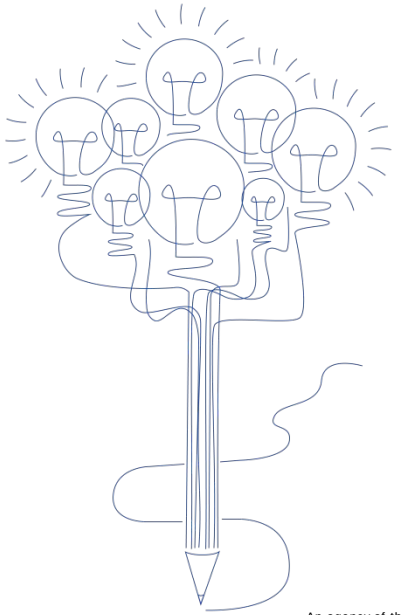
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Catalysing the integration of science and technology in drug development

EMA's core recommendations

Human Stakeholders Workshop



Presented by Enrica Alteri on 24 October 2018
Head of Division, Human Medicines Research and Development Support

An agency of the European Union

Science

Precision medicine

ATMPs

PRIME

Regulator

Evolution of science and technology demands integration of regulatory advice along the development continuum

Technology

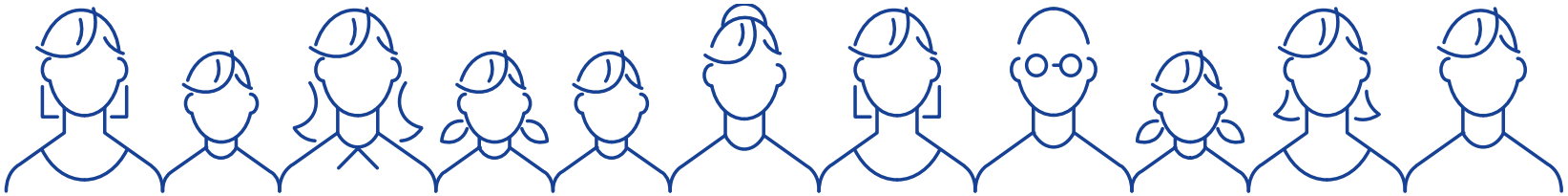
Novel manufacturing

Medicine+device

Nanomedicines

New materials

Product to patient

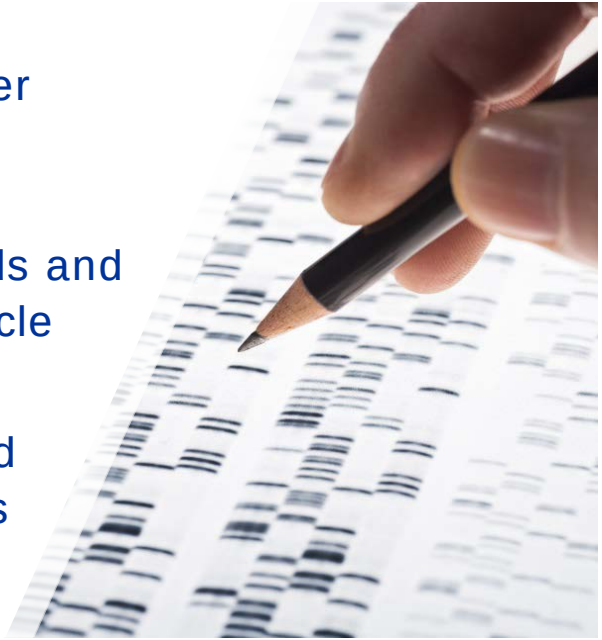


Core recommendations—Science

- Support developments in precision medicine, biomarkers and ‘omics’
- Support translation of Advanced Therapy Medicinal Products (ATMPs) cell, genes and tissue-based products into patient treatments
- Promote and invest in the Priority Medicines scheme (PRIME)

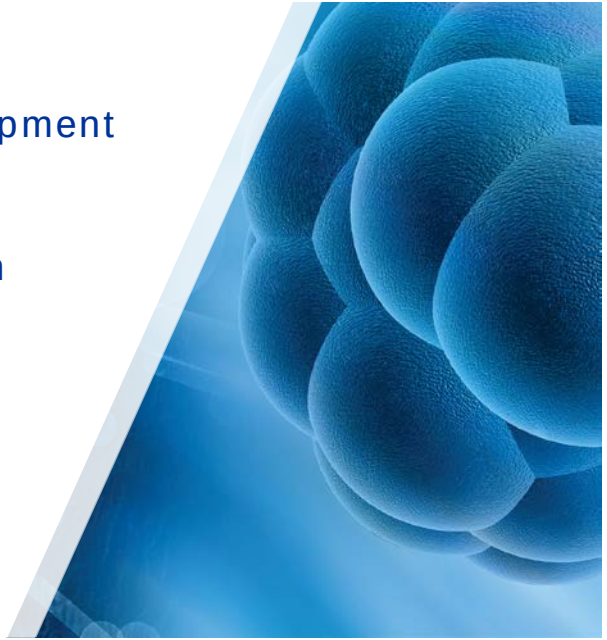
Support developments in precision medicine, biomarkers and ‘omics’

- Enhance early engagement with novel biomarker developers to facilitate regulatory qualification
- Address the impact of emerging ‘omics’ methods and their application across the development life cycle
- Evaluate, in collaboration with HTAs, payers and patients, biomarker impact on clinical outcomes



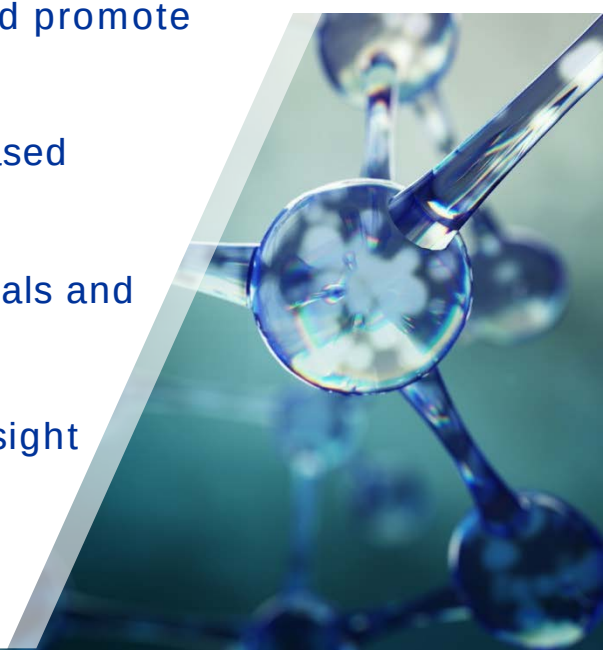
Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments

- Identify therapies that address unmet medical need
- Provide assistance with early planning, method development and clinical evaluation
- Support evidence generation, pertinent to downstream decision-makers
- Address the challenges of decentralised ATMP delivery locations
- Raise global awareness of ATMPs to maximise knowledge sharing, promote data collection



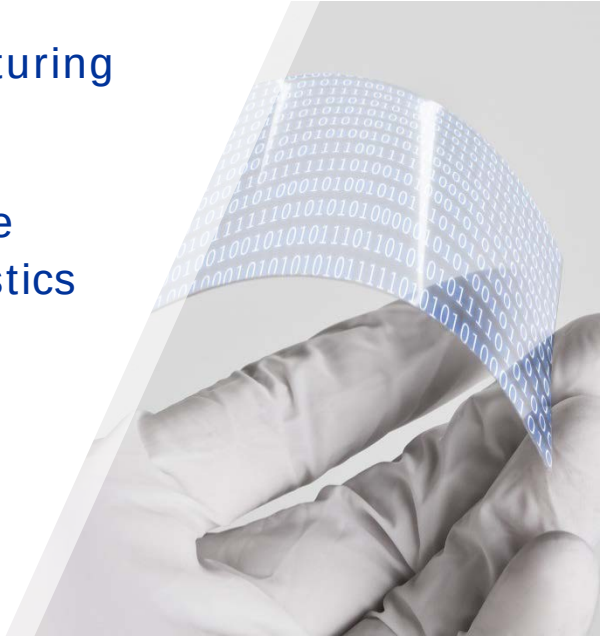
Promote and invest in the Priority Medicines scheme (PRIME)

- Invest in external communication to better explain and promote PRIME
- Evaluate current capacity and identify areas for increased investment
- Shorten the time between Scientific Advice, clinical trials and MAA submission
- Collaborate with stakeholders to ensure efficient oversight post-approval
- Leverage collaboration with patients, healthcare professionals, academia and international partners



Core recommendations—Technology

- Facilitate the implementation of novel manufacturing technologies
- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Develop understanding of and regulatory response to nanotechnology and new materials in pharmaceuticals



Facilitate the implementation of novel manufacturing technologies

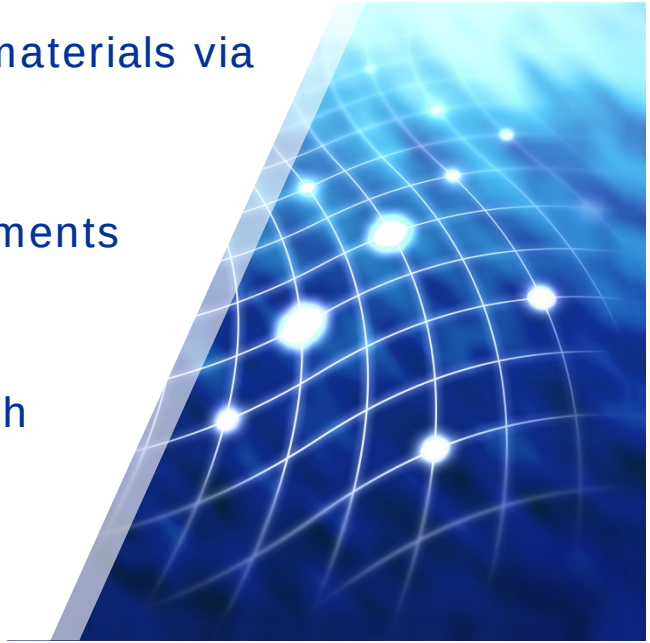
- Recruit expertise in novel manufacturing technologies to enhance the assessment process
- Identify bottlenecks and propose modernisation of relevant regulations to facilitate novel manufacturing
- Address regulatory challenges in point-of-care manufacturing, e.g., concept of batch control, role of the Qualified Person
- Facilitate a flexible approach in application of Good Manufacturing Practice

Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

- Define how risk-benefit of such products is assessed and communicated
- Enrich expertise at the interface between medicines, medical devices and borderline products
- Facilitate the regulatory pathway between notified bodies and medicines' regulators
- Gain insight in innovation on drug-device combination products via horizon scanning

Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals

- Raise awareness of new nanomedicines and materials via the EU-Innovation Network
- Generate guidance addressing PK/PD requirements and long-term efficacy and safety
- Develop guidance on regulatory pathways with Device Regulators and Notified Bodies



Core recommendations—Regulator

Diversify and integrate the provision of regulatory advice along the development continuum

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Promote more integrated medicines development aligning Scientific Advice, Clinical Trials approval and Good Clinical Practice oversight

Create complementary and flexible advice mechanisms to support innovative product development expanding multi-stakeholder consultation platforms

Facilitate translation of innovation via a re-engineered Innovation Task Force and synergy with an evolving EU-Innovation Network platform

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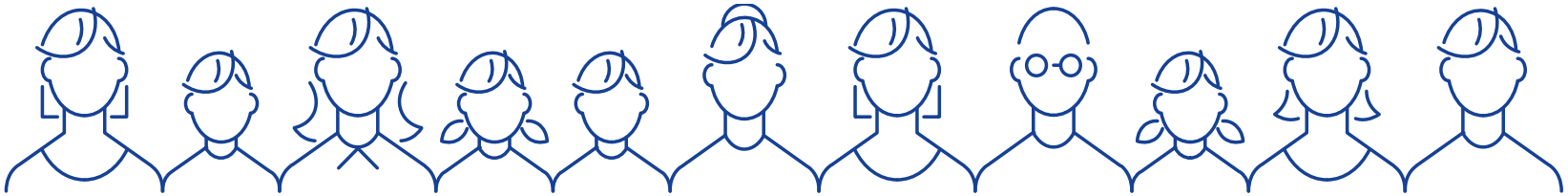

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