European Federation of Pharmaceutical Industries and Associations

Responding to the needs of the 21st century Patient: Addressing challenges and opportunities across the European Regulatory Framework

View from the industry






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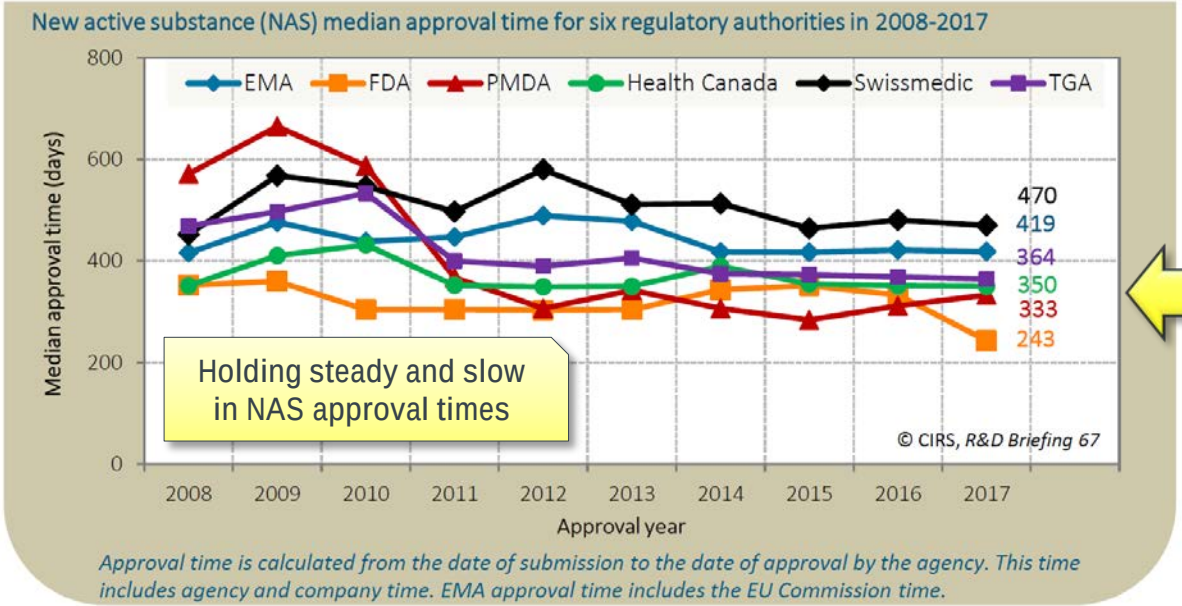
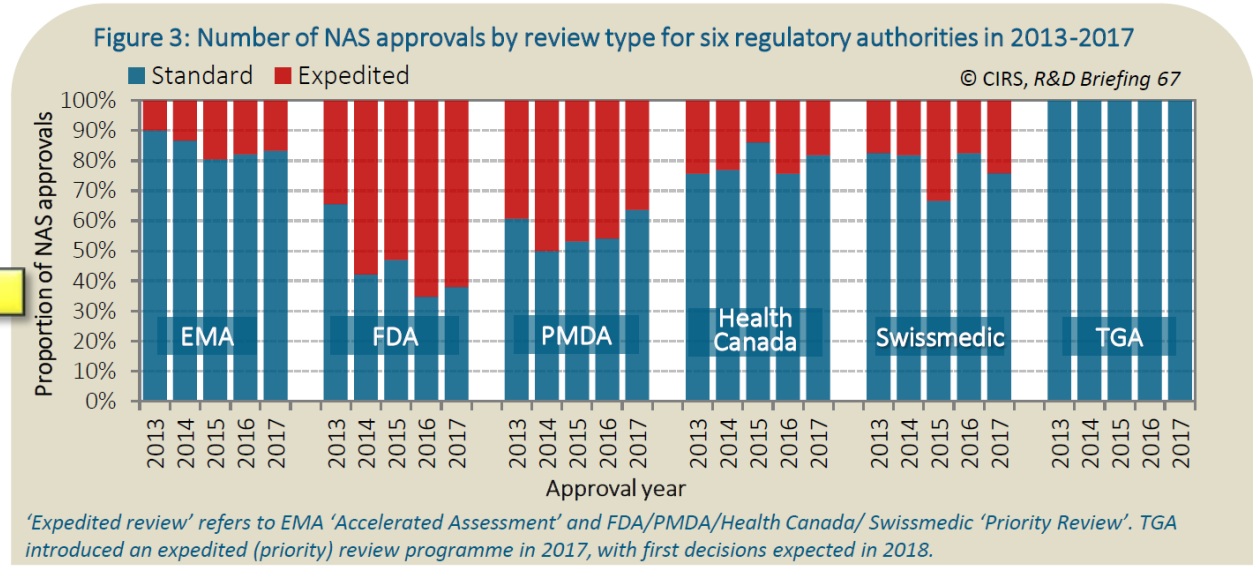
MSD and Chair, EFPIA Regulatory Strategy Committee

EMA Regulatory Science to 2025

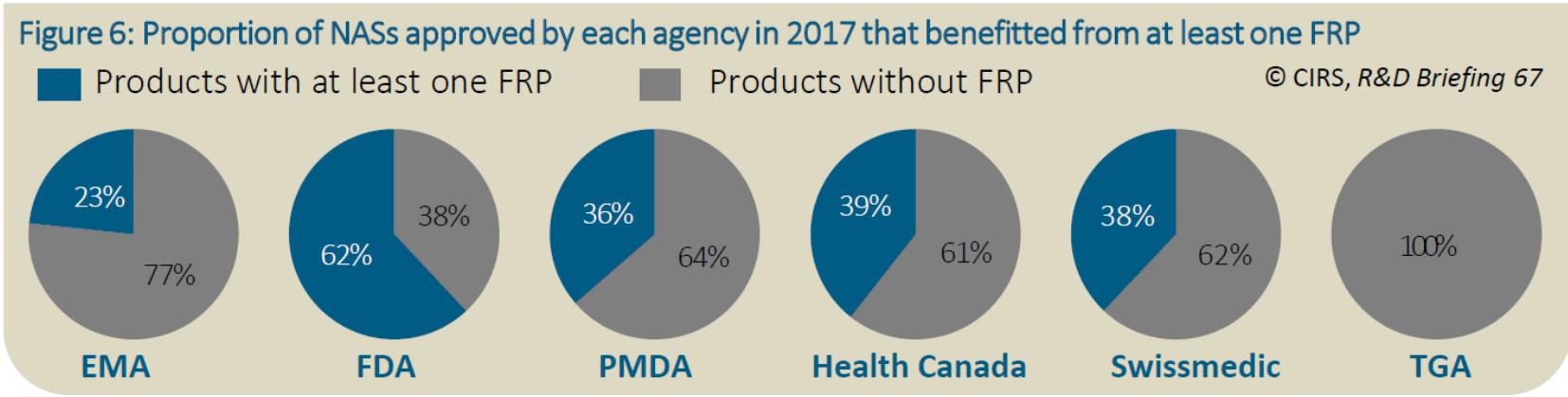
Multi-Stakeholder Workshop – 24 October 2018

Priorities for strengthened regulatory strategy in the EU





Accelerated Assessment and PRIME still exceptional routes



Considering "Facilitated Regulatory Pathways" (priority, accelerated approval, conditional approval, orphan designation), EMA still offers a modest opportunity compared with other regions and countries

Figures from Bujar et al (2018) *R&D Briefing 67: New drug approvals in six major authorities 2008-2017.* Centre for Innovation in Regulatory Science. London, UK.

Regulatory Strategy Committee (RSC) – Delivering 4E for 2023

EFPIA's 4E for 2023 Regulatory Strategy Plan, endorsed by the EFPIA Board in 2017, aims to address the challenges and opportunities faced by the EU regulatory system

The RSC Vision	*To drive for an agile, competitive and world-class regulatory system in Europe and beyond that embraces advances in science, technology and medicines, accelerating access to innovative healthcare solutions and optimised patient outcomes.*

ENSURE
a competitive world-class regulatory system

EVOLVE
the framework for innovation

ELEVATE
multi-stakeholder engagement

EXPAND
global convergence

Ensure a competitive, world-class regulatory system

Aim for impact: Agile, competitive, world-class regulatory system that embraces advances in science technology and medicines, accelerating access to innovative healthcare solutions and optimised patient outcomes. Europe as the best place in the world to develop and license a medicines.

Key metrics, EXAMPLE:
Critical assessment and EFPIA position of gaps and enhancements needed in soft law and legislation in Europe, with benchmark to other regions

Evolve the framework for innovation

Aim for impact: Regulatory system more adaptable to evolving science and technology leading to faster integration into regulatory practice. More relevant and better quality evidence that accelerates regulatory and HTA review, and supports fulsome review of value of medicines across all stakeholders,

Key metrics, EXAMPLE:
Demonstrating the European scientific and regulatory advice is able to qualify new sources of data and new technologies faster - joint EMA and HTA advice becomes a norm

Elevate multi-stakeholder involvement

Aim for impact: Decisions, including on product information more adapted towards patients' needs while ensuring the patients are appropriately engaged during the process. Broader applicability of joint advice to further streamline the new medicines development process. Study design that serves multiple stakeholders moving away from sequential data generation.

Key metrics, EXAMPLE:
Evidence that patient's needs are in the center throughout the lifecycle of a medicine. Implement and optimise electronic product information (ePIL) project (infrastructure and legislative framework).

Expand global convergence

Aim for impact: Maintaining Europe at the forefront of regulatory excellence while embracing the developments in other jurisdictions. International support for fast adaption to scientific & technological standards. Expand global convergence of regulatory standards and improve cooperation & reliance between Regulatory Authorities to shorten approval times and reduce inspection/testing.

Key metrics, EXAMPLE:
Agreement with EC and member states on ICH Q12 without exceptions. Reduced approval time and inspection/testing. Mutual Recognition agreements cover vaccines and waive import testing.

Framework to deliver the vision of 4e for 2023

To drive for an agile, competitive and world-class regulatory system in Europe and beyond that embraces advances in science, technology and medicines, accelerating access to innovative healthcare solutions and optimised patient outcomes.

- EFPIA RSC 5 year work plan developed
- Committed investment from industry in evidence to drive regulatory change
  - REVEAL study on evidentiary standards and acceptance for decision-making
- Prioritisation given to innovative regulatory approaches and new sources and uses of evidence to support decision making
- Establishing a base line and dashboard to signal the right routes for change
- Exploring legislative and broader mechanisms as the means for change
- Undertaking meaningful stakeholder engagement to engender a shared vision for regulatory innovation
- Returning EMA / Europe to the international regulatory science frontier

EMA – REGULATORY SCIENCE TO 2025

A shared agenda for excellence

4e for 2023

- Agile, competitive, world-class regulatory systems
  - **Ensure** through analysis of gaps and opportunities in regulatory framework
- Embraces advances in science, technology and medicines
  - **Evolve** the framework for innovation, addressing evidentiary sources and uses
- To accelerate access to innovative healthcare solutions and optimized patient outcomes
  - **Elevate** multi-stakeholder involvement to focus decisions, support on patients' needs and preferences
  - **Expand** global convergence to deliver European leadership on regulatory standards and practices for the benefit of all

EMA Regulatory Science Strategy

- Regulatory science as the foundation
  - Enabling and leveraging **research and innovation in regulatory science**
- **Catalysing integration of science and technology** in drug development
  - Driving **collaborative evidence generation**
  - Improving the **scientific quality** of evaluations
- To achieve a new and active role at the **crossroads between science and healthcare**
  - Advancing **patient-centred access** to medicines in partnership with healthcare systems
  - Addressing **emerging health threats** and **availability/therapeutic challenges**