EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Relocation of EMA, challenges and consequences

21st DGRA Annual Congress

23 May, Bonn, Germany

Presented by Prof Guido Rasi, Executive Director, European Medicines Agency

An agency of the European Union

- EMA relocation to Amsterdam
- Operational preparedness
- Brexit business continuity planning and its consequences
- Glimpse into the future of regulation

EMA relocation to Amsterdam

EMA relocation milestones

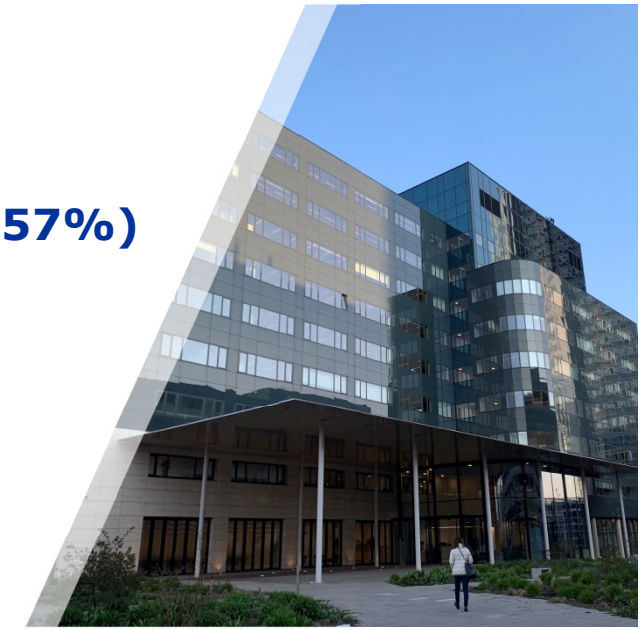





07/2018	01/2019	03/2019	4–8/03/2019	11/03/2019	Q4 2019
Seat Agreement signed by EMA and Dutch authorities	Temporary building in Amsterdam (Spark) handed over by Dutch Authorities to EMA	Last meeting in London	Week of transition/staff teleworking	EMA starts operating from Amsterdam	Expected completion of EMA permanent building in Amsterdam

Staff relocation

- As of 30 April 2019, EMA staff was **791** in total
- **451** were already relocated to the Netherlands **(57%)**
- **312** staff on consecutive teleworking **(39%)**
- **28** staff on long-term leave **(4%)**



Operational preparedness

Operational preparedness

EC and EMA published a **Notice to MAHs** of centrally authorised medicines products for human and veterinary use 2nd May 2017

Unless a ratified withdrawal agreement establishes another date, UK would become a 'third country' from 30 March 2019, 00:00h (CET)

Deadline for the UK's withdrawal was pushed back

Operational preparedness

Update: Extension of the period under 'Article 50'

European Council agreed to a further extension of the **date for the UK's withdrawal** which will last as long as necessary and, in any event, **no longer than 31 October 2019**.

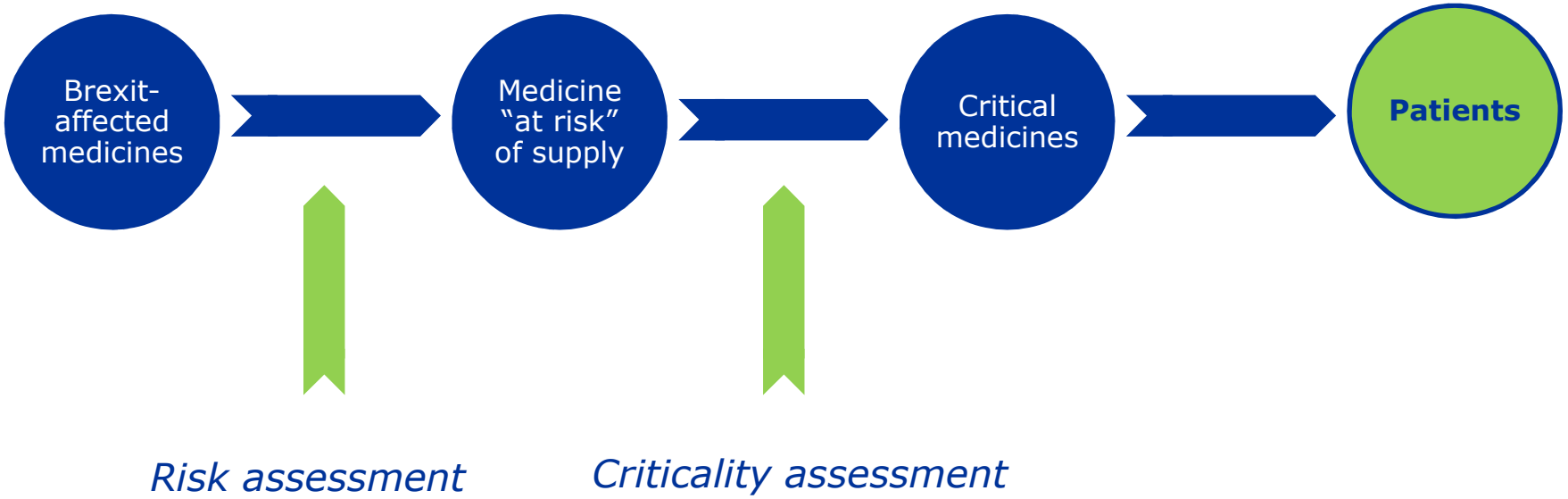
The UK **remains a Member State** for the duration of the extension

EMA is asked to call on all **pharmaceutical companies** in the EU to **continue their preparedness** for the UK's withdrawal

Operational preparedness

- To ensure companies were ready to take the necessary steps to enable undisrupted supply of their medicines in the EU, EMA analysed the potential supply issues for CAPs
- This was complemented by a survey to pharmaceutical companies, follow up meetings with MAHs of medicines at risk of supply, and reminder letters sent to MAHs of Brexit-affected medicines
- A risk matrix was developed to facilitate the risk assessment performed by EMA
- Medicinal products at risk of supply were subject to a criticality assessment.

Operational preparedness



Operational preparedness

Current situation: key figures (1/3)

- The vast majority of companies have carried out the required changes to ensure that their CAPs can remain on the market in the EU post-Brexit

Transfers of marketing authorisations from the UK to the EU

- Of the **400** marketing authorisation transfers that needed to be completed by pharmaceutical companies in time for Brexit, **4** (for human medicines only) are still pending

Operational preparedness

Current situation: key figures (2/3)

Qualified Persons for Pharmacovigilance (QPPVs) / Pharmacovigilance System Master Files (PSMFs):

- QPPVs: required changes made for **236** out of **335** products (99 outstanding*)
- PSMFs: required changes made for **256** out of **376** products (120 outstanding*)

***Total** number of products with QPPVs and/or PSMFs in UK that still require changes to be made = 124

Operational preparedness

Current situation: key figures (3/3)

Batch release sites:

Required changes made for **93** out of **119** products

Quality control exemptions:

MAHs that are unable to transfer sites from the UK to the EU27 by Brexit date may be permitted, for a limited period of time, to rely on quality control testing performed in the UK under certain conditions.

The vast majority of requests for delay have been granted.

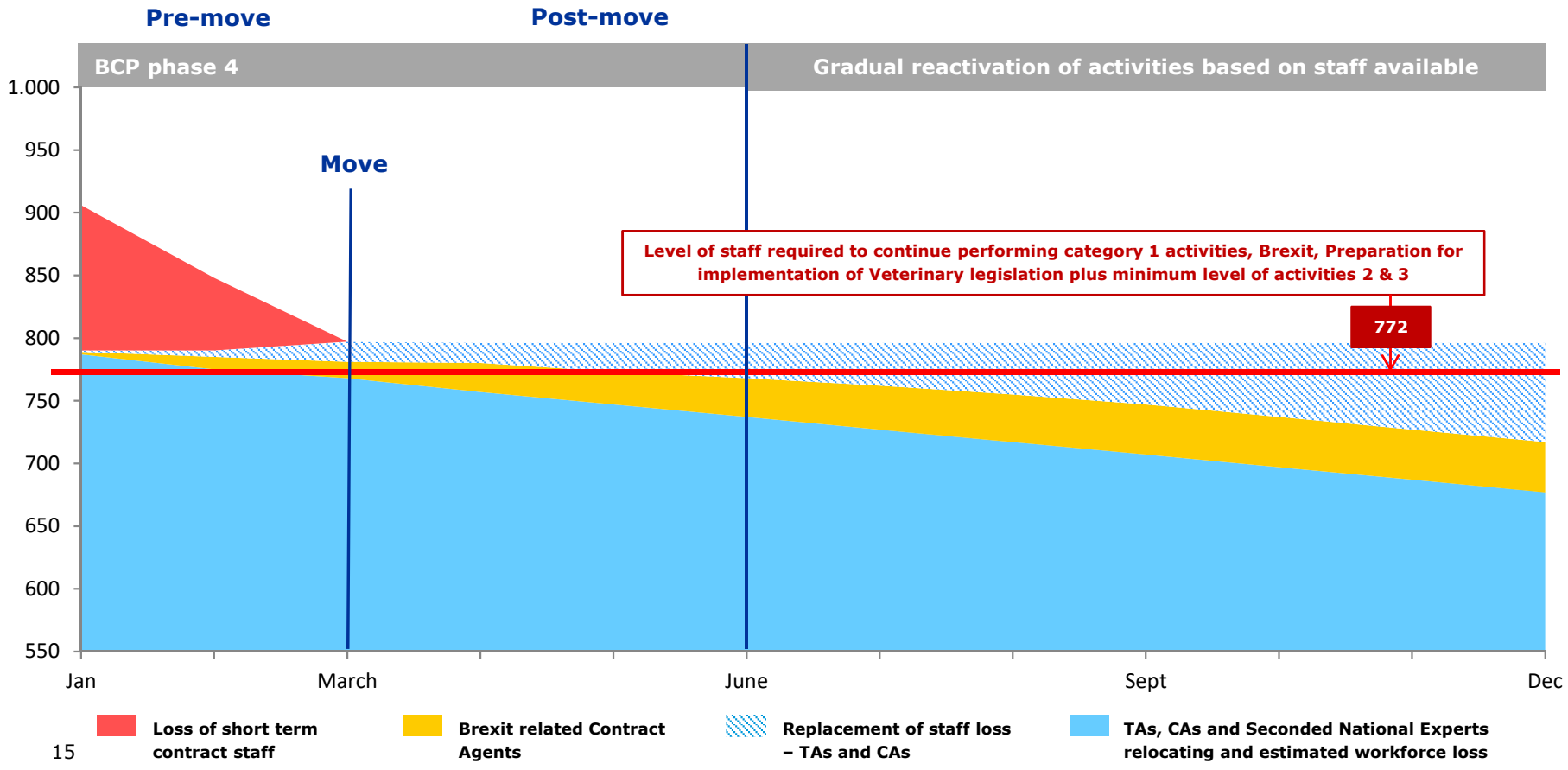
EMA business continuity planning and its impact

EMA Business Continuity - Phase 4

To ensure **continuation** of its **main activities**

To cope with the **anticipated staff loss of 25% of its total workforce**

Gradual reactivation of activities will be discussed at the June 2019 Management Board Meeting


Pre-move
Post-move
BCP phase 4
Gradual reactivation of activities based on staff available
1.000
950
900
850
800
750
700
650
600
550
Move
Level of staff required to continue performing category 1 activities, Brexit, Preparation for implementation of Veterinary legislation plus minimum level of activities 2 & 3
772
Jan
March
June
Sept
Dec
Loss of short term contract staff
Brexit related Contract Agents
Replacement of staff loss – TAs and CAs
TAs, CAs and Seconded National Experts relocating and estimated workforce loss

Impact of BCP on EMA activities

- **Guidelines**: Work on a total of **119 guidelines** for human medicine and **24 guidelines** for veterinary medicine had to be put on hold
- **Transparency**: suspension of landmark policy on proactive publication of clinical data
- **Information systems**: delay in much needed upgrades to our existing IT infrastructure
- **Trainings**: were cut back, but are key to making the Agency and the network fit for the future
- **International collaboration**: was scaled back.

2019: Year of transition

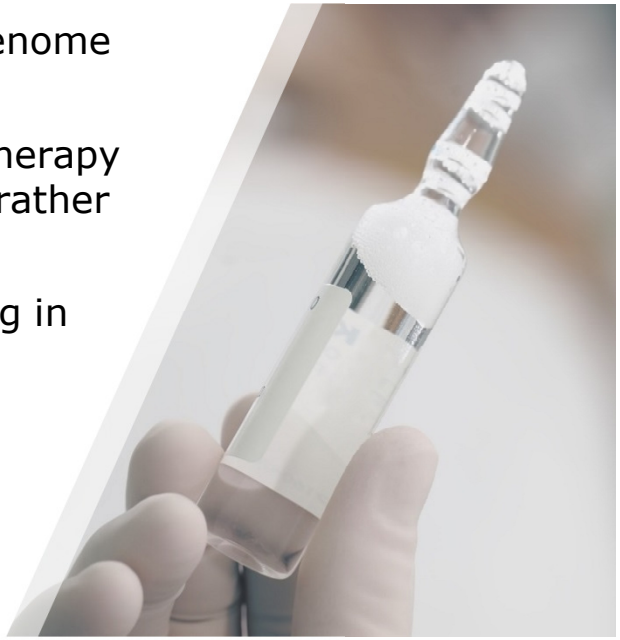
- 2019 *de facto* will be divided into two parts:
  - January-June: EMA has to
    - Address an important staff loss
    - Cope with the consequences of the physical relocation to Amsterdam
    - Cope with an important workload increase as a direct result of the Brexit arrangements
  - July-December: EMA will
    - Gradually take-up previously suspended/reduced activities
    - Prepare for the future (2020-2025 strategy), with particular emphasis on
      - Regulatory Science Strategy
      - Corporate ICT Strategy

Future of regulation

Macro environment of the Agency - ATMP and digitalisation

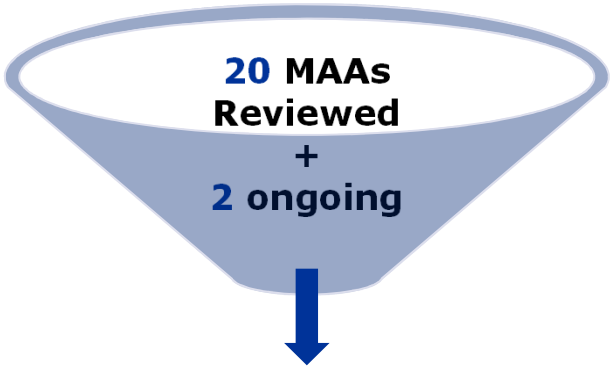
Trends from the global medicinal regulatory environment

- Increasing momentum from all gene and cell therapy, genome editing
- Accelerated development and deployment of advanced therapy medicinal products (ATMPs); need to treat as processes rather than medicines for value assessment
- Mechanisms that support private-public consortia working in pre-competitive space
- Wide spectrum of potential uses of Real World Data and Real World Evidence in clinical studies
- Data sharing in the cloud, analysed and shared with sponsors and regulators



10 years of EU marketing authorisation for ATMPs

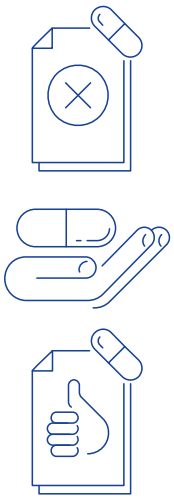
Over 500 clinical trials using ATMPs in EU



14 positive opinions

MAA = Marketing authorisation application

Status March 2019



4	Withdrawn/non renewed (commercial reasons)
9	Licensed
1	Positive opinion (pending EC decision)

Innovative medicines – challenges for regulators

- Novel technologies: e.g. genome editing
- Innovative manufacturing approaches: point-of-care manufacturing, release and control
- Borderline products: contribution of each component to clinical benefit-risk
- Data requirements: small patient populations / comparators / registries
- Evidence generation: approval / post-marketing / market access

An evolving role for medicines regulatory agencies

To progress from R&D to patient access

Protecting patients and **enabling innovation**

Gatekeeper

Fostering scientific excellence in the **evaluation and supervision** of medicines

Enabler

Supporting research and innovation to stimulate the development of better medicines

Connecting stakeholders together to bridge gaps

What are regulators doing to enable innovation?

- Providing **regulatory guidance and support** to medicines developers / academia / healthcare professionals / investors
- Providing a **supportive scientific environment** and **standards**:

  - ✓ Adapt evidence standards to specific products and feasibility of studies
  - ✓ Contribute to the **progress of regulatory s**cience
  - ✓ **Qualification** of scientific **methods**
  - ✓ Collaborate with **HTAs** to define **data requirements for market access**

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EMA Regulatory Science to 2025

#RegScience2025

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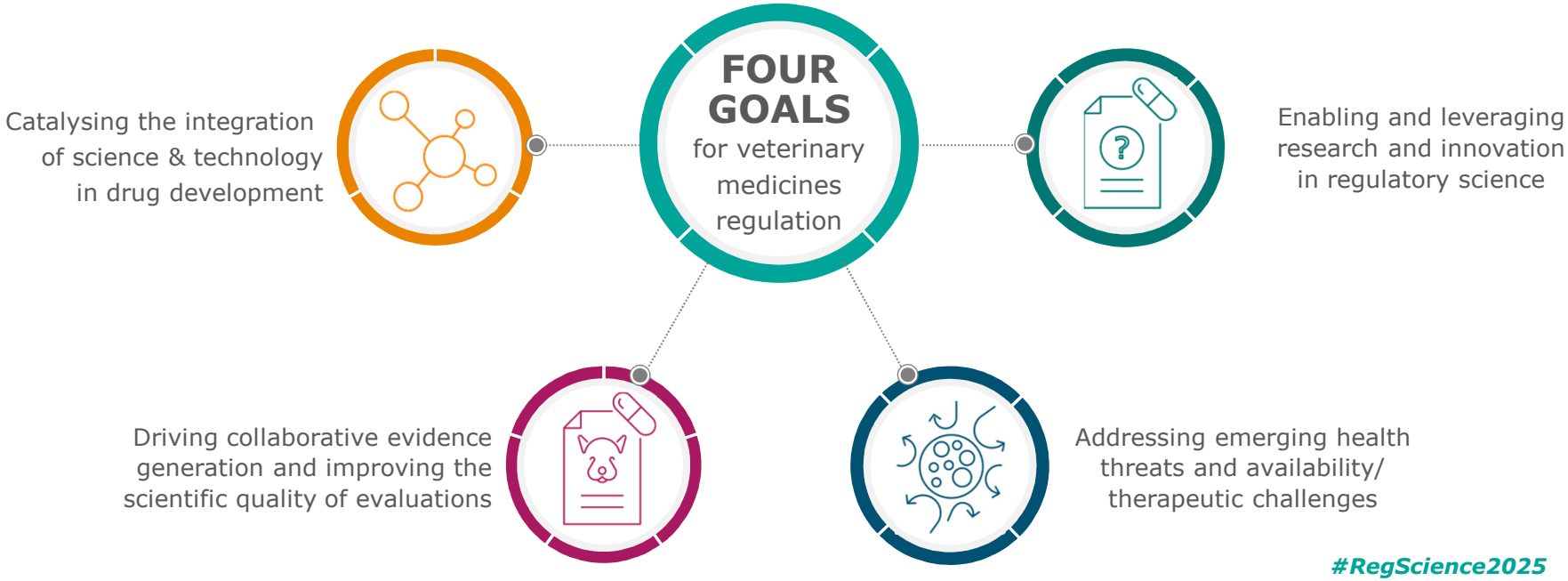
EMA Regulatory Science to 2025



#RegScience2025

EMA's Regulatory Science Strategy

To build a **adaptive** regulatory system
that will encourage innovation in human and veterinary medicines

- Enable the full potential of the EU network
- Guidance on modernised medicines developments
- Facilitate the optimisation of regulatory science
- Assess benefits and risks of innovative therapies and diagnostics based on new technologies

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Consultation to June 2019

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Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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