National authorities would constitute the CCB membership (1 member per member state) and be an integral part of the EMRN:

- Providing experts for scientific assessments and working groups, and local advice/contact
- Implementing control systems and procedures for products placed in their market with local enforcement
- Be responsible for pharmacovigilance
- Receiving fees from the CCB for services provided, as well as fees for products placed on the national markets.

The European Commission's role:

- Legal caretaker of the system
- Shared responsibility with the member states for an efficient running of the procedures
- Providing legal advice
- Participation in the EMRN
- Chairing the CCB.

Companies will need to:

- Invest in the development and registration of veterinary medicines
- Submit dossiers to the required standard and pay scientific assessment fees
- Place and maintain the products on the market
- Pay accession fees (pay and do) before putting their product on each market
- Comply with all legal obligations throughout the life cycle of the product.

This system will accommodate both small and large companies.

1-1-1 CONCEPT

The 1-1-1 concept is a single procedure for all products with 1 dossier, 1 European scientific assessment and 1 decision for marketing authorisation.

Organised through a **central coordination body,** with **national agencies as the backbone,** and would apply to **all** new and existing EU products, generics, classical and hi-tech products.

- **1 single dossier** in English submitted to the central coordination body which assigns the assessment team
- **1 single European scientific assessment,** with an assessment team using the best competence within the EMRN, and with a single fee paid to the central coordination body
- **1 single decision** and a single European marketing authorisation valid in all member states, with the payment of a national fee for placing on the market of a member state (pay and do).

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The animal health industry and regulatory reform: **the 1-1-1 concept in a nutshell**

THE COMMON GOALS

- A single market for veterinary medicines in Europe
- Public and animal health protection, safe food supply
- Ensuring competitiveness of European industry
- Reduction of administrative burden, better regulation.

OBJECTIVES

- Enhanced availability of veterinary medicines
- Efficient use of resources
- One simplified, efficient and robust regulatory system.

Why do we need a single system?

The current licensing system is complex, leading to a high administrative burden and inefficiencies. A lack of sufficient alignment between member states implementing the legislation and guidelines creates additional bureaucratic hurdles.

The 1-1-1 concept is a preferred solution

As it would maintain existing safety standards, while:

- Improving veterinary medicines' availability
- Reducing administrative burden, thereby improving competitiveness
- Ensuring a harmonised and practical implementation of the legislation leading to predictable, efficient and proportionate regulatory procedures
- Achieving a better regulation and simplification, creating a regulatory environment proportionate to the needs of the animal health industry
- Utilising resources efficiently within national competent authorities.

THE 1-1-1 CONCEPT PROPOSES A SINGLE SYSTEM BASED ON:

- **1** single EU dossier
- **1** single assessment using the best European competence available
- **1** decision for marketing authorisation

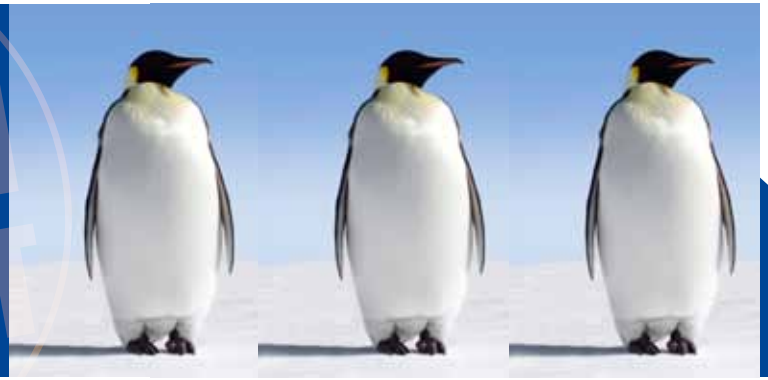
and this for ALL products.

1-1-1 CONCEPT

The benefits of 1-1-1

A more efficient regulatory system would benefit all stakeholders through:

- Efficient use of the European Medicines Regulatory Network's (EMRN) resources: reducing bureaucracy, removing duplication, attracting/retaining high quality staff
- Workload reduction for the national authorities
- Fair and equitable regulatory environment for all applicants
- Harmonised implementation leading to an efficient and proportionate system
- Better regulation, giving increased public confidence
- Increased access to EU markets creating business opportunities for industry, including SMEs
- Improved product availability benefiting animal health and welfare through improved access to veterinary medicines for pet owners, vets and farmers
- Enhanced food safety, food security, and protection of public health from zoonotic diseases
- Resources released to provide market control and surveillance, which will increase public confidence in the EMRN.



Structures and responsibilities

A Central Coordinating Body (CCB) would:

- Have 1 member per member state
- Have joint responsibility for the efficient running of procedures
- Have administrative support from a central secretariat
- Assign the scientific assessment team (from a pool of experts within the EMRN)
- Coordinate the harmonised standard of assessment
- Adopt decision based on the scientific assessment
- Issue a European marketing authorisation
- Be chaired by the European Commission with vice-chairs from member states
- Appoint a 2nd scientific team for referrals and arbitration when necessary.

The central secretariat would report to the CCB and its duties would entail:

- Receiving and validating applications
- Receiving fees and issuance of the European marketing authorisation
- The regulatory management of the scientific assessment process
- Appointing a national language project manager if so requested
- Management of databases
- Coordination of the pharmacovigilance and inspections, publication of guidelines etc.