

CONFERÊNCIA ANUAL DO INFARMED, I.P. 2024

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GOOD
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The views and opinions expressed in this presentation are solely my own and do not necessarily represent those of my organization or any affiliated entities

Defining new regulatory strategies

Keeping up with the news

$\frac{C}{M} \frac{B}{E} \frac{G}{B}$

PINK SHEET
CITELINE REGULATORY

Pink Sheet >> Geography >> Europe

EMA Seeks Feedback On COI Policy Changes Following Legal Rulings

01 Nov 2024 • By [Anabel Costa-Ferreira](#)

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CITELINE REGULATORY

Pink Sheet >> Agency Leadership >> EMA

New EMA Fees Could Shake Up Pharma Submission Strategies

01 Nov 2024 • By [Vibha Sharma](#)

The Economist

Menu Weekly edition The world in brief Search

Report: A new prescription

View all chapters

Technology Quarterly | Intelligent design

Artificial intelligence is taking over drug development

Regulators need to up their game to keep up

FINANCIAL TIMES

S COMPANIES TECH MARKETS CLIMATE OPINION LEX WORK & CAREERS LIFE & ARTS HTSI

Pharmaceuticals sector + Add to myFT

Europe falls behind China in playing host to clinical drug trials

Pharmaceutical companies turn to jurisdictions with simpler regulatory regimes

Escassez de medicamentos em Portugal aumentou 47% em 2023. Mais de um terço são genéricos

Joana Morais Fonseca
19 Fevereiro 2024



Nieuws
Europees Parlement

Startpagina Pers Agenda Veelgestelde vragen online persdossier

Pers / Draghi to MEPs: "Europe faces a choice between exit, paralysis, or integration"

Draghi to MEPs: "Europe faces a choice between exit, paralysis, or integration"

Persbericht [PLENAIRE VERGADERING](#) 17-09-2024 - 16:09

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EMA Takes Steps To Improve Predictability Of Drug Submissions

25 Jan 2023 • By [Vibha Sharma](#)

Pillars shaping regulatory strategies

Delivering for healthcare systems and patients

$$\frac{C \quad B \quad G}{M \quad E \quad B}$$

Advancing science,
fostering innovation
and competitiveness

*Societal and Network
aspirations*



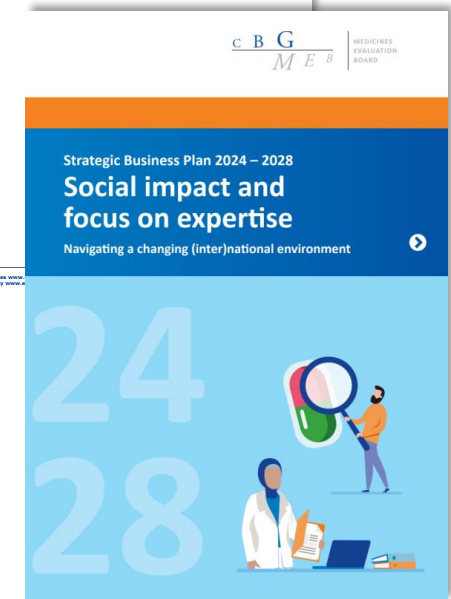
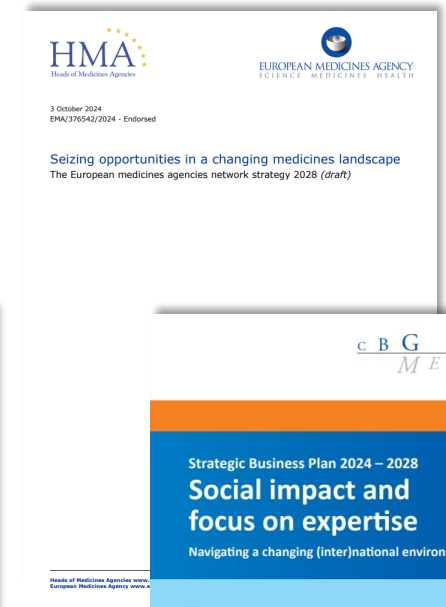
Regulations in a dynamic environment

Time to change our ways

$\frac{c \ B \ G}{M \ E \ B}$

A selection of key legislative actions (adoption dates)

1995	EMA founded: first centralized procedure
2000	Orphan medicines regulation
2001	Clinical trials directive
2006	Pediatrics regulation
2010	Pharmacovigilance regulation
2011	Falsified medicines directive
2014	Clinical trials regulation
2021	HTA regulation
2024	Fees regulation
????	Pharma Package



Pace of innovation: preparing for complex technologies through regulatory science research

$\frac{c}{M} \frac{B}{E} \frac{G}{B}$



Create new methods to generate evidence for decision-making

Develop tools for developing and evaluating medicinal products

Systematically address gaps and advance regulatory science

EU platform for Regulatory Science Research: academic, public and non-for-profit regulatory science researchers and regulators

Future proofing the European Medicines Network: goals for sustainability

$\frac{C}{M} \frac{B}{E} \frac{G}{B}$



3 October 2024
EMA/376542/2024 - Endorsed

Seizing opportunities in a changing medicines landscape
The European medicines agencies network strategy 2028 (draft)

$\frac{C}{M} \frac{B}{E} \frac{G}{B}$ MEDICINES
EVALUATION
BOARD

Strategic Business Plan 2024 – 2028

**Social impact and
focus on expertise**

Navigating a changing (inter)national environment



24
28



Reinforce scientific and regulatory
capacity and capability of the network

Attracting, training and retaining
expertise

Resources allocation throughout
the Network

Centres of Excellence for assessments
and/or regulatory capabilities

To drive innovation, we must adapt and lead in a changing world: *Social impact and focus on expertise*

$$\frac{c \ B \ G}{M \ E \ B}$$



People

Talent development from a shared EU talent pool (regulators, industry, academia and health systems)



Process

Re-imagine our ways of working: Centres of Excellence



Patients

Adapt with purpose to deliver for patients and health systems



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