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SCIENCE MEDICINES HEALTH

Pharmaceutical legislation – Highway to innovation

EMA's perspective on key provisions designed to stimulate innovation

RSNN
Regulatory Science Network Netherlands

Presented by Tony Humphreys on 6 June 2023
Head of Regulatory Science and Innovation Task Force

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Six key political objectives

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"Triple A"

ACCESS

AVAILABILITY

AFFORDABILITY

"Triple C"

Competitive regulatory framework

Compliance Environmental Sustainability

Combat AMR

Access to medicines

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Current challenges

Access is not timely and differs across Member States:

90% variance between Northern and Western European countries and Southern and Eastern European countries

Average waiting time across the EU is from 4 months to 29 months

Proposed solutions

Incentives for innovation and access: Targeted approach vs current "one- size-fits-all" with 8 years of unconditional data protection

Earlier market entry of generic and biosimilar medicines

- Faster authorisation

- Pre-authorisation support

Modulation for the majority of innovative medicines

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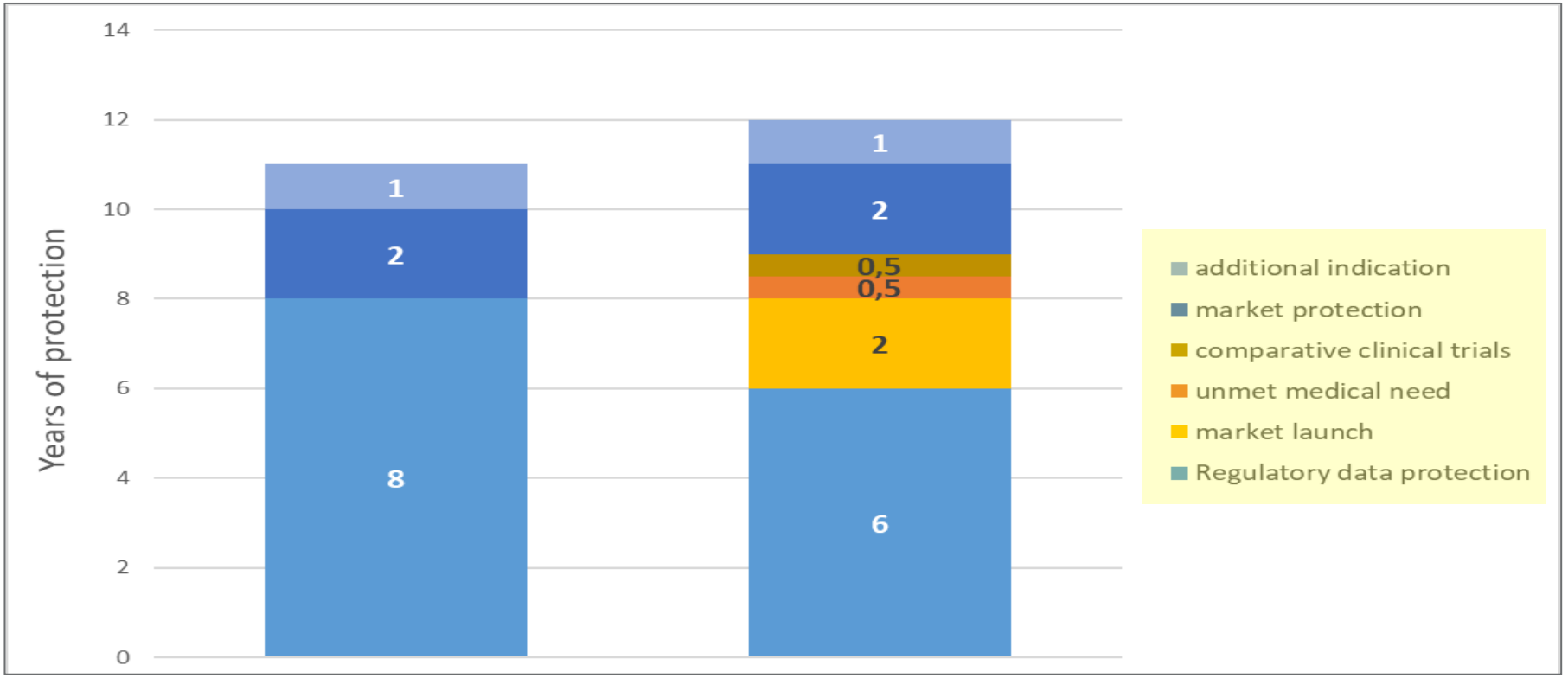
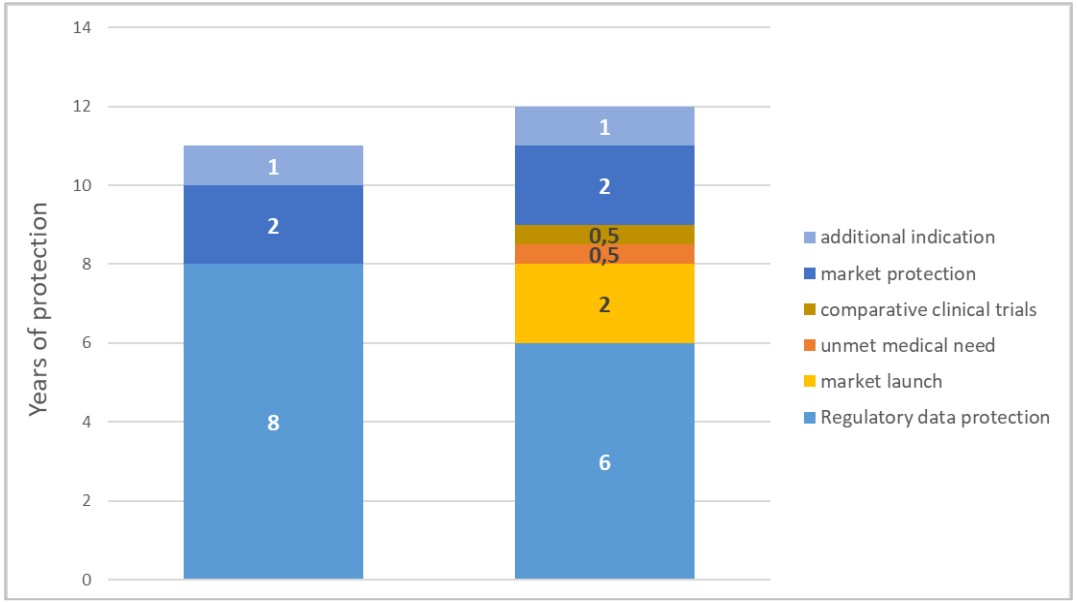


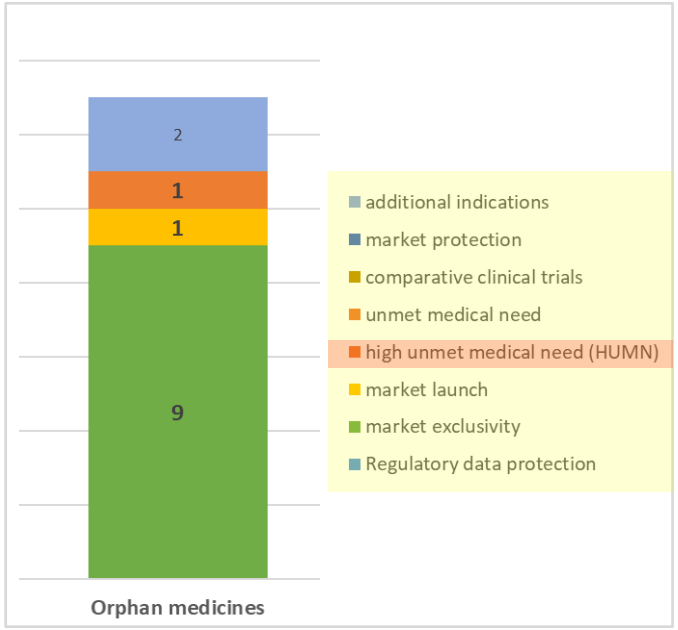
Current system, max 11 years protection

Proposed system, max 12 years protection

Modulation for the majority of innovative medicines



Current system, max 11 years protection **Proposed system, max 12 years protection**



Proposed system, max 13 years protection

A streamlined regulatory framework

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Current challenge

- **Longer approvals** times than in other regions (US 244 days)
- **Administrative burden** and compliance costs for the industry
- **The clock stop mechanism**

Proposed solutions

- **Faster authorisation:**
  180 days standard procedure
  150 days accelerated procedure
  Regulatory efficiency:
  simplified procedures, better use of data and digitisation, regulatory sandboxes
- **Pre-authorisation support** to promising medicines to accelerate development and attract investments
- **Lower regulatory burden** (especially important for SMEs and not-for-profits)

Combatting AMR

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Current challenge

- AMR causes **35000 deaths per year** in the EU. It amounts to +/-1.5 bn EUR per year in healthcare costs
- By 2050, **10 million deaths globally each year**
- **Current market failure/ Lack of effective antimicrobials**
- **Lack of market incentives** 0,5 bn EUR cost of a new antibiotic

Proposed solutions

- Measures on **prudent use of antimicrobials** – prescription, restricted quantities, education etc.
- Regulatory incentives with **transferable exclusivity vouchers** under strict conditions
- Financial incentives with **procurement mechanisms** (HERA)

  5 Targets, incl on the total **EU consumption of antibiotics for humans** (ECDC) →reduction by 20% by 2030 (Council Recommendation)

AMR voucher

- Additional year of data protection
- Strict conditions (only novel antimicrobials, full transparency of all funding, obligation of supply, max 10 vouchers in 15 years, review after 15 years, etc.)

Development support 1/2

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Scientific Advice extended to involve **other bodies established in other relevant Union legislation** e.g., Medical Devices authorities/expert panels, HTAs, payers, SoHO, Clinical Trials Coordination Group (CTCG)

PRIME codified in legislation as "enhanced scientific and regulatory support for priority medicines" incl reference to Emergency Task Force (ETF) consultation for Public Health Emergency (PHE)-related products

Rolling Review adapted for **non-crisis situations** as a "phased review of complete data packages": only for "products that offer an exceptional therapeutic advancement in areas of (High) Unmet Medical Needs" products

Development support 2/2

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Regulatory sandbox

- EMA to set up environment with MSs and developers to test adapted, waived or deferred requirements for a product or category of products that provide major advantage to patients and cannot be developed in full compliance with current rules
  - ❖bacteriophages
  - ❖smart drug-device software dependent implants
  - ❖preventative/human germline editors

"Borderline products" and novel product types

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CHMP's MP classification decision

- Possibility to request CHMP scientific recommendation on whether a product, potentially falling under Centralised Procedure, **is a Medicinal Product or not**, prior to consultation of equivalent advisory mechanisms in other legal frameworks.

New definitions

- Functional excipient (+ can also be inspected)
- Bio-hybrid (=hybrid of a biological)
- "Integral combination of a medicinal product with a medical device"
- "Medicinal product in exclusive use with a medical device"

Novel types of applications/authorisations

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Platform Marketing Authorisation

- Allowed to adapt Active Substance where necessary to tailor the product to characteristics from an individual patient/group or infectious agent

Combination pack

- Concept defined, and new legal basis added

TEMA

- Temporary Emergency Marketing Authorisation, allow adaptations of the requirements and a tailored evaluation in case of Public Health Emergencies (PHE)

Conditional MA

- maintained and extended for new indications

Hospital Exemption (HE) for ATMPs

- More harmonised requirements for authorisation of manufacturing, preparation and use, pharmacovigilance & traceability, data collection on safety and efficacy;
- EMA will maintain a centralised repository of HE authorisations from MS.

An ambitious revision of the EU Pharmaceutical Legislation to:

- Maintain and reinforce the position of the EU pharmaceutical industry both within EU and globally
- Attract pharmaceutical research and development by providing a future-proof, stable legal framework and a favourable environment
- Boost regulatory support for the development of promising medicines
- Provide a more targeted incentives framework for innovation with a focus on patient access and addressing unmet medical needs
- Boost innovation and EU competitiveness through an efficient and simplified regulatory framework to reduce regulatory burden

Any questions?

Further information

Anthony.Humphreys@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
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