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EU Regulatory Network: Challenges after 2 years pandemic situation, current situation

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Dr. Christa Wirthumer-Hoche
Head of the Austrian Medicines and Medical Devices Agency,
Vienna, AUSTRIA

Pharmaceutical Strategy

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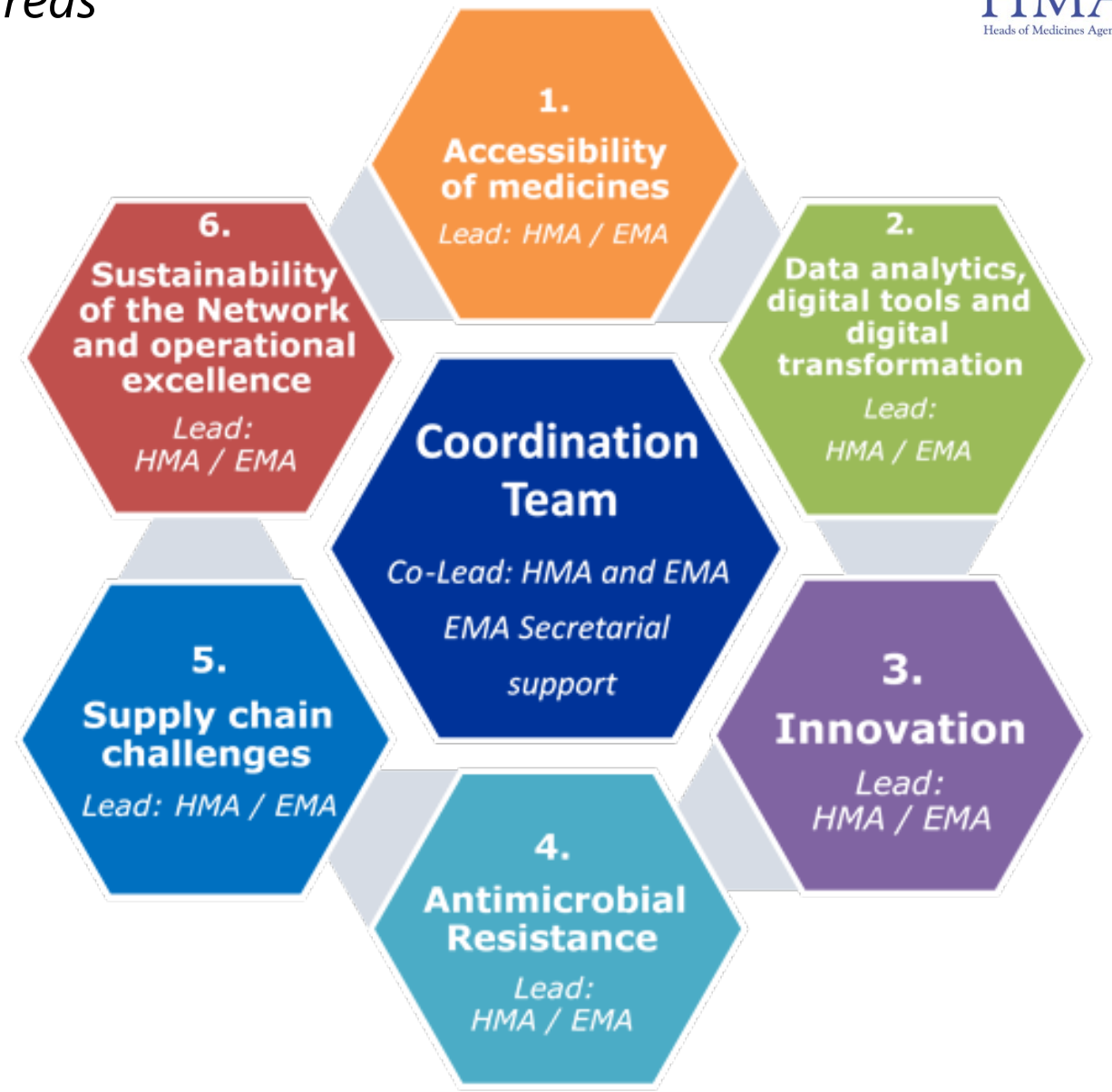
Access to affordable medicines for patients

- Competitivness
- Innovation for unmet medical need
- Sustainability

Strategy for the network

focussing on six key areas



Revision of the EU general pharmaceuticals legislation

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As part of the EU pharmaceuticals strategy, and drawing lessons from the COVID-19 pandemic, the Commission plans to evaluate and revise the EU's general legislation on medicines for human use to ensure a future-proof and crisis-resistant medicines regulatory system.

- The revision will aim to:
  - ensure access to affordable medicines
  - foster innovation, including in areas of unmet medical need
  - improve security of supply
  - adapt to new scientific and technological developments

Challenges and actions during pandemic situation

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- **Additional** developments/products for marketing authorisation on top of the current work of CP and MRP/DCP
  - Priority for Covid 19 (only centrally)
  - What are the bottlenecks? Ressources!
- **Multi National Assessment Teams** (MNAT)
  - Successful in the centralised procedure
  - Also for the decentralised procedure?
- **Exeptional** urgency in the CP for Covid 19 products
  - Rapid Scientific Advice (SA), rapid Paediatric investigation plan (PIP)
  - Rolling review for Covid 19 products – will be keep this procedure for innovative products?
  - ETF (Emergency Task Force) – scientific position outside formal procedures

How to support in updating the Pharmaceutical legislation?

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- EMA and EMRN – workshops
  - Covid 19 lessons learned – operational aspects – efficient working models
    - Rolling review, premature dossiers, submission date, ….
  - Communication aspects
    - Common messages from regulators and public health policy bodies at the EU and national level
    - Clear communication necessary – in close collaboration with ECDC and HERA
- 13 concept papers
  - Technical inputs

Future proof system – some thoughts

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Opportunity to address challenges faced by the EMRN regarding

- Its capacity – increasing workload in NAPs and CAPs
- Agility of the system
  - Is the current system sustainable?
- New technologies and emerging trends in medicines authorisation

Avoid/reduce duplication of work / work in silos

- Worksharing (mandatory)
  - ASMF
  - Evaluation of BE studies / biosimilarity
  - Purely nationally submitted variations

Sustainability – National fees / Fee Reg for central activities

Re-think Variation Regulation

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- High number of variations are submitted purely nationally – demands a lot of NCA-capacities
  - ➢ Mandatory worksharing procedures?
- Reduce administrative burden
  - Reduce level of details required in the dossier
  - Covid experience - Conditional MA – very intensive life cycle management
- Post approval change management protocols
- More data driven / digital solutions
- „master file – like“ approach
  - Allow multiple use of assessments (BE-studies, platform technologies, ASMFs)

Procedures (1/2)

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No pre-mature dossiers

- Define criteria/issues that help to identify what would be a premature dossier
- Rejection of pre-mature dossiers – certain amount of the fee to be paid

Timing of procedures

- Reduce unpredictability
  - Agreement for a joint submission date between the applicant and RMS/ Rapporteur – binding for both sides
  - In case of non-compliance of the applicant – penalties?

More agile and flexible processes

- Act more dynamically – in DCP and CP
- Possibility of allowing voting in CMDh to resolve referrals without the need to refer to CHMP - all MS, not only RMS/CMS

Learning from Vet Reg

Procedures (2/2)

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Study by the „Technopolis Group“ on behalf of the EU-Commission

- Evaluation and impact assessment of the general pharmaceutical legislation
- Analyse the very complex system

MRP/DCP products:

- Inclusion of new CMS in already ongoing DCPs
- Zero-day MRP/RUPs

Cancellation of the following provisions:

- „Sunset clause“ & renewal after 5 years
- „Medicines under additional monitoring“ & the black symbol
- Risk management plans e.g. for generics

CAPs:

- Obligation discussed to market in the majority of EU-MSs, incl so-called „smaller markets“ (ongoing pilot „market access strategy“)

Rolling review – in CP

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Restrict to greatest patient need

Exceptional and should only apply to emergency products

Develop criteria

Appropriate use criteria outside a crisis

Timelines

Stable data package, standard timelines, followed by an accelerated MA assessment

Acceptance of Reald World Data (RWD)/ Real World Evidence (RWE)

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- Revised Pharm. Legislation should allow the use of RWD
- RWD - complementary data on S/E on radomised Clinical Trials
  - To complement MAA with evidence from RW
- Data-driven Med. Regulation – „turn data into decisions on medicines“
  - Medicines for unmet medical need
- Pharmacovigilance system
  - Allow to monitor better medicines safety and effectiveness once on the market
- Crises prepardness
  - Provide an invaluable resource to prepare and respond to future healthcare crises and pandemics
- DARWIN EU
  - Promote a more efficient and robust approach to the use of RWD

DARWIN EU - Importance of data!

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- DARWIN EU vision:
  - Establish a **network of data, expertise, and services**, that supports better decision-making throughout the product lifecycle with reliable evidence from real world healthcare data.
- DARWIN EU: Benefits
  - DARWIN EU will significantly **increase the capacity** of the Network to undertake high-quality observational studies based on real-world data**.**

National and EU **regulation of medicines**:

Drug development – disease epidemiology, unmet need, historical controls, planning

Authorisation – contribution to BR, controls, extrapolation to general and/or special populations

Post-authorisation – benefit-risk monitoring, extension of indication, risk minimisation measures

Product information (PI)

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Rules on product information represent an important tool to deliver on access, availability and future proofing of the legislation

- Rules on ePI to replace the paper PL
  - Replace or complement paper with PI in an electronic format
  - Currently: pilots ongoing in diff MSs – use of ePI instead of paper for identified products
    - E.g. hospital only products
  - Use of pictograms
- Harmonised rules for multi-country packages of medicines
  - Availability Hospital products
  - Pandemics/health emergencies - EN pack only – if urgent + e PI
  - Information in multilanguage format via means of mobile scanning technologies

Conclusion

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- At the beginning of the implementation of the 2021-2025 strategy, which was delayed due to Corona, we have
  - the revision of the pharmaceutical legislation (including Orphan and Paediatric legislation)
  - and the lessons learned from the pandemic situation.
- A number of discussions have already taken place and there has been a lot of input for the update of the legislation.
- We are now waiting with great interest to see what the Commission's draft promised for December 2022 will look like.

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DI Dr. Christa Wirthumer-Hoche

Head of the Austrian Medicines and Medical Devices Agency

BASG -
Bundesamt für Sicherheit im Gesundheitswesen

Traisengasse 5
1200 Wien
T +43 (0) 50555-36000

christa.wirthumer-hoche@ages.at
www.basg.gv.at