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SCIENCE MEDICINES HEALTH

Regulatory challenges and priorities for medicines in Europe

XII meeting of the Network of Medicines Competent Authorities of Iberoamerican Countries

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This presentation

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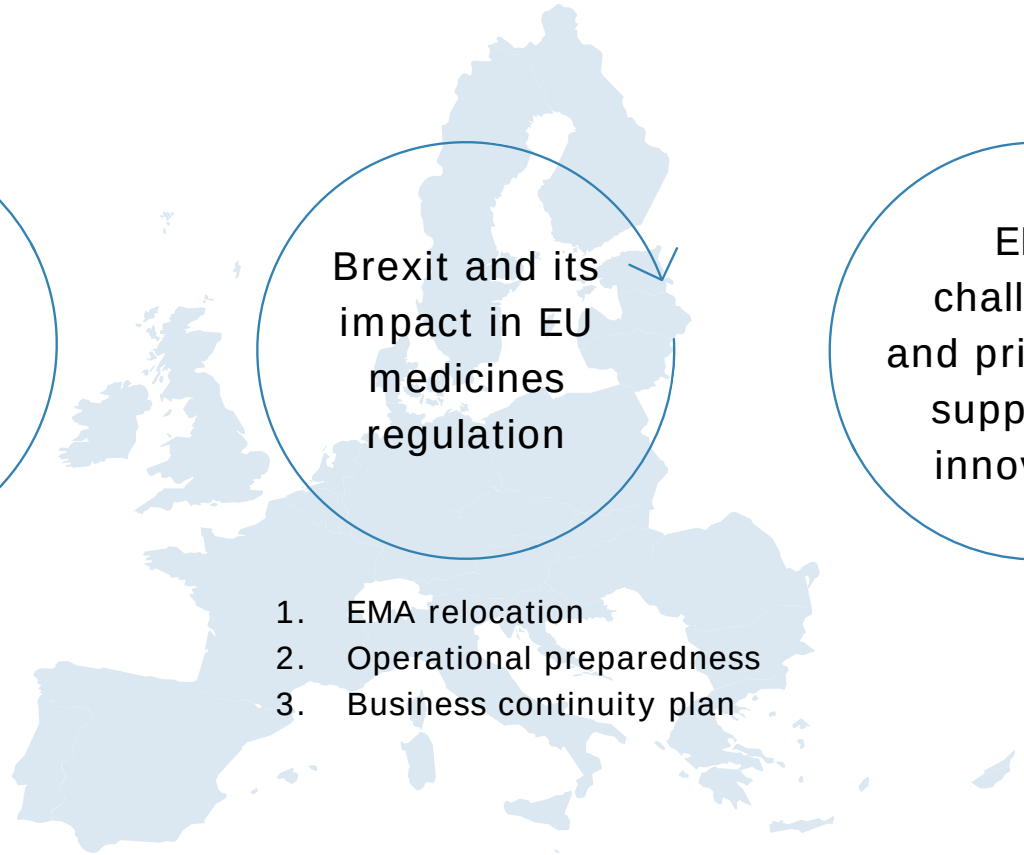
The EU regulatory system

Brexit and its impact in EU medicines regulation

1. EMA relocation
2. Operational preparedness
3. Business continuity plan

EMA challenges and priorities – supporting innovation



The EU regulatory network for medicines

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- ~50 national regulatory authorities
- European Medicines Agency
- European Commission

What do we do?

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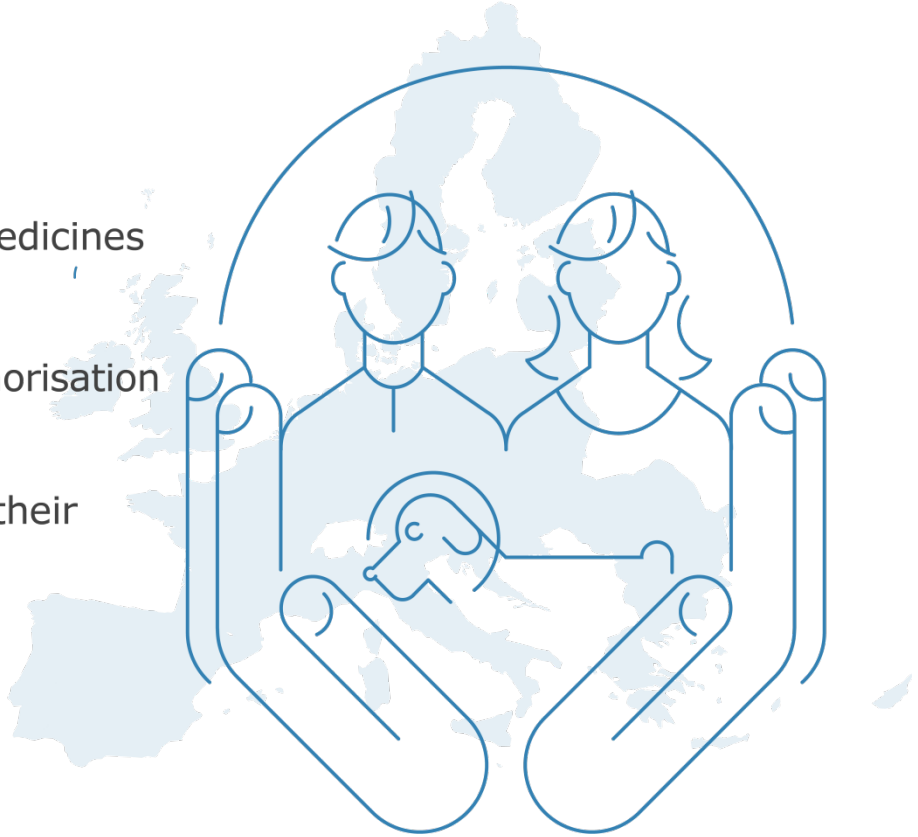
Protect human and animal health

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- Provide reliable information on human and veterinary medicines to patients and healthcare professionals



Authorisation of medicines in the EU

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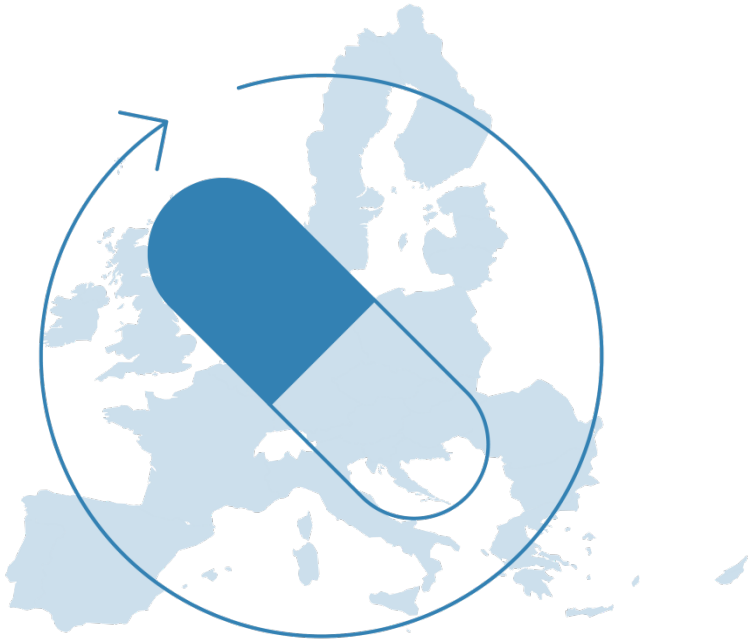
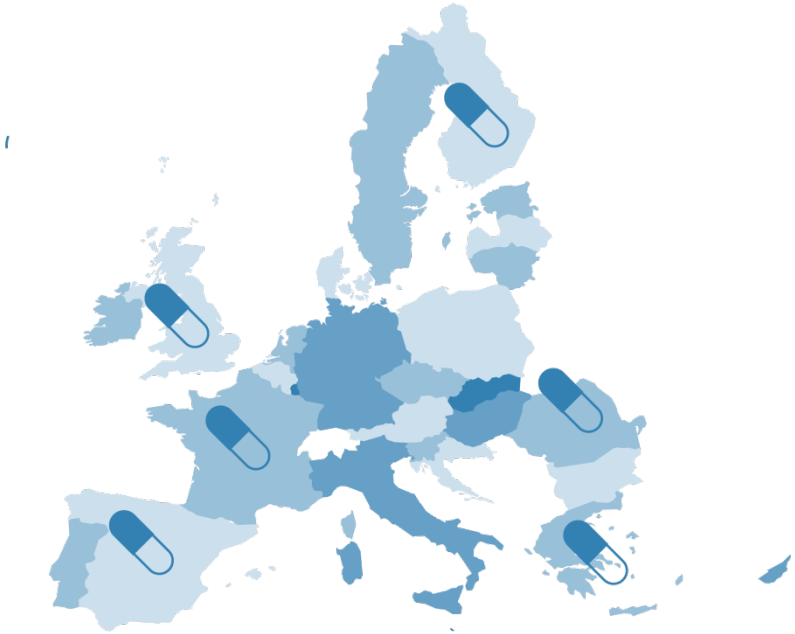
Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via NCAs)

Centralised procedure (via EMA)

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- **Single EU-wide assessment and authorisation valid throughout the EU**
- EMA committee gives a benefit/risk recommendation
- The European Commission grants marketing authorisation

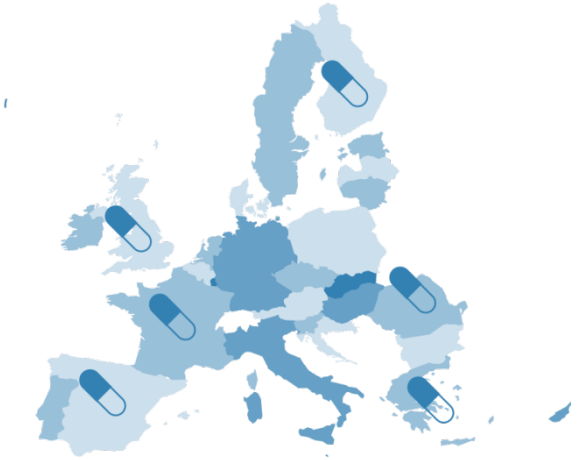
Centralised procedure (via EMA)

The Centralised Procedure is mandatory for most innovative medicines and critical therapeutic areas

EMA enables one application, one assessment, one marketing authorisation for the whole of the EU

National procedures

- **Decentralised procedure**
  - Medicines not yet authorised in the EU and outside the mandatory scope of the centralised procedure
  - Companies can apply to one or more Member States
- **Mutual recognition procedure**
  - First approval followed by recognition of the authorisation in other Member States
- **Purely national procedure**



National procedures (via NCAs)

Concerns mostly generics and medicines with known active substances

Who we are

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~4000 scientific experts from across Europe

7 Scientific Committees

1 Management Board

CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC

28 Member States' representatives

4 Civil society representatives

2 European Commission representatives

2 European Parliament representatives

1995 EMA established

28 working parties

~900 staff members

How is EMA organised?

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Management Board

Executive Director

EMA staff

CHMP **CVMP** **COMP** **HMPC** **PDCO** **CAT** **PRAC**

7 Scientific Committees + 28 Working Parties + 8 Scientific Advisory Groups

National competent authorities
~4000 European experts

EU Institutions

Council of the European Union

European Commission

European Parliament

European experts

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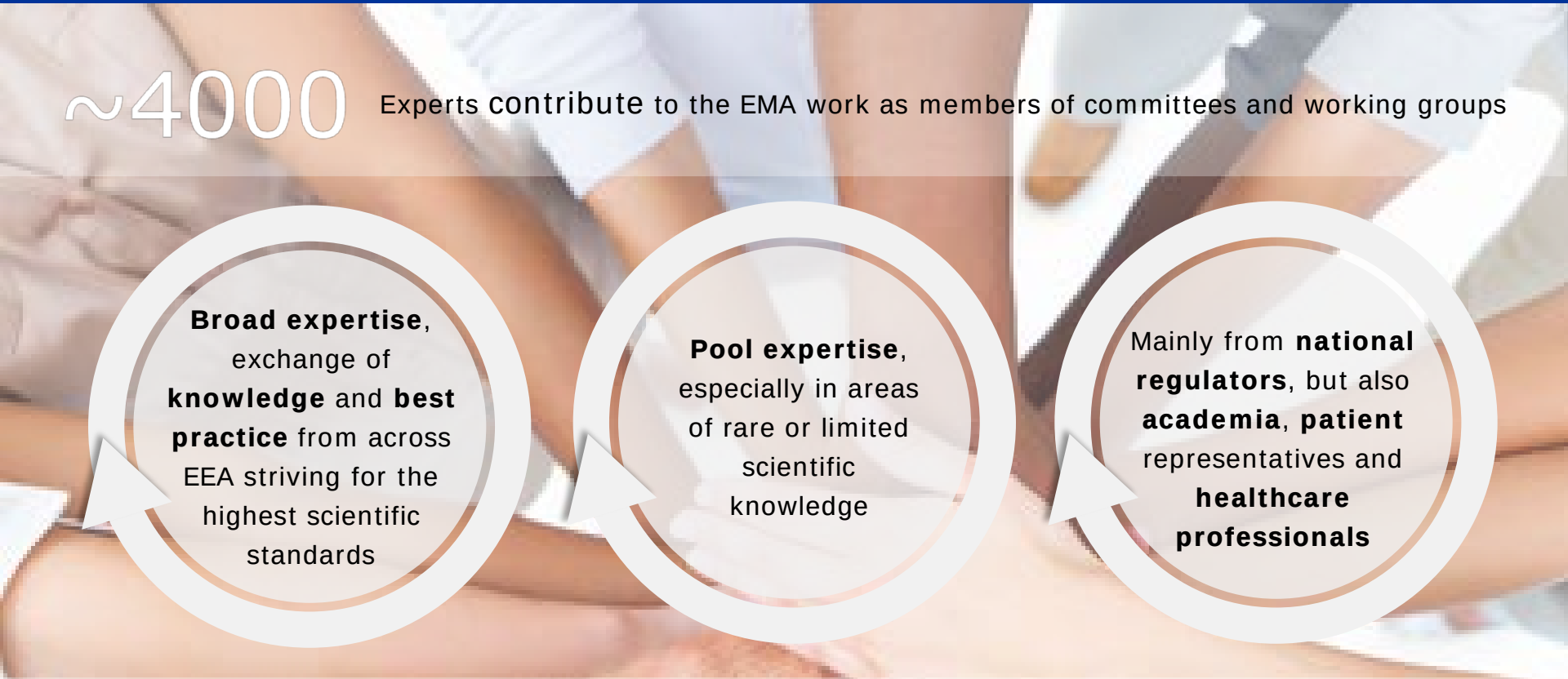


~4000 Experts contribute to the EMA work as members of committees and working groups

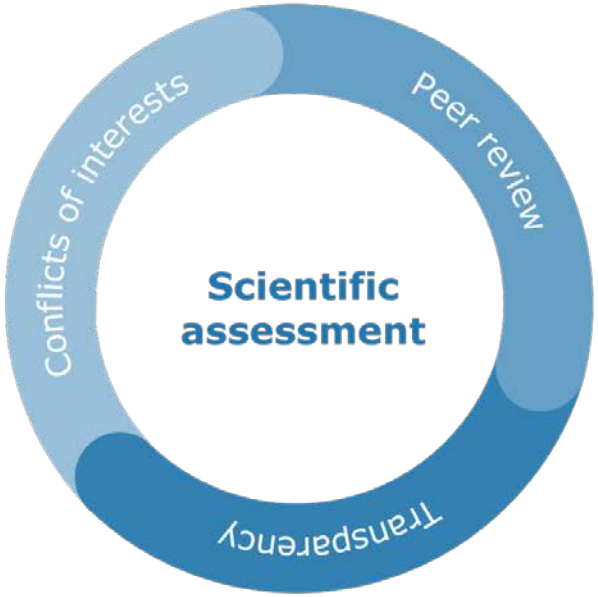
Broad expertise, exchange of **knowledge** and **best practice** from across EEA striving for the highest scientific standards

Pool expertise, especially in areas of rare or limited scientific knowledge

Mainly from **national regulators**, but also **academia**, **patient** representatives and **healthcare professionals**

All experts make annual public declaration of interest and EMA manages competing interests to ensure impartiality and integrity of outcome

A fully transparent system

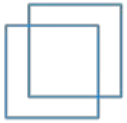


Managing conflicts of interests

EMA's scientific experts, staff and Management Board members must not have any financial or other interests that could affect their impartiality.

Peer review

EMA's assessments are carried out by a rapporteur and a co-rapporteur, and are subject to committee discussions and peer review.



Transparency

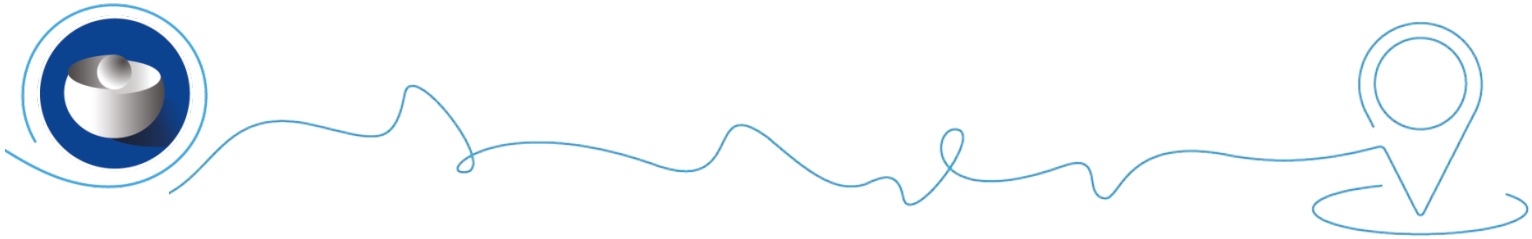
Assessment reports, agendas and minutes, allow public scrutiny of how EMA works and reaches its decisions.

This presentation

Brexit and its impact in EU medicines regulation

1. **EMA relocation**
2. **Operational preparedness**
3. **Business continuity plan**

1. EMA relocation to Amsterdam



Current state-of-play concerning the relocation

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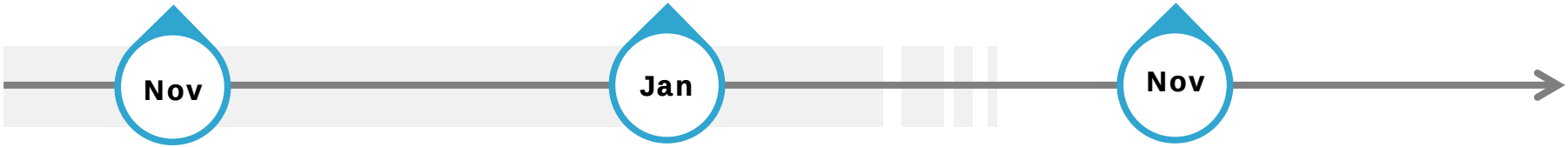
20 November 2017
Selection of Amsterdam as EMA's new host city

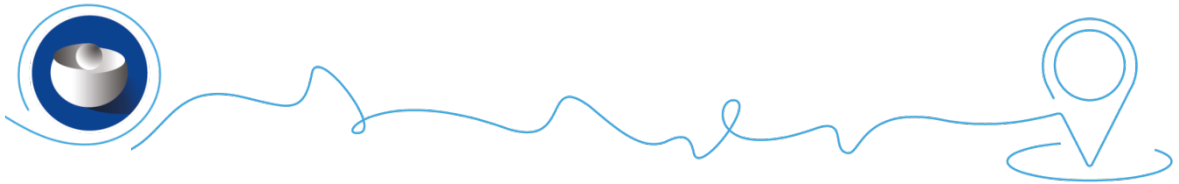
1 January 2019
Interim building ready (AMS – Sloterdijk)

15 November 2019
Permanent building ready (AMS – Zuidas)



Close cooperation with the Dutch authorities on:

- Permanent premises
- Temporary premises
- Staff relocation
- Financial and legal aspects
- External communication



Tracking tool published

(www.ema.europa.eu / About Us / UK's withdrawal from EU / Relocation to Amsterdam)

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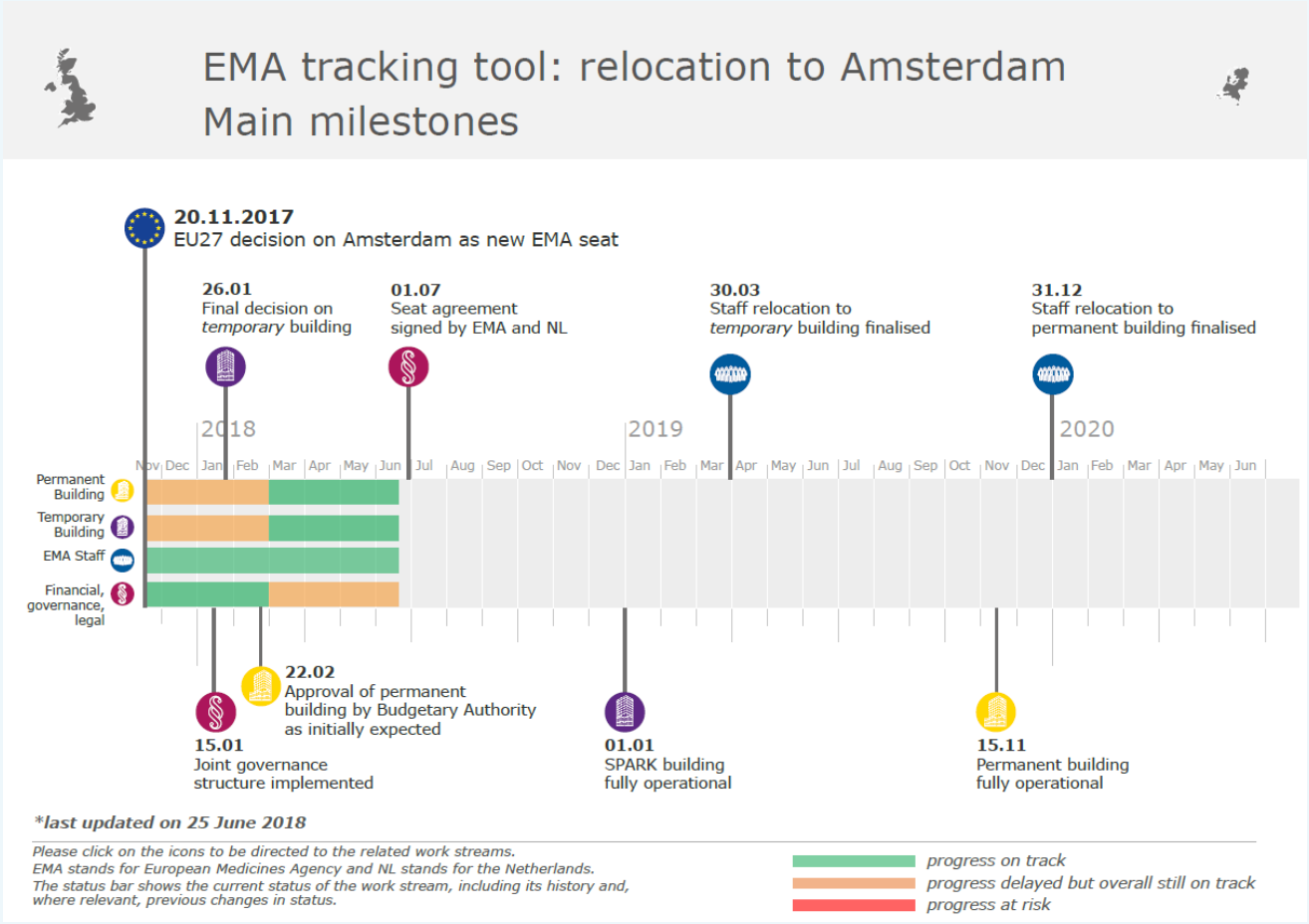
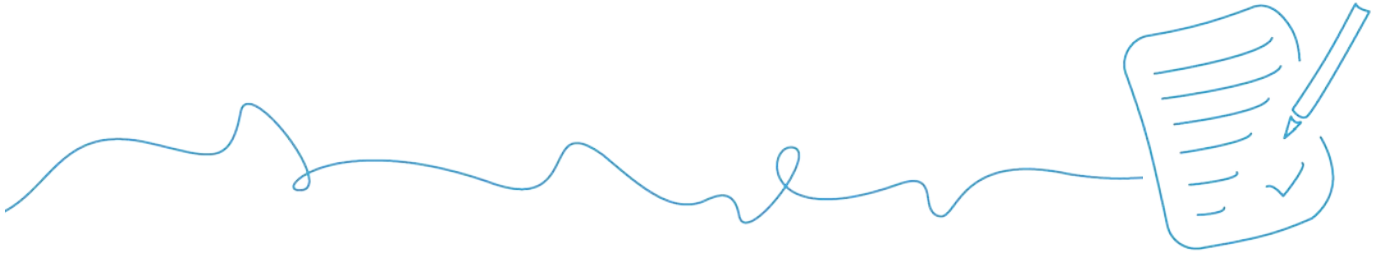


2. Operational preparedness



Scientific committees, procedures and inspections

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- **Involvement of UK** in centralised procedures: ~15%
- April 2017: **EMA starts discussion with EU27** how to redistribute UK workload after Brexit
- **EMA survey** on NCA capacity and willingness to increase involvement in centralised procedures
- April 2018: **EMA published methodology** for redistribution of UK work jointly developed with EU27
- **First phase of redistribution of UK** centralised product portfolio now finalised

Scientific committees, procedures and inspections

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- **Over 370 centrally authorised products** transferred to new EU27 (Co-)Rapporteurs plus Iceland + Norway

- **EMA provides guidance** to pharmaceutical companies (human + veterinary) to prepare for UK withdrawal from EU

  → to ensure that companies are ready and enable undisrupted supply of medicines

- **EMA also surveys** pharmaceutical companies to identify centrally authorised products potentially at risk of supply disruption

3. EMA Business continuity plan

Business continuity plan (BCP)

- 2017: **EMA Brexit preparedness BCP** was developed to prepare for scenario when "business as usual" is no longer possible, because
  - EMA has to ensure that necessary human resources are available to work on EMA Brexit preparedness
  - EMA is no longer in position to compensate staff loss through recruitment

- **Phase 1 of this BCP** was launched on 1 May (for some activities 3 July) 2017 based on prioritisation of activities

- **Phase 2 of BCP** started on 1st January 2018

Business continuity plan (BCP)

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- Activities are **temporarily suspended or scaled back**
- A **stepwise implementation -** activities grouped in **3 categories** as follows:

Category	Activities covered
Category 1 (highest priority) activities	Core scientific activities and supporting IT applications, corporate/communication/other IT activities necessary for EMA's operation, legal obligations put on EMA
Category 2 medium priority) activities	Either strategic activities or other core activities, sub-classified into 2A and 2B
Category 3 (lowest priority) activities	Non-strategic activities such as governance and support activities

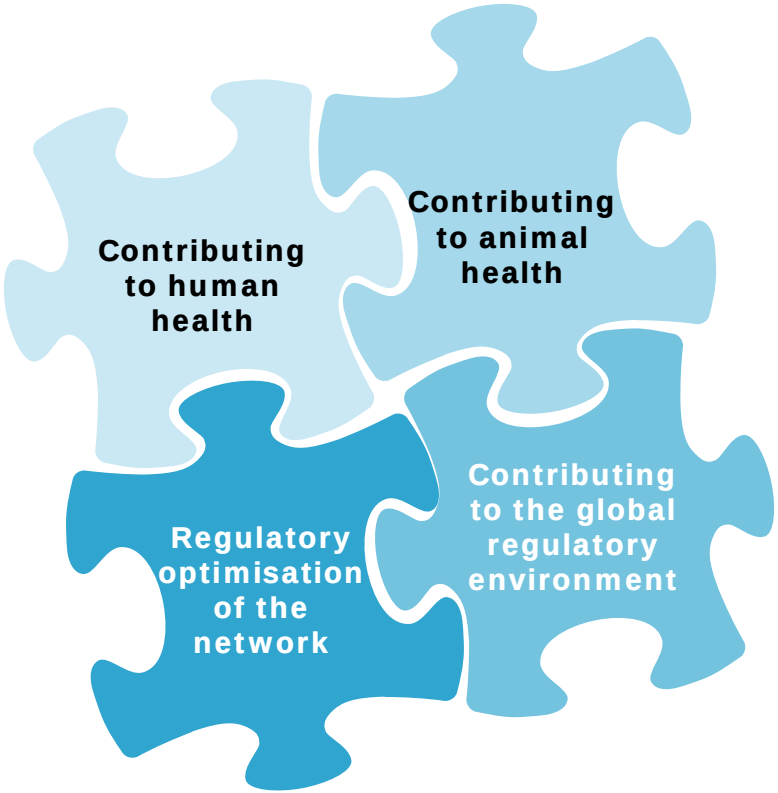
Business continuity plan (BCP) – next phases

- Management Board in June endorsed **next phase of BCP**:
  - **further re-prioritisation** of EMA's activities throughout 2019 to maintain as far as possible the Agency's core activities (evaluation, maintenance and supervision)
  - **1 October 2018** to enable staff to be mobilised to cover critical functions where needed
  - To be monitored on an ongoing basis

This presentation

EMA challenges and priorities – supporting innovation

EU medicines agencies network strategy to 2020



EU medicines agencies network strategy to 2020 built on 4 pillars:

- Human health
- Veterinary medicines
- Operation of the network
- Global regulatory environment

✓ Alignment with EMA multiannual programme

Contributing to human health

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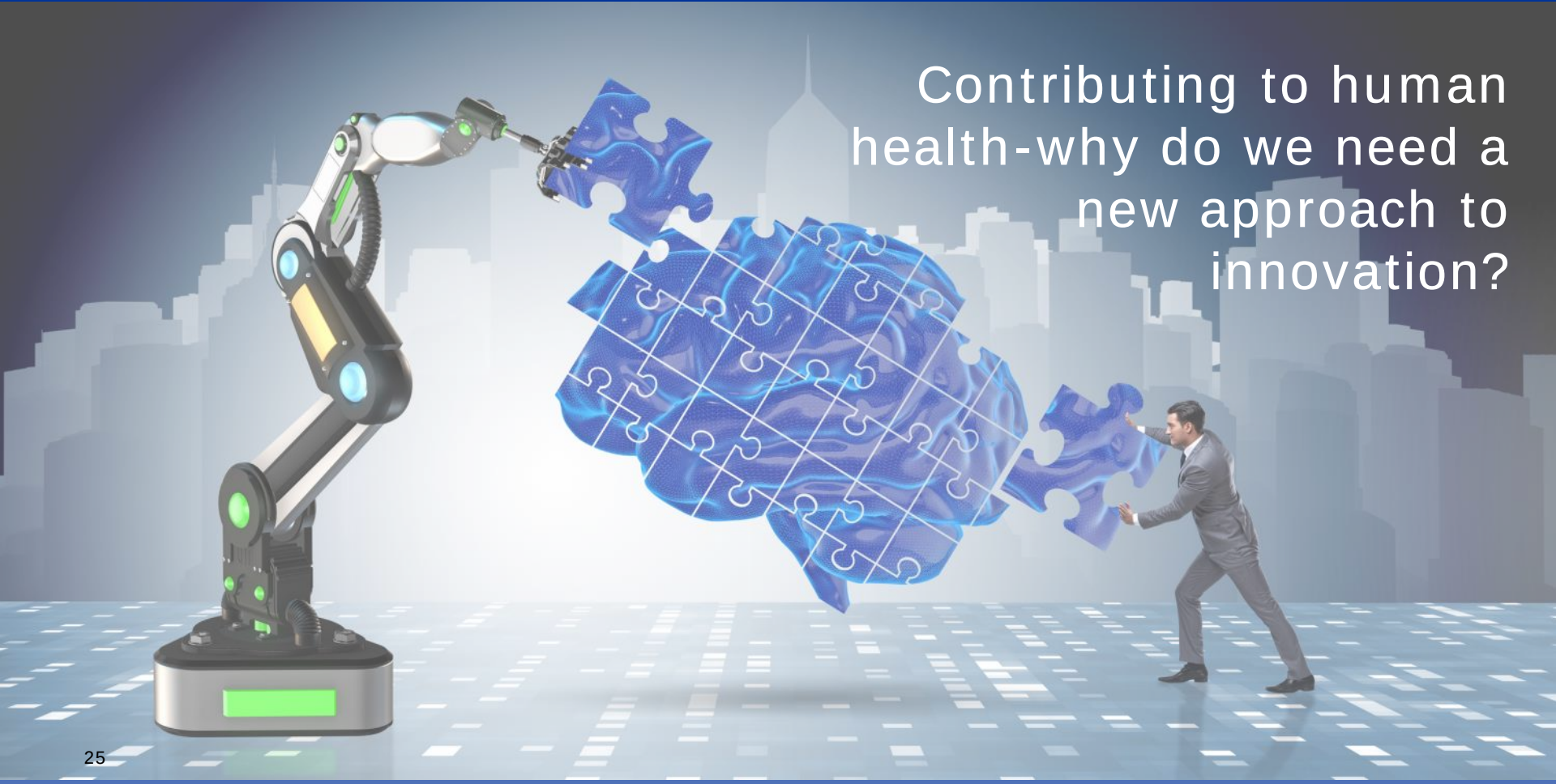
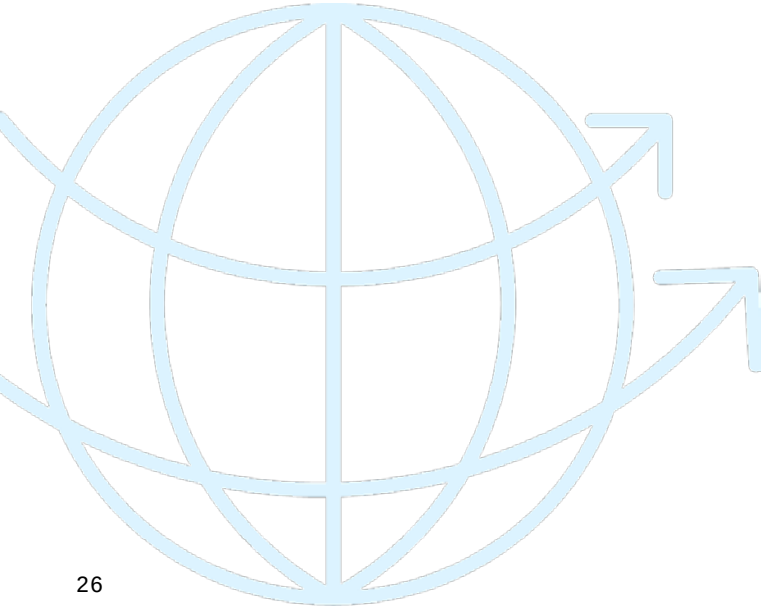
- **Key public health priorities**, including medicines availability and antimicrobial resistance
- **Ensure timely access** to new, beneficial and safe medicines for patients
- **Support patient-focused innovation** and contribute to a vibrant life science sector in Europe
- **Strengthen regulatory** capability and transparency

Contributing to human health-why do we need a new approach to innovation?

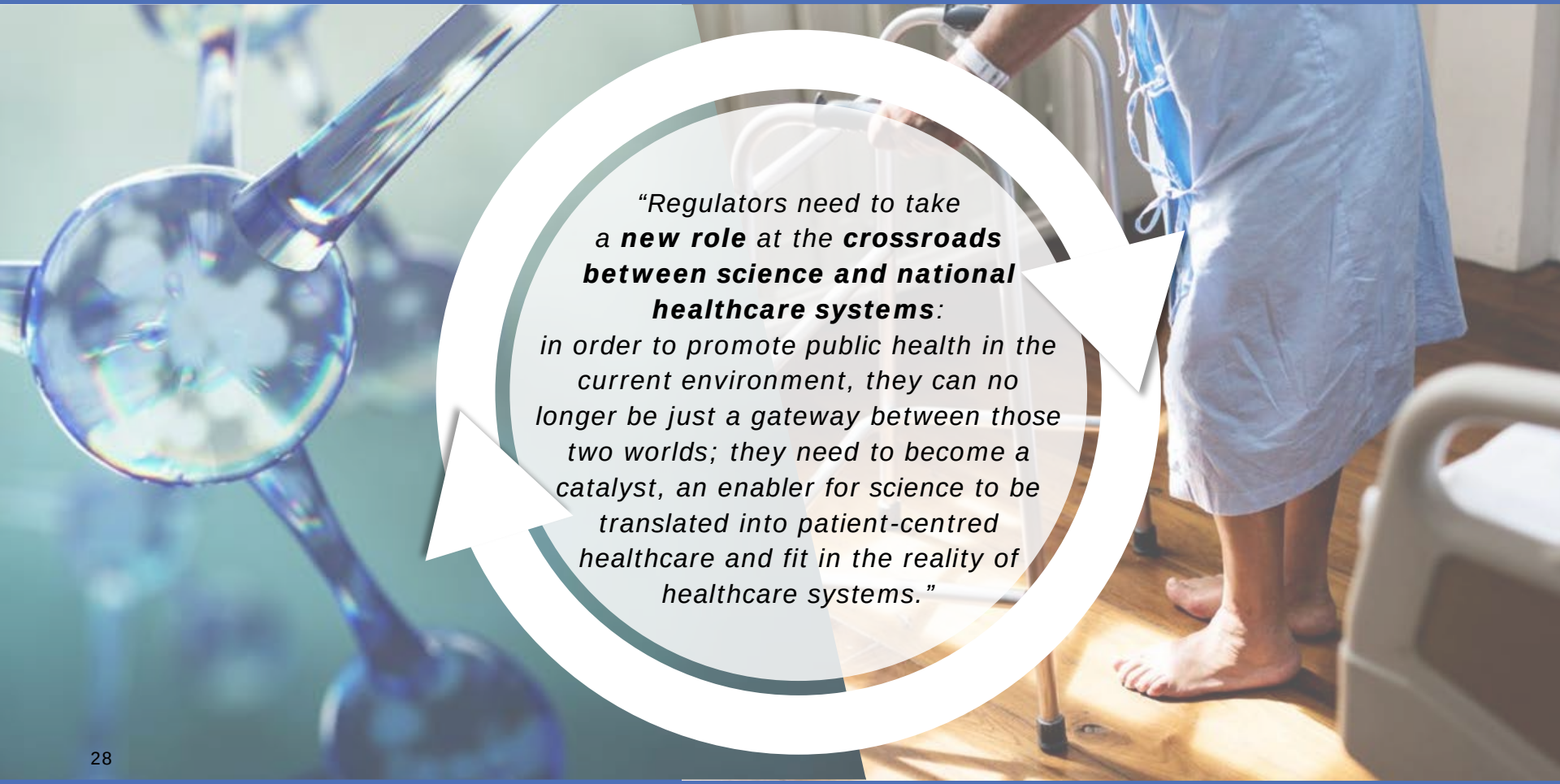


Regulatory Agencies: a changing role?



- From treatment to potential cure
- From treatment to prevention
- From anatomical to molecular (and beyond?) driven diseases taxonomy
- From RCT to **?**CT (RWE, AI)
- From drug prescription to therapy delivery
- From risk/benefit to clinical added value
- From approval to access

New role for regulators



*"Regulators need to take a **new role** at the **crossroads between science and national healthcare systems**: in order to promote public health in the current environment, they can no longer be just a gateway between those two worlds; they need to become a catalyst, an enabler for science to be translated into patient-centred healthcare and fit in the reality of healthcare systems."*

Regulators as **enablers** between science and healthcare systems

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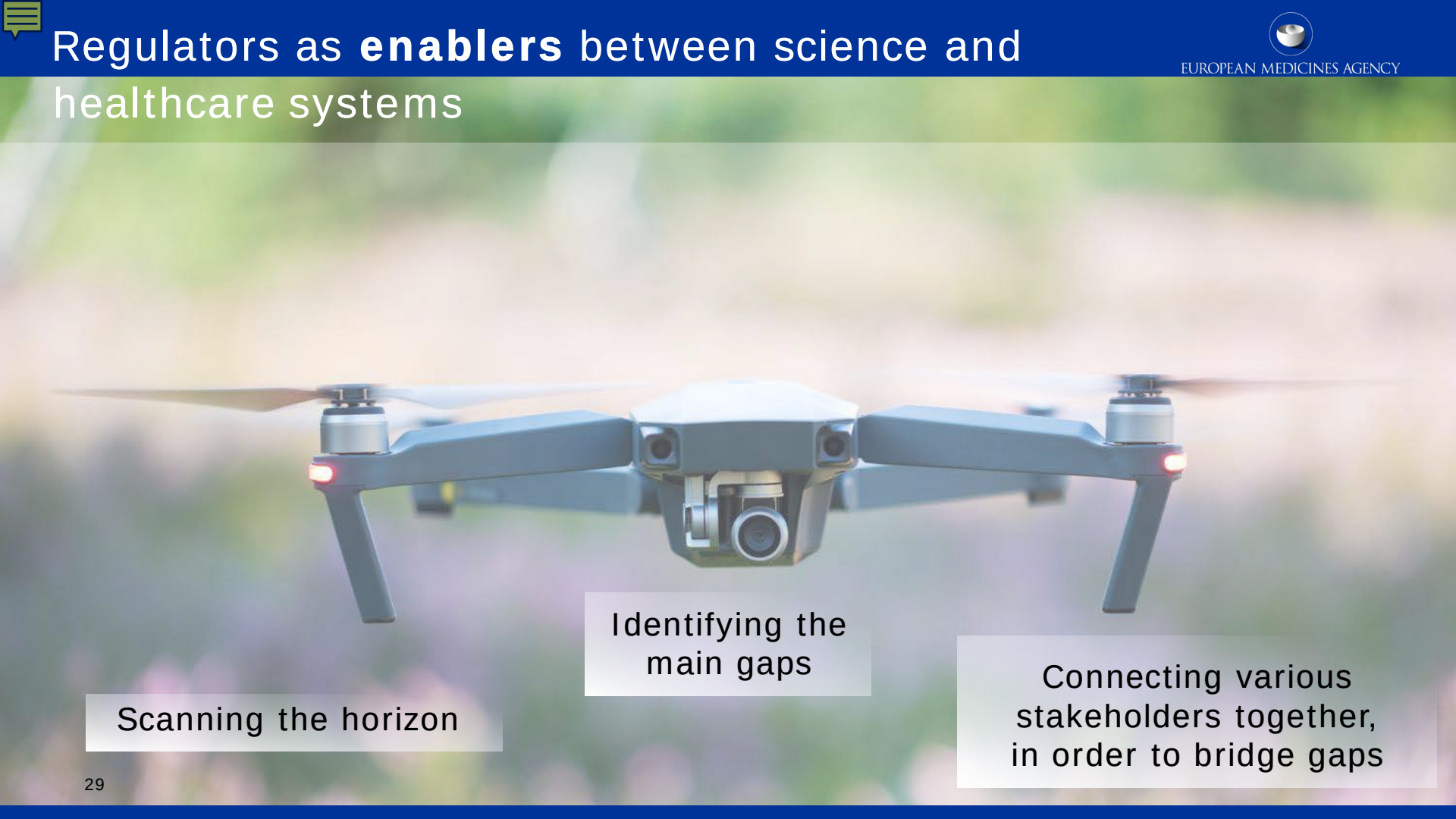

Scanning the horizon

Identifying the main gaps

Connecting various stakeholders together, in order to bridge gaps

‘Evidence by design’

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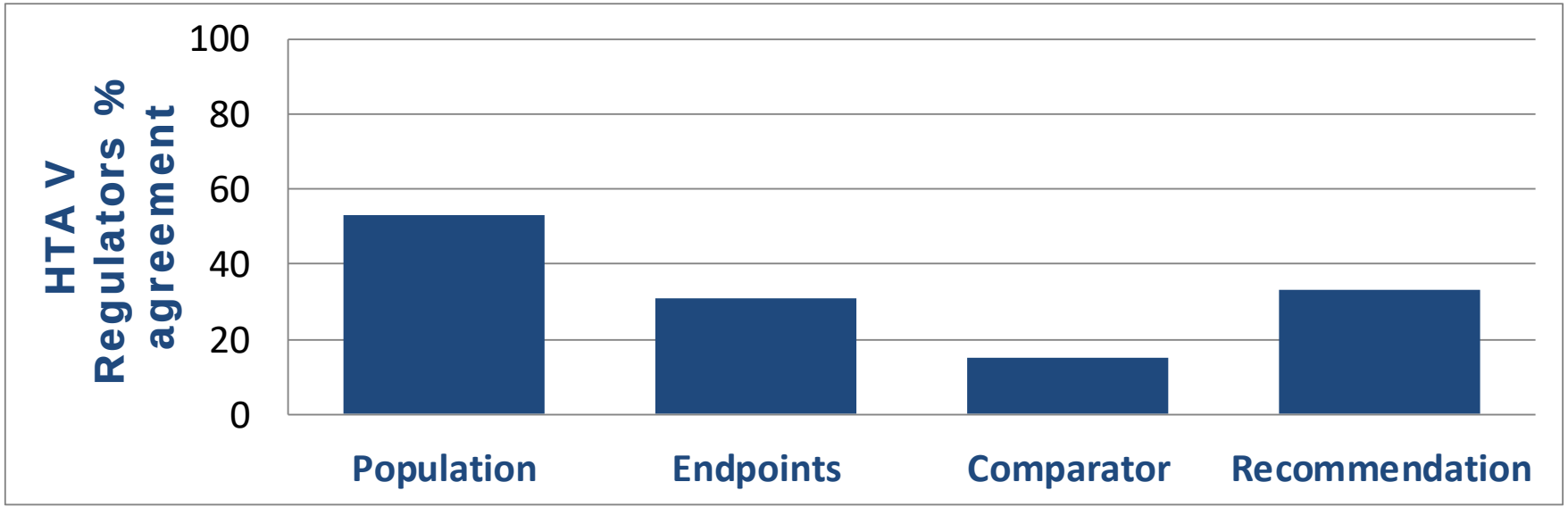
facilitating patient access through data that serves the entire decision-making chain

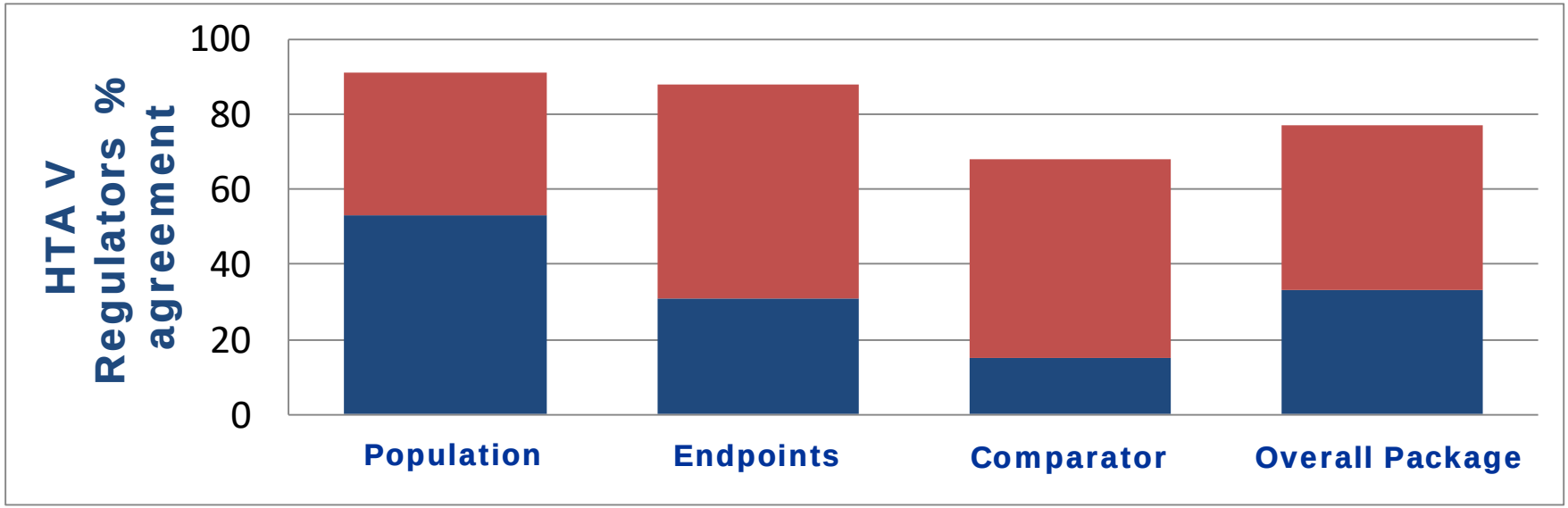
- **Starting point:** Decision makers (regulators, HTAs and payers)
  - answer different questions
  - have different requirements in terms of evidence
- **Aim:** Alignment of the design of the evidence generation plan
  - Planned studies (populations / comparators / design of trial / endpoints)
  - Requirements for post-licensing evidence generation (e.g. registries)

Expectation: Optimised evidence generation plan ➔ Improve access for patients

Can parallel advice help?



Can parallel advice help?



How can players along the technology lifecycle work together to support the introduction of innovative health technologies

- **Collaboration on topic identification and prioritisation** by various players
- **Early flag of innovation** that would benefit from closer engagement across decision makers

e.g. parallel consultation (scientific advice) involving various decision-makers to ensure evidence generation meets different needs

e.g. readiness for subsequent decision making in a timely manner, respecting different remits

e.g. preparedness of patient registries to collect relevant information in a robust manner

Collaboration between decision makers on Horizon Scanning activities can enable better preparedness of the healthcare systems for development and introduction of innovation.

Enhanced engagement with stakeholders

- **Academia – EMA framework of collaboration with academia**
  (to formalise and structure the collaboration between the Agency and Academia in the wider context of the European Regulatory System for Medicines)
- **Clinical investigators** – through learned Society and European associations
- **HTAs/Payers** – Collaboration in the frame of the EMA-EUnetHTA 2017-2020 Work Plan
- **SMEs** – certification of quality and non-clinical data
- **Early access tools are strongly directed to support ATMPs:**
  scientific advice, PRIME, accelerated assessment, conditional marketing authorisation, marketing authorisation under exceptional circumstances; pipeline meetings; innovation task force.
- **Patients** - framework for interaction between EMA and patients and consumers

To **build expertise** to evaluate increasingly complex products, regulators need to **reach out to many stakeholders** and even **interact with new players** outside the health arena.

Contributing to human health – other key priorities

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- **Medicines availability**
  - Europe increasingly confronted with supply challenges and shortages/lack of availability of both new and well-established medicines
  - EMA/HMA Task force established - prevent problems with supply of medicines, improve management and communication
- **Antimicrobial resistance (AMR)**
  - Rational use of antibiotics **-** aiming at making the EU a best practice region on AMR
- **Generics and biosimilars**
  - Which give patients more (affordable) choices – improve accessibility
  - EU at the forefront of biosimilar development

Contributing to the global regulatory environment

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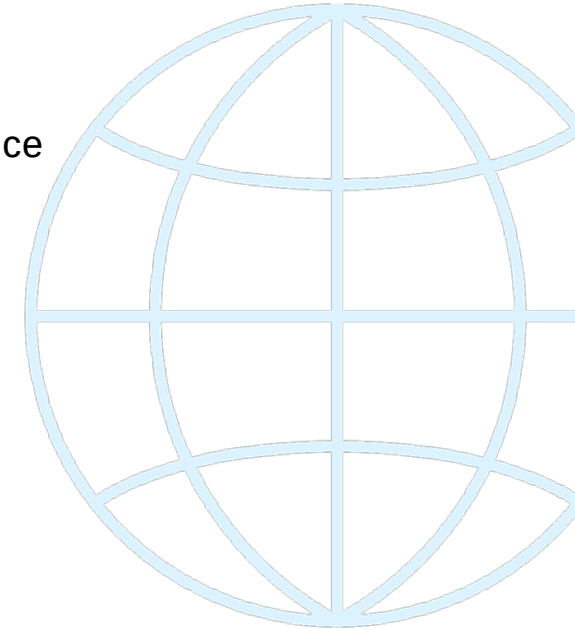
- Assure product supply chain and data integrity
- Convergence of global standards and contribution to international fora
- Ensure best use of resources through promotion of mutual reliance and worksharing
- Support training and capacity building and promote the EU regulatory mode



Closing remarks

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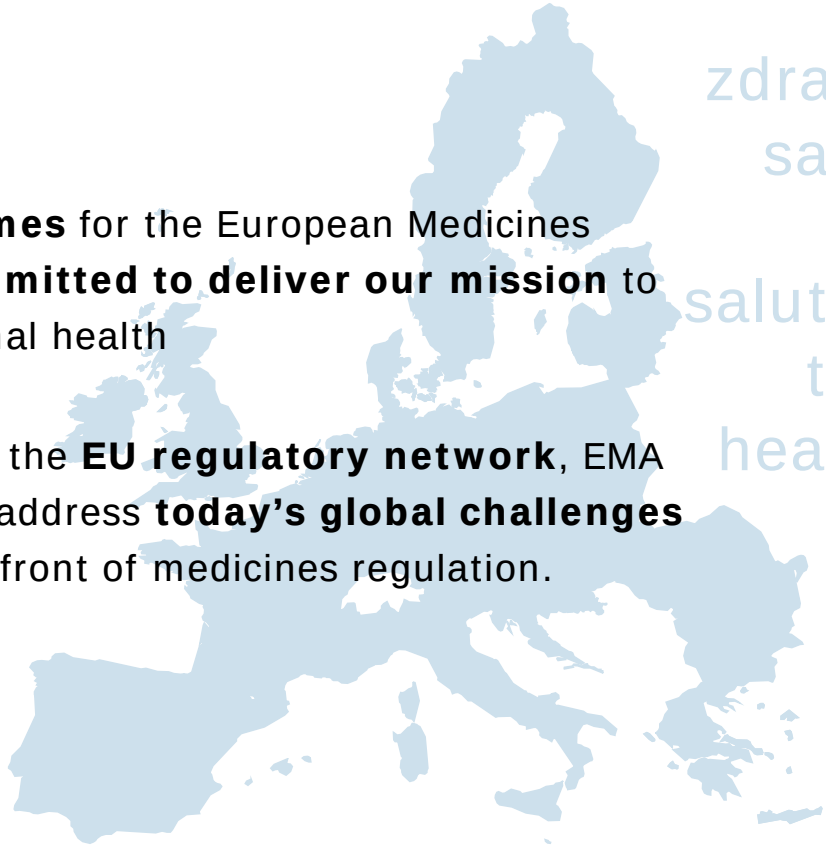
- Despite **challenging times** for the European Medicines Agency, we remain **committed to deliver our mission** to protect human and animal health

- With its NCA partners in the **EU regulatory network**, EMA will continue to work to address **today's global challenges** by remaining at the forefront of medicines regulation.



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Any questions?

Further information

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Safety monitoring of medicines

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- EMA continuously monitors and supervises the safety of medicines that have been authorised in the EU, to ensure that their benefits outweigh their risks
- EMA coordinates the **EU pharmacovigilance system**
- The **Pharmacovigilance Risk Assessment Committee (PRAC)** of EMA is dedicated to the safety of medicines
- EMA operates **EudraVigilance**, an EU web-based information system that collects, manages and helps analysing report of adverse effects of medicines
- **Public hearings** are now a tool available during EU safety reviews of medicines