



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Experience and Perspective

Regulatory challenges in the drug-food continuum

IMI Stakeholder Forum 2017 · Microbiome forum

Presented by Nino Mihokovic on 19 October 2017
Quality Specialist, European Medicines Agency

Disclaimer: *The contents of this presentation are the views of the author and do not necessarily represent an official position of the European Medicines Agency*

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EMA in the EU

Who do we work for?



over **500** million people living in the European Union

28 member states

27% of global sales of medicines

24 official languages



What do we do?

**Protect human
and animal health**

The diagram features a central dark blue circle with the text 'Protect human and animal health'. From the right side of this circle, four light blue, ribbon-like shapes branch out to the right, each containing a bullet point. The background behind the circle and ribbons is a light blue color with a subtle pattern of overlapping circles.

- Facilitate development and access to medicines

- Evaluate applications for marketing authorisation

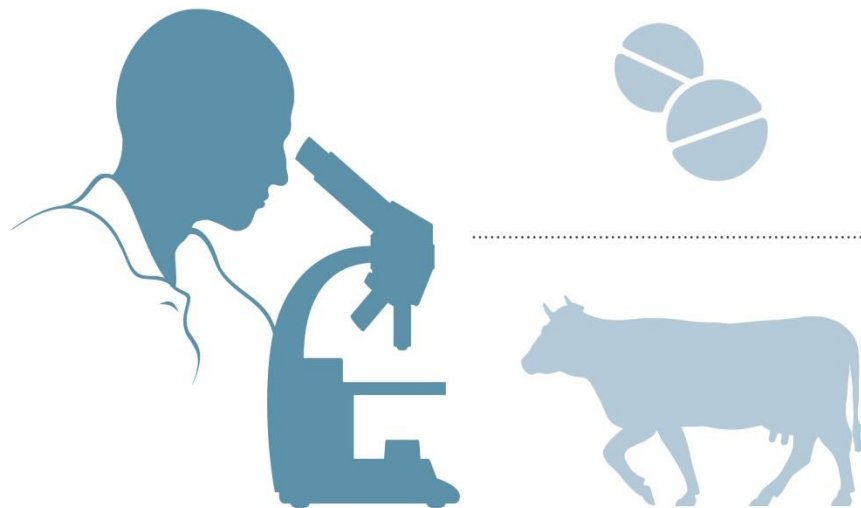
- Monitor the safety of medicines across their life cycle

- Provide information on human and veterinary medicines to healthcare professionals and patients



Who we are

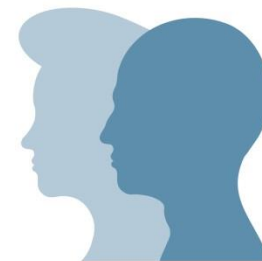
~4000 Scientific experts from right across Europe



7 Scientific committees

- CHMP
- CVMP
- COMP
- HMPC
- PDCO
- CAT
- PRAC

over 1000 marketing authorisations recommended

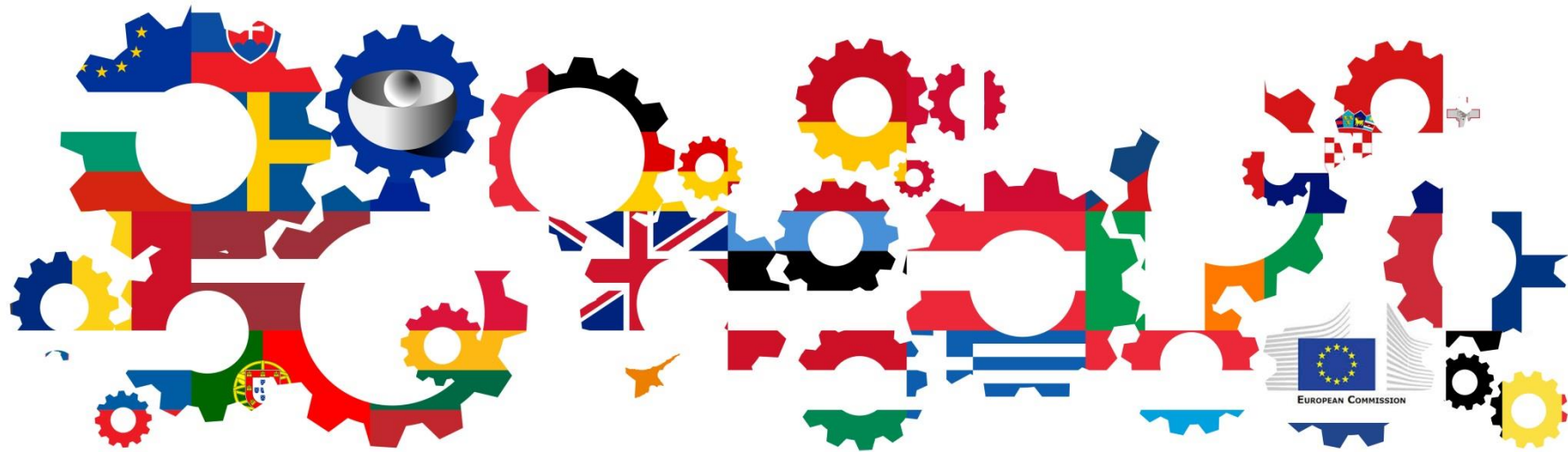


1995 EMA established to evaluate medicines for use in the EU

28 Working parties

~890 Staff members

The European medicines regulatory network



~ 50 national regulatory authorities

European Commission

European Medicines Agency

How is EMA organised?

Management Board

Executive Director

EMA staff

CHMP

CVMP

COMP

HMPC

PDCO

CAT

PRAC

+ 28 working parties
+ 8 scientific advisory groups

**National competent authorities
~4000 European experts**



EU institutions



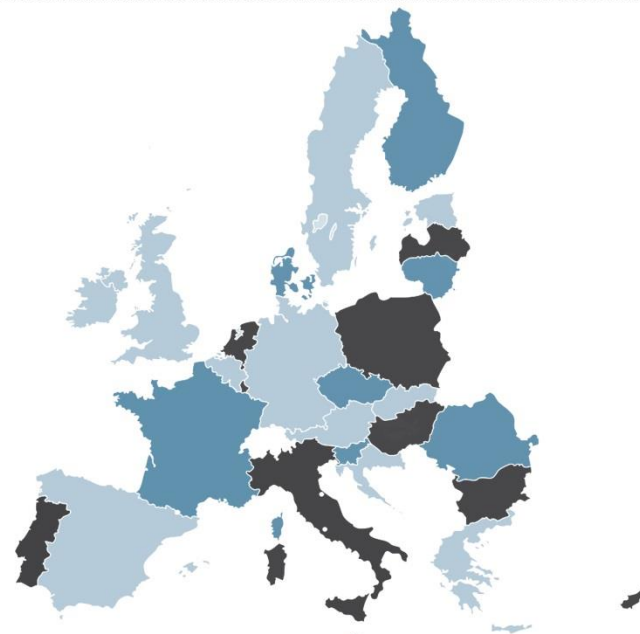


How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via NCAs)



Which medicines are approved through the centralised procedure?



- ✓ Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- ✓ Medicines derived from biotechnology processes, such as genetic engineering
- ✓ Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- ✓ Officially designated 'orphan medicines' (medicines used for rare human diseases)



What is the benefit of the centralised procedure for EU citizens?

- Medicines are authorised for all EU citizens at the same time

- Centralised safety monitoring

- Product information available in all EU languages at the same time





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Scientific challenges

There are a number of challenges as regards chemical, manufacturing and control aspects. In particular, such challenges pertain to characterisation of live bacteria, control strategy, donor selection and testing (for faecal transplants), and establishing a link between product quality/composition, mechanism of action and potency/effectiveness.

Regarding product safety, there is a theoretical risk for transfer of antibiotic resistant genes from a product strain to the host's microbiome.



Regulatory challenges

There is no harmonised view regarding classification of products containing live bacteria, either as isolated strains, or as faecal transplantation therapy. These types of products could potentially be classified as medicinal products, medical devices or food supplements, depending on their objective characteristics, the intended treatment claim or mechanism of action. In light of this consideration, determination of an appropriate classification should be discussed on a case-by-case basis in accordance with the Agency and/or national competent authorities.

European Commission, DG HEALTH & FOOD SAFETY (SANTE), Unit B4 – Medical Products: Quality, Safety and Innovation should also be involved in discussion on classification and e.g. donor screening requirements.



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EMA experience

In the last few years, developers have engaged in early informal dialogue with the EMA's Innovation Task force (ITF) in connection with products containing live bacteria. These interactions have entailed the exchange of information as regards the identification of certain legal, regulatory and scientific issues for the development of a medicinal product or border products.

There have also been a number of CHMP scientific advice procedures pertaining to these types of products. The legal basis for the provision of scientific advice is laid down in Article 57(1)(n) of the Agency's founding Regulation (Regulation (EC) No 726/2004).



EMA experience

At present, there are no medicinal products for human use containing live bacteria, which have been authorised under the centralised procedure in accordance with Regulation (EC) No 726/2004. As a result, there are currently no imminent plans for the development of EU guidance covering these products given the limited experience to date (Work plan for the Biologics Working Party (BWP) for 2017).



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Supporting research and innovation of medicines

Pre-authorisation

Innovation task force (H&V)

Paediatric investigation plan (PIP) (H)

Scientific advice (H&V)

Qualification of novel methodologies (H)

Advanced therapy medicinal product classification (H)

Regulatory and administrative assistance for small- and medium-sized enterprises (H&V)

Orphan designation (including protocol assistance, fee reductions, market exclusivity) (H)

Marketing authorisation application evaluation

Post-authorisation (When a medicine is available on the market)





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Conclusions and recommendations

The Applicants are encouraged to proactively seek agreement on technical challenges with the EMA, through the CHMP Scientific advice procedure, and make use of relevant existing platforms for providing advice (e.g. informal ITF Briefing meetings in order to discuss the issues arising from innovative aspects related to the development of a medicinal product).



Thank you for your attention



Further information

Nino.Mihokovic@ema.europa.eu

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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