Mapping regulators' early interactions procedures to support innovation

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Introduction & Aim

Early interactions procedures with regulators are implemented to support innovative medicines development, and the specific challenges they face.

The support comes in the form of services and regulatory procedures allowing medicines' developers to interact with regulators through existing mechanisms during the development of a medicinal product.

The procedures are generally dependent on the type of product developed, and on the status of the stakeholder trying to contact the regulator early. This entails a case-by-case approach to support innovation. The regulators have designed relevant tools to support different types of actors with specific challenges (SMEs, academia, industry). In addition to dedicated services and procedures, guidance developed by regulators as well as regulators' participation in various meetings also aim to support medicines' development, even though these aspects will not be considered here.

Despite limited human resources (EU and national level), Regulators have established new ways to facilitate dialogue between the institutions and the stakeholders where gaps and needs have been identified. The poster showcases the principal mechanisms in place in the European Union (EU) and in the Member States of the EEA regarding both innovative medicines and Advanced Therapy Medicinal Products (ATMPs) specifically. Communicating on the existing support at both levels bridges the knowledge gap on the existing opportunities for early interactions with regulators.

EMA's services and procedures to support innovation medicines' development

Academia/Non-profit! | **SME status holder** | **All types of developers**

What type of medicine am I developing?

ATMPs

Support to meet regulatory requirements on quality, safety & efficacy, possible until the submission of marketing authorisation applications

ATMP Pilot Academic

Innovative medicines

Special incentives To gather robust data on the medicines' benefits and risks, to optimise development plans, and to enable accelerated assessment

PRIority MEdicines (PRIME)

Dedicated advices and procedures (e.g., to comply with legal requirements) & fee reductions

SME Office

ATMPs

Scientific assessment by CAT of quality data and, when available, non-clinical data generated

Certification procedure

Innovative medicines

To gather robust data on the medicines' benefits and risks, to optimise development plans, and to enable accelerated assessment

PRIority Medicines (PRIME)

Advices on various tests and trials necessary to demonstrate quality, safety and efficacy of medicines

Scientific advice

Free of charge meetings with multi-disciplinary group on scientific, regulatory issues

Innovation Task Force briefing meetings

Discussions with experts in quality assessment & GMP inspections

Quality innovation group

ATMPs ?

I need to know if a product is an ATMP and which type within EU legal definitions

Recommendation on classification

Interactions with multiple regulators to support medicines' development

EMA + FDA

Clearer understanding of EMA & FDA respective regulatory requirements & scientific recommendations on product's development

What type of medicine am I developing?

Innovative medicine

Hybrid or complex generic product

Parallel scientific advice

Pilot Parallel advice

EMA + HTA Bodies

Health technology development

Scientific advice from EMA & individual recommendations from HTA bodies on initial evidence generation for MAA/Reimbursement, and Post Licensing Evidence Generation

Parallel EMA/HTA body Scientific Advice for the Interim Period

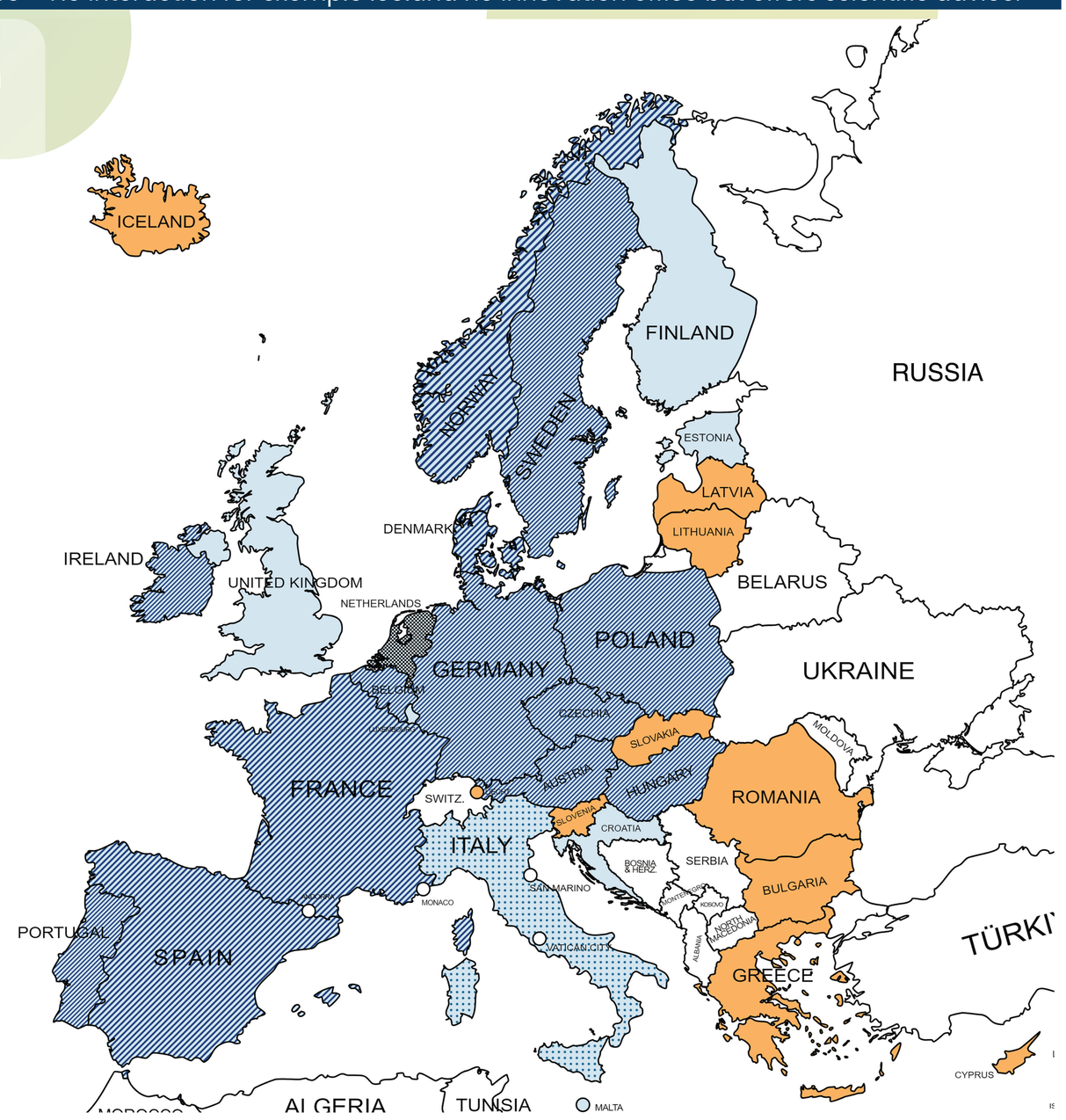
FDA: Food and Drug administration, HTA: Health Technology Assessment bodies, EMA: European Medicines Agency, MAA: Marketing Autorisation Applications, GMP: Good Manufacturing Practices

Interactions with national competent authorities

Medicine developers can contact national competent authorities to interact with one or multiple regulator(s) at national level. List of national competent authorities in the EEA available on EMA's website.
Available Procedures → scientific advice, Simultaneous National Scientific Advice (ex.)
Available Services → Innovation offices (ex.)
Some EEA countries have national competent agencies but no innovation offices and do not offer SNSA.
No innovation office ≠ No interaction for exemple Iceland no innovation office but offers scientific advice.

Innovation offices and participation in Simultaneous National Scientific Advice (SNSA) in EEA countries and the UK

- Countries with innovation offices
- Countries without innovation offices
- Innovation office and leading or participating in SNSA
- Innovation office and observer role in SNSA
- 2 Innovation offices: 1 leading or participating role and 1 observer role in SNSA



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