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Realignment of the EU-network: Perspectives from the Management Board and NCA

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DI Dr. Christa Wirthumer-Hoche

Vienna, Austria

Geschäftsfeldleitung – AGES Medizinmarktaufsicht

The EU-network

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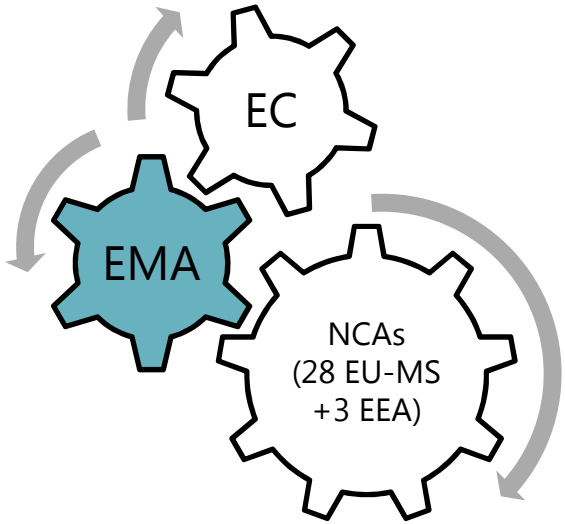

Network of all national medicines regulatory authorities (NCAs) - human and veterinary, EU-MSs and EEA, united in the Heads of Medicines Agencies (HMA)

EU-Network

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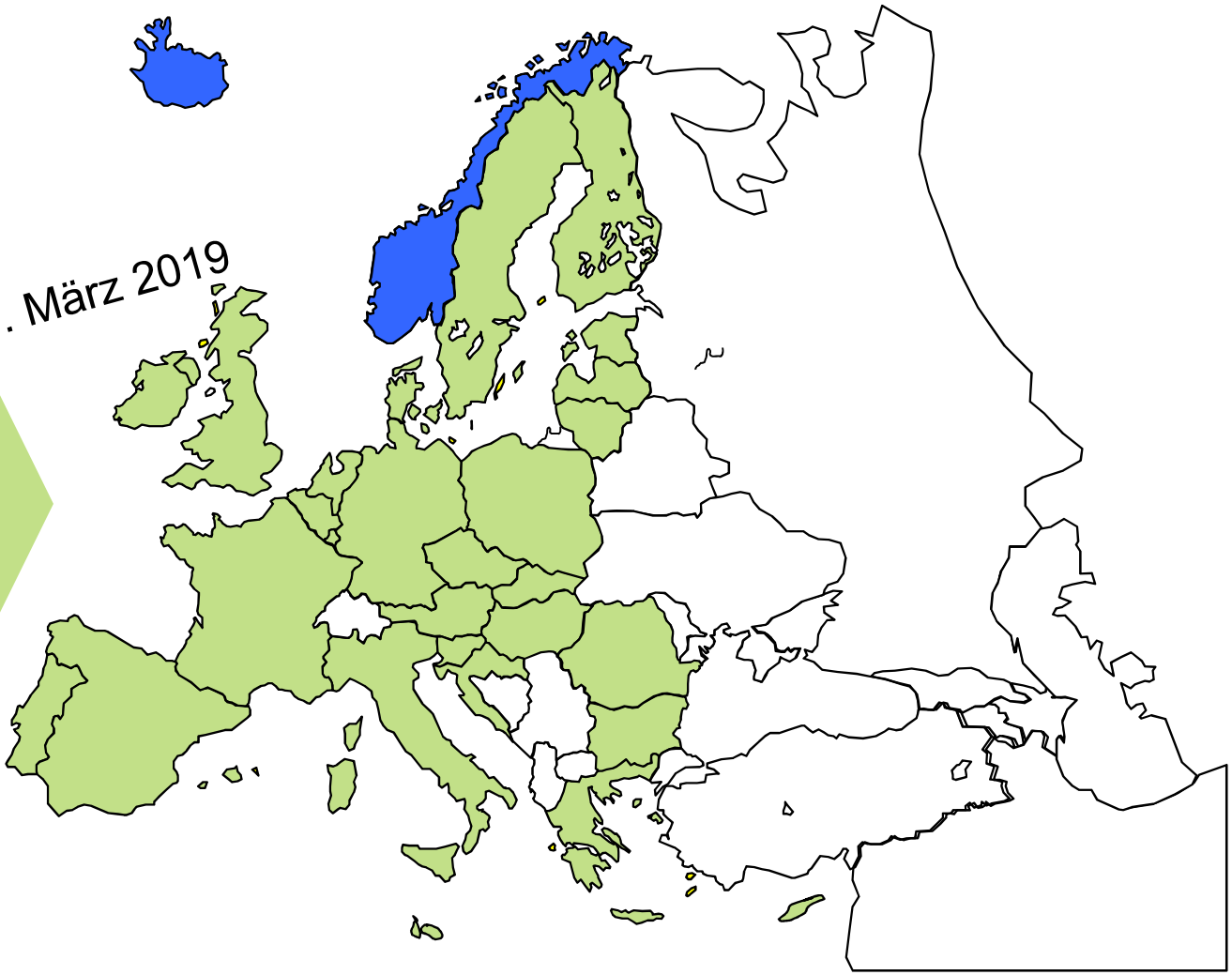
EU / EEA
"United in Diversity"

Political Union of 28 States

UK – Brexit
Deadline: 29. März 2019

508 Mio inhabitants

24 official languages



Brexit – basic assumptions

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- 23 June 2016 Brexit referendum
- 29 March 2017 – Art 50 letter
- United Kingdom will leave European Union on 29 March 2019, thereby becoming a 'third country'
- Little time left: only less than 10 months left to get prepared
- Outcomes of UK-EU27 negotiations still unclear
- Preparing for third country scenario is only option to guarantee regulatory continuity

Brexit –
EU-UK transition agreement

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- 19 March 2018: provisional transition agreement reached between EU27 and UK
- Agreement runs from 29 March 2019 until 31 December 2020
- Article 123, paragraph 6 crucial for medicines regulation:
  "During the transition period, the United Kingdom shall not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union or of Member States acting jointly (…)."
- **Transition agreement EU-UK does not change scenario for medicines regulation after 29 March 2019**

Regulatory activities

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- Brexit-response in EU medicines regulatory network
  - **EMA Working Groups on Committees Operational Preparedness** (centralised procedures) – human and vet.
    - Mandate from the EMA-MB
  - **HMA Brexit Task Force** (BTF) (decentralised procedures – MRP/DCP) – human and vet.
    - Mandate from the HMA

2 mapping exercises

in order to be able to plan resource management in view of the workload which will need to be (re)-distributed

Brexit - centralised procedures

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- EMA working groups on Committees Operational Preparedness (hum + vet) have worked out an approach for (re)distribution of new and existing procedures
  - 30 April – new (Co)-Rapp communicated to MAHs
  - Knowledge transfer package to new Rapp/Co-Rapp
- New (Co)-Rapp will only take full responsibility for the re-allocated medicinal products as of 30 March 2019.
- EMA has almost finished all preparations necessary at this time
- UK expertise will be missed

Brexit – decentralised procedures (1)

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- No centralised approach possible for MRP/DCP
- MAHs in drivers seat
- Large number of procedures/products involved (new and existing), redistribution of existing products is still pending (3216 procedures =6037 products, 31/01/2018).
- UK procedures having only one CMS - 29,1%
  - "Automatic switch of procedures" – under discussion
- CMDh and CMDv have a crucial coordination role

Brexit – decentralised procedures (2)

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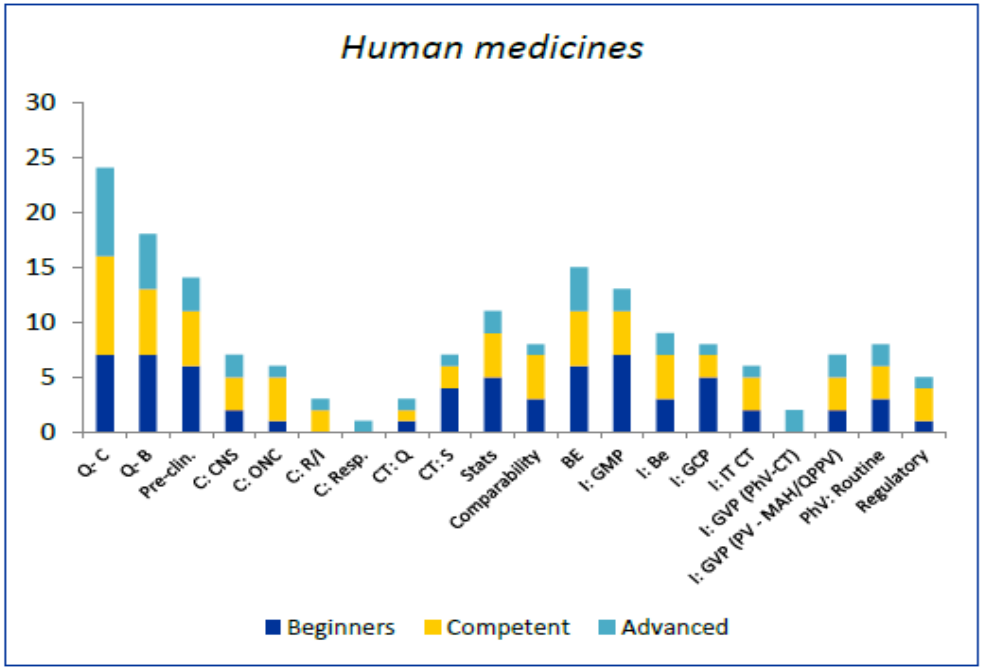
- EC has clarified that MAA still ongoing on March ´19 with UK as RMS will have to be resubmitted with a different RMS after this date
- Ressources: HMA consultation of the 2nd HMA-EMA survey about DCP/MRP capacity and training needs
  - Training needs



RMS Switches initiated from UK since March 2017 (Total: 214; CTS 13/04/2018)

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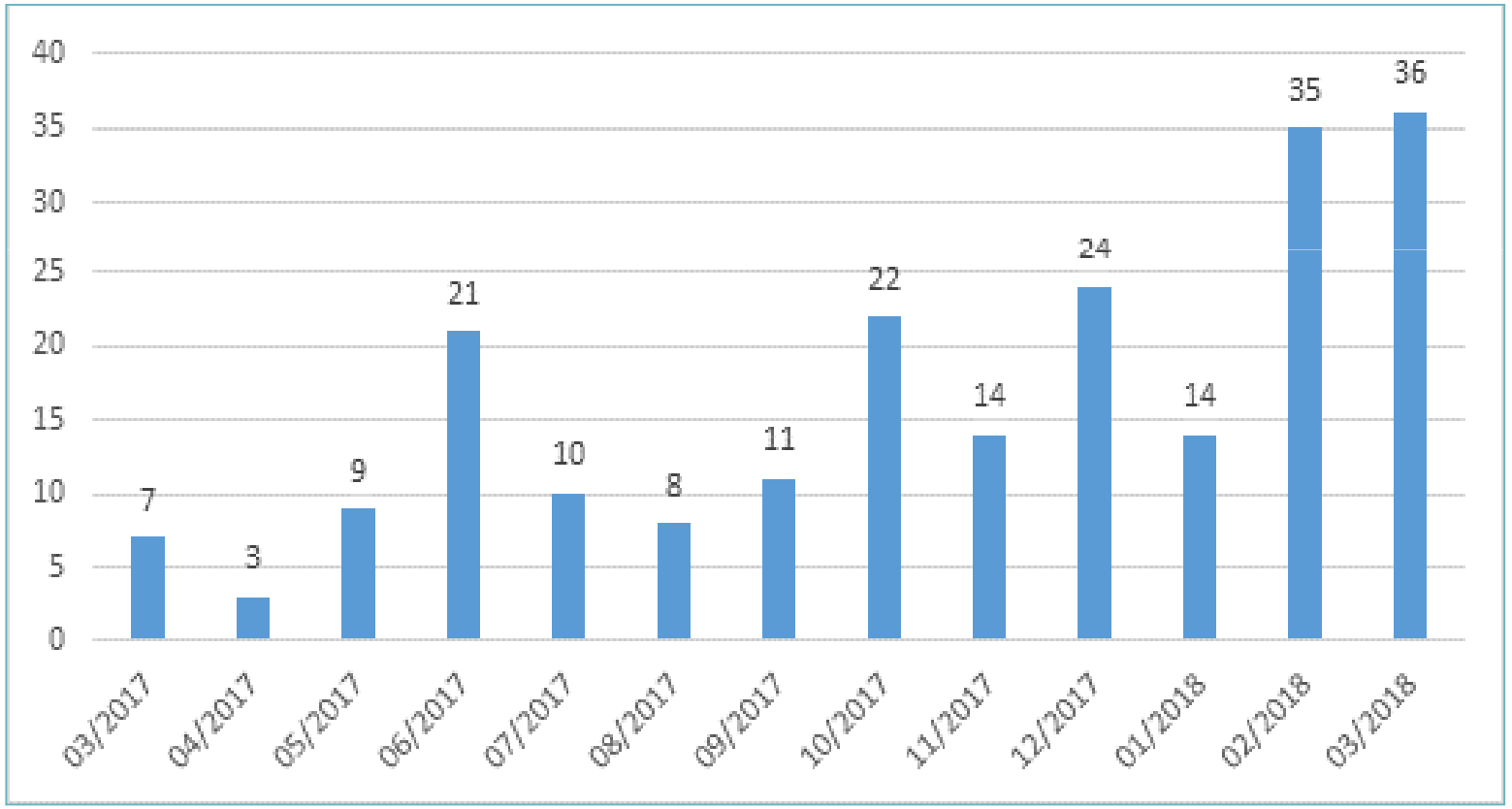

Brexit – what else has to be considered?

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- 29 March 2019: EU legislation governing medicinal products ceases to apply to the UK
- EU law: MAHs must be established in the EU or EEA
- This includes key activities and personnel:
  - Batch release
  - Quality Control (QC)
  - Qualified Person (QP)
  - Qualified Person Responsible for Pharmacovigilance (QPPV)
  - Pharmacovigilance System Master File (PSMF)
  - Clinical trial sponsor or representative of clinical trials

Overview of challenges in the system

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- Assessments of the dossiers are performed by experts in the 28 (+3) EU-MSs, after 29.3.2019 - 27 (+3) MSs
- EMA
  - 7 Committees (election of new chairs)
  - ~ 4.000 scientific experts from across EU
  - Working Parties
  - Scientific Advisory Groups
  - Scientific Advice Working Parties

➢ Current architecture - optimal to assure the **capacity** to deal with **workload** and the availability of **best scientific expertise**

➢ The same resources at NCAs underpin all activities!

EU Medicines Agencies Network Strategy 2020

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HMA Heads of Medicines Agencies

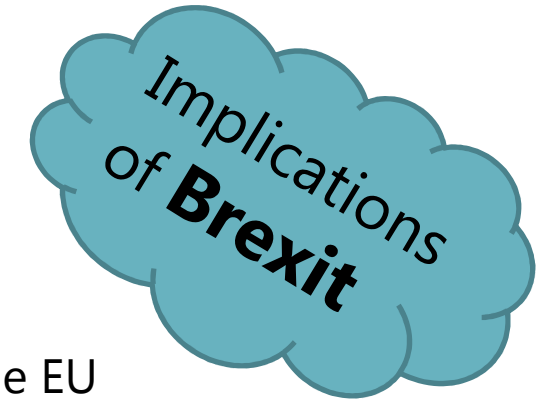
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strategy structured in 4 strategic themes

- Contributing to human health
- Contributing to animal and human health in relation to veterinary medicines
- Optimising the operation of the Network
- Contributing to the global regulatory environment

Multi Annual Workplan was developed – for EMA & HMA

EU Medicines Agencies Network Strategy to 2020



- 11 Priorities
  - Antimicrobial resistance
  - Availability of appropriately authorised medicines
  - Competence development programme through the EU Network Training Centre
  - Developing an efficient, effective and collaborative approach on inspections to address sustainability
  - Innovation and access to new medicines
  - International collaboration
  - Optimisation of the regulatory operations
  - Responding to public and animal health emergencies
  - Strengthen surveillance
  - Implementation of the telematics strategy
  - Support for better use of medicine

HMA /joint EMA-HMA WGs

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Maintenance

- Network Training Centre
- PhV Audit
- Benchmarking of Agencies
- Innovation Network

Priority focused

- Timely Access to Medicines
- Better Use of Medicines

Product focused

- Homeopathics
- Veterinary Vaccines
- Borderline Products

Procedure focused

- Joint Audit Programme
- Pharmacovigi-lance Oversight
- Regulatory Optimisation Group
- Clinical Trials Facilitation Group
- Veterinary Pharmcovigi-lance (ESS)

Profession focused

- Communication Professionals
- Enforcement Officers
- EMACOLEX
- Quality Managers

Co-lead EMA

HMA/ joint EMA-HMA task forces

Maintenance focused

- Brexit
- Sustainability of the Network

Priority focused

- Availability of Medicines
- Antimicrobial Resistance
- Big Data
- Improvement of Veterinary Legislation

Co-lead EMA

Availability of medicines

Shortages of medicines: global problem

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- **Causes** are **varied**: economical (marketing / reimbursement decisions), manufacturing or quality related (GMP)
- Significant impact on users and healthcare systems due to:
  - medicines rationing
  - delay of critical treatments
  - use of alternatives that may be less efficacious or increase risk of medication errors and adverse events

Joint EMA/HMA Task Force

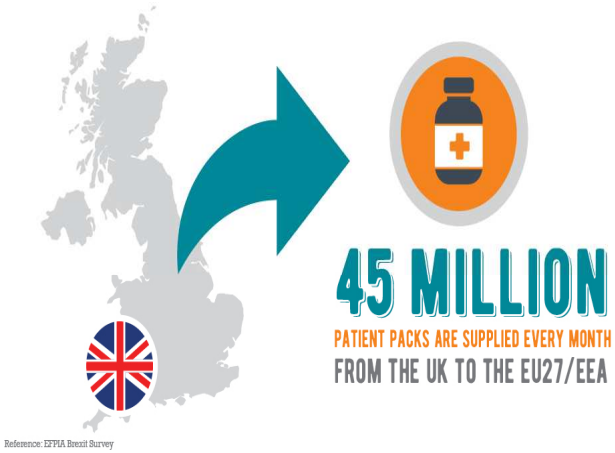
1. Availability issues recognised as **priority topic** in **EU Medicines Network Strategy to 2020**
2. **Joint EMA/HMA task force** with aim to:

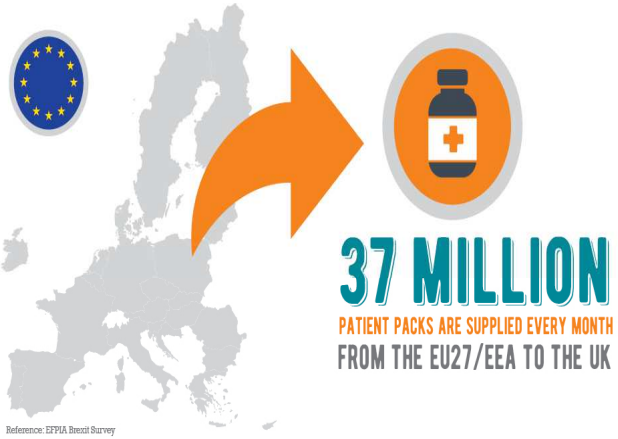
- assess reasons why authorised medicines are not marketed in MSs
- establish definitions and metrics to enhance shortage management
- develop communication strategies within network and with other actors in the healthcare system

- **Theme 1**: Marketing of authorized medicinal products – helping to make authorised medicines available through current regulatory framework
- **Theme 2**: Supply Chain Disruption – focus on prevention of supply disruptions
- **Theme 3**: Communication

Making Health a Priority in Brexit Negotiations

- **EFPIA Brexit Survey:** Survey of EFPIA members about impact of Brexit and Brexit contingency planning.





- **Business Continuity Planning: EFPIA member companies have been advised to plan for a 'no deal scenario'**
- **EU regulatory framework: required changes in case of 'no deal scenario'**
- **Shape of future EU-UK relationship**

Upcoming issues and possible availability problems

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- **Falsified Medicines Directive** (FMD) – Feb 2019
  - Do the new requirements harm the availability of medicines?
    - in connection to the deadline?
    - in connection to the cost of the new system?
    - in connection to some unexpected IT problem?
- **BREXIT**
  - Medicinal products from UK to EU

Austrian
Federal Office for
Safety in Health Care

BASG

Christa Wirthumer-Hoche

BASG -
Austrian Federal Office for Safety in Health Care

Traisengasse 5
1200 Vienna

christa.wirthumer-hoche@ages.at

www.basg.gv.at