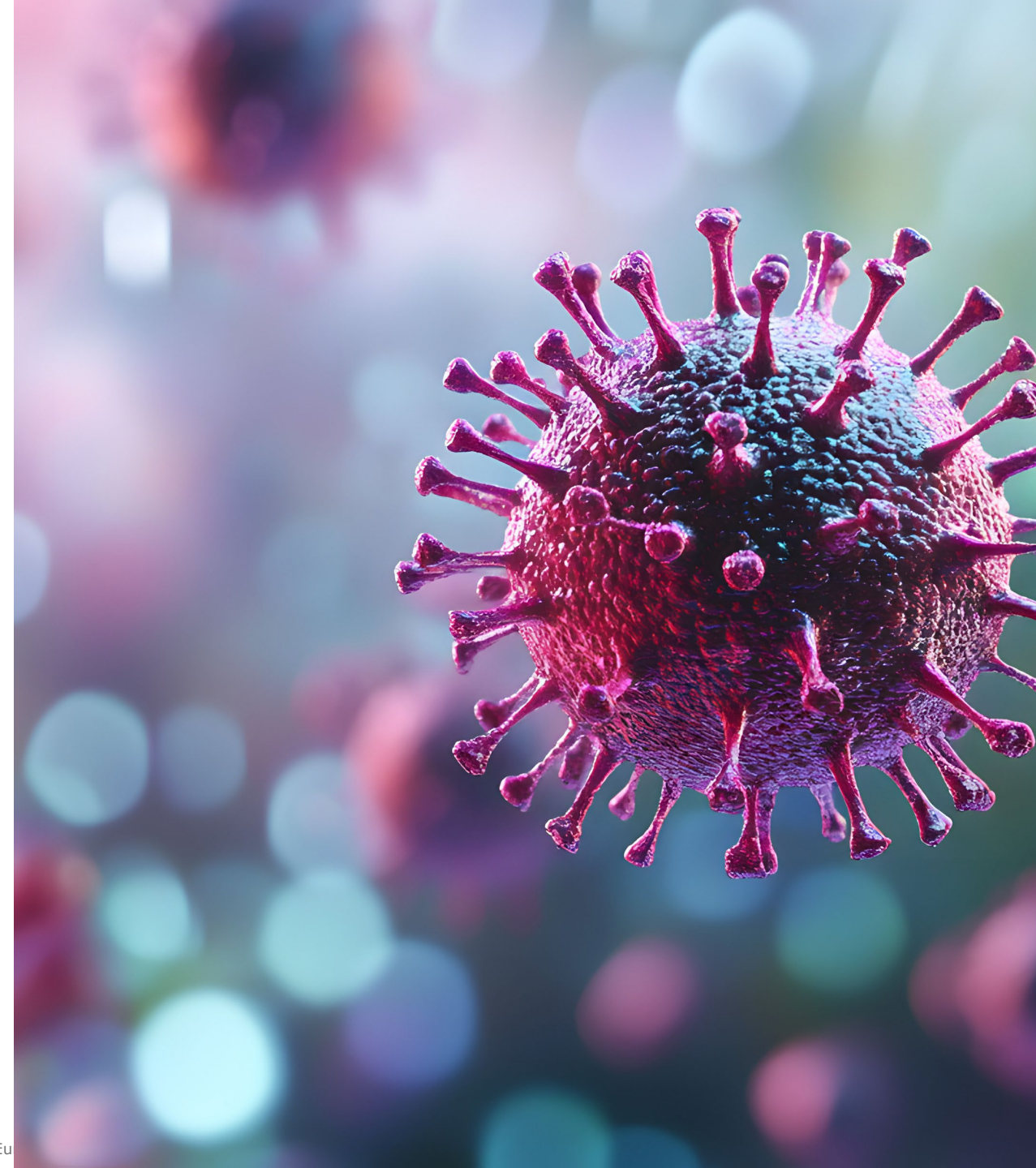
Fostering innovation

- Innovative vaccines
- Novel therapies and technologies
- Novel approaches to meet unmet needs
- Regulatory innovation



Innovative vaccines

- Modernisation of old vaccine ranges
- Implementation of available regulatory tools (e.g. VAMF, vPTMF)
- mRNA technology
- Next-generation vaccine approaches (virus-like particles, DNA vaccines)
- Vaccine platforms (DNA, RNA, vector)
- New delivery systems (nanoparticles)
- New adjuvants and immunomodulators
- Vaccines against parasitic diseases



Vaccine Antigen Master File (VAMF)

Definition

- Stand-alone part of marketing authorisation application (MAA) dossier containing all quality data for an antigen.
- Common to one or more MAs.

Certification

- Centralised evaluation procedure handled by EMA.
- As part of an initial MAA or as a separate procedure.
- Certificate valid throughout the EU *(for any authorisation route).*

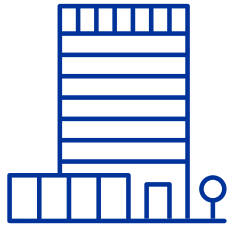
Use of VAMF

- VAMF certificate can be used to support future applications for vaccines containing the same antigen.

Vaccine Antigen Master File (VAMF)

Main benefits

- Single assessment for authorities / single dossier to be handled by applicants
- Speed up assessment procedure – data in VAMF not reassessed
- Increase predictability



EMA guidance

- Procedural advice for VAMF certification (link)
- Guideline on data requirements for VAMFs (link)

Experience to date

- 9 certifications issued in 2024

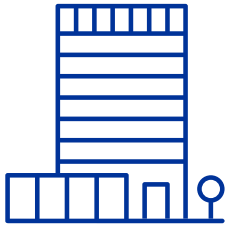
Vaccine Platform Technology Master File (vPTMF)

Definition	• Technologies with common backbone carrier/vector that can be modified with different antigens/inserts for each vaccine. • Stand-alone part of MAA dossier containing all data that will be common to the vaccines based on the platform (Q, S, E).
Certification	• Centralised evaluation procedure handled by EMA. • As part of an initial full MAA or as a separate procedure. • Certificate valid throughout the EU *(for any authorisation route).*
Use of vPTMF	• vPTMF certificate can be used to support future MAAs for vaccines based on the same platform.

Vaccine Platform Technology Master File

Main benefits

- Single assessment for authorities / single dossier handled by applicants
- Speed up assessment procedure – data in MF not reassessed
- Foster the use of platforms for development of vaccines
- Reductions in data requirements for vaccines using the same PT
- Increase predictability



EMA guidance

- Procedural advice for vPTMF certification (link)
- Guideline on data requirements for vPTMF (link)

Experience to date

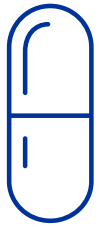
- 2 certifications issued in 2024

Novel therapies and technologies

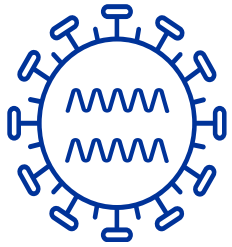
- **Novel Therapies**
  - Gene therapy, regenerative medicine, tissue engineering, blood product therapy, phage therapy
  - Veterinary medicinal products issued from nanotechnologies
  - Any other therapy considered a nascent field (in veterinary medicine)

- **Novel Technologies**
  - AI applications
  - Advanced manufacturing methods (continuous processing)
  - 3D bioprinting of tissues and implants
  - Digital monitoring solutions for precision medicine

Novel therapies classification



Veterinary medicinal products other than biological



Biological veterinary medicinal products **other than immunological**

Biological immunological veterinary medicinal products

- Vaccines including nanotechnology (delivery system or adjuvants)
- Vaccines including novel technologies (novel adjuvants, delivery systems
- Nucleid acid vaccines (mRNA, DNA; recombinant; viral vector vaccines)

Questions and answers on classification of veterinary medicinal products

Novel therapies and Regulation (EU) 2019/6

- Taking into account the specificities of novel therapy products, specific requirements additional to the standard requirements for evaluation of quality, safety and efficacy may be appropriate.
- Deviations from the requirements in the annex may be possible when scientifically justified.
- To address data gaps or uncertainties at the time of product authorisation, implementation of post-authorisation measures or studies may be considered on a case-by-case basis.
- Risk management plan to be included in the dossier.

Novel approaches to meet unmet needs

- Rapid response frameworks for emerging disease threats
- Targeted solutions for therapeutic gaps in minor species
- Alternatives to combat antimicrobial resistance
- Next-generation antiparasitics to address resistance
- Environmentally sustainable product formulations and delivery
- One health solutions

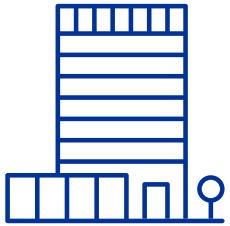
Applications for Limited Markets (Article 23)

Definition	• VMPs for diseases that occur infrequently or in a limited geographical area or • VMPs for species other than cattle, sheep (meat), pigs, chickens, dogs and cats
Applications under Art. 23	• Marketing authorisation (MA) can be granted if benefit of availability outweighs certain gaps in safety or efficacy • Validity limited to 5 years (renewable)
Eligibility	• Eligibility to be confirmed by EMA (also for national authorisation • Voluntary • Valid at the time of eligibility (re-evaluated at submission)

Applications for Limited Markets (Article 23)

Main benefits

- Some data requirements may be lifted for safety and/or efficacy
- Flexibility on data requirements for LMs **not eligible** under Art.23



EMA guidance

- Reflection paper on eligibility (*currently under revision*)
- Guidelines for IVMPs and non-IVMPs on efficacy, safety and residue data requirements for LM Art. 23

Experience to date

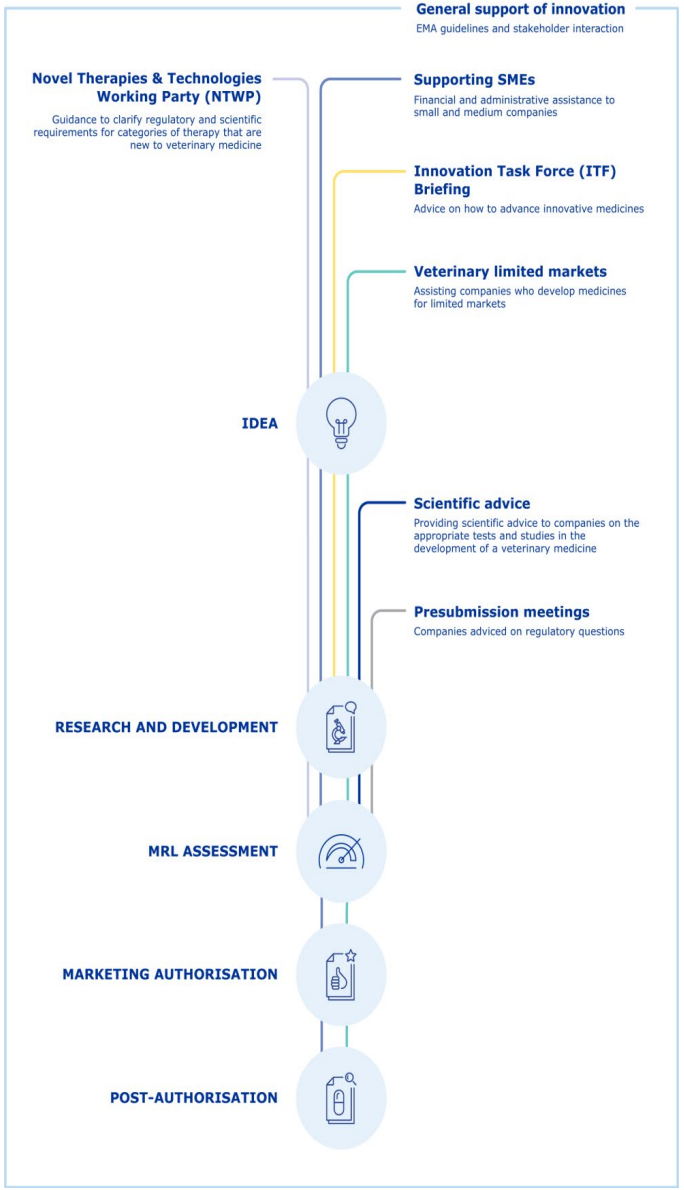
- **13 products** confirmed as eligible for Art. 23 in 2022.
- **13 products** confirmed as eligible for Art. 23 in 2023.
- **11 products** confirmed as eligible for Art. 23 in 2024.

Regulatory innovation

- New regulatory tools and pathways for faster approval.
- Big data RWD/RWE integration in safety and efficacy assessment.
- AI applications (manufacturing, development, pharmacovigilance).
- One Health approach to regulatory decision-making.
- Collaborative frameworks between industry and regulators.
- Flexible approach for novel therapies.
- Improve processes to remove unnecessary administrative and regulatory burden.
- Regulatory efficiency and predictability.

Support to innovation: available tools

- Early enquiries (**AskEMA**).
- **Pipeline/portfolio and technology** meetings with industry.
- Innovation task force (**ITF**): early stages of development, general or product-specific, advice on legal, regulatory and /or scientific aspects.
- **Academia** liaison.
- **SME Office**: provides regulatory, financial and administrative assistance to companies designated as micro, small and medium-sized enterprises.
- **Guidance and guidelines** on procedural, regulatory and scientific issues.
- **Scientific advice**: later stages of development, pre-submission or during evaluation.
- **Pre-submission meetings**: final stages of development, product-specific.



Support to innovation: available tools

Scientific advice (SA)

Of the **27 scientific advice reports** finalised in 2024:

- 7 for immunologicals, 12 for chemicals and 8 for biologicals.
- 14 claimed to include a new active substance.
- including companion and food-producing animals.

Pre-submission meetings

- More than **13 meetings** (including pipeline) held in 2024
- Additionally, seven written responses were prepared for enquiries on product development.

Guidance and guidelines

- Since July 2021, more than **22 guidelines** were finalised and published
- Guidance on phages, VAMF, vPTMF, DNA vaccines, benefit-risk, live recombinant vaccines, limited markets, etc.

Key regulatory considerations

- **Early planning**: regulatory requirements for the authorisation of innovative medicines should be considered early in research.
- **Adequate preparation**: a clear strategy for regulatory procedures.
- **Collaborative approach**: strengthen collaboration between regulators and developers.
- **Early communication**: efficient dialogue with regulatory bodies at key stages of development.
- **Address gaps** in available guidance to ensure predictability.
- **Clear regulatory support** for innovative product development.
- **Increase awareness** of available support.
- **Efficient use** of available support.

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