Geopolítica y política farmacéutica: la ETS en un nuevo contexto estratégico

Datos, evidencia, decisiones: generando valor para la gestión y las políticas sanitarias

Sevilla, 17 al 19 de junio de 2026

#JornadasAES

XLV Jornadas de Economía de la Salud

Index

1

Exponential growth of science and technology

The time span of scientific and technological progress is constantly decreasing. Without time to assess and be aware of the impact of an advance, we must be prepared to incorporate the next

2

Increasing pressure for early access to innovation

Innovation, even the earliest, can not be hidden anymore and general population and public opinion generally accept that access to treatments must be immediate

3

Growing possibility of a data driven decision making

Data is a key enabler for faster development of therapies, improving care and allocating health-system spend to optimize outcome for patients, promoting a shift in value

4

Balancing uncertainty and lost opportunity due to delayed access

Balancing uncertainty due to early access with addressing unmet medical needs requires innovative approaches which, in turn, should not make the process unmanageable

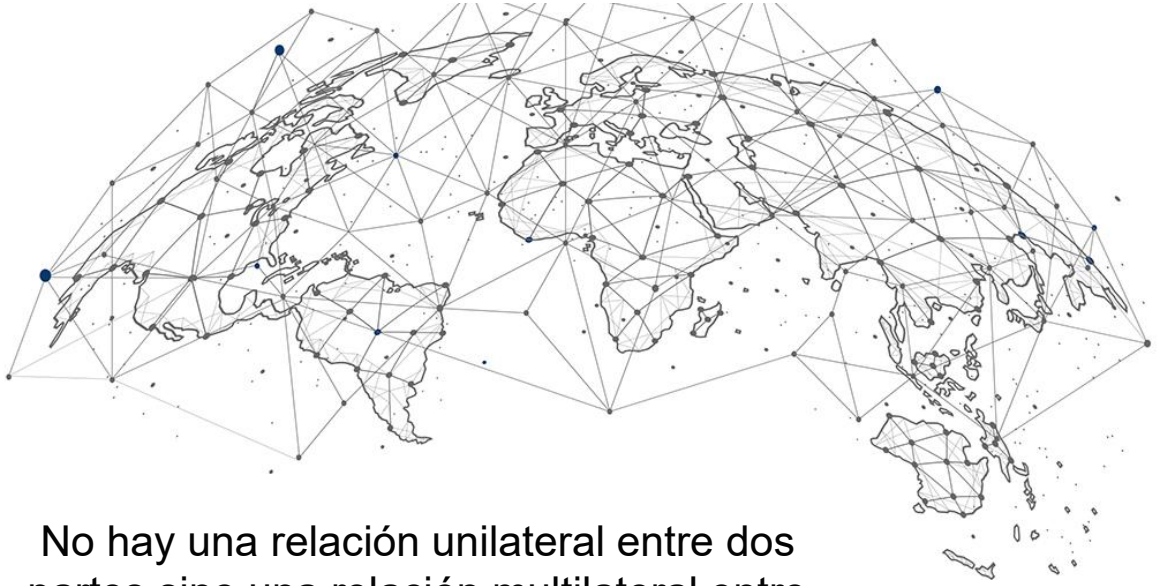
5

The pressure of demographics

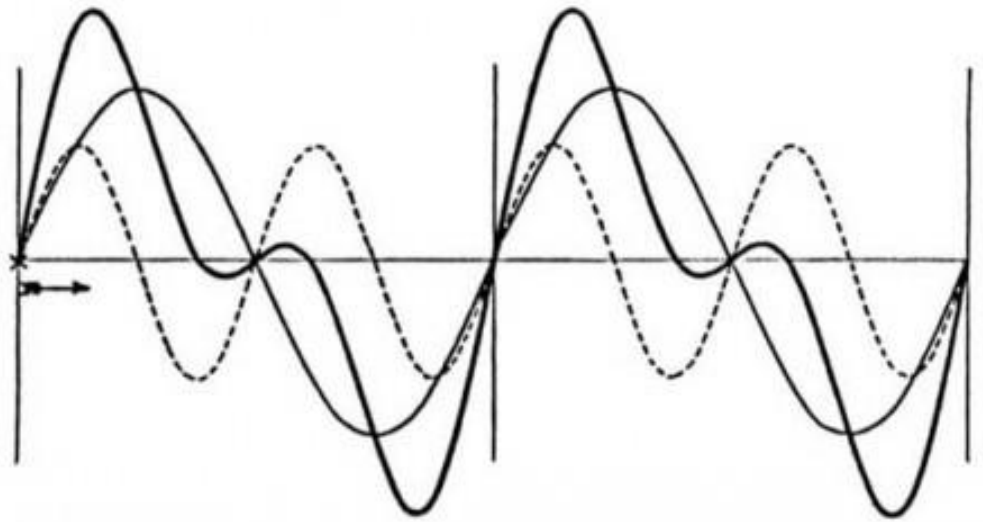
Aging increases the chances of suffering cancer. Increasing survival without cure generates needs in successive lines of treatment. Fragile and vulnerable target populations

6

Risk of a massively medicines-focused approach to health care



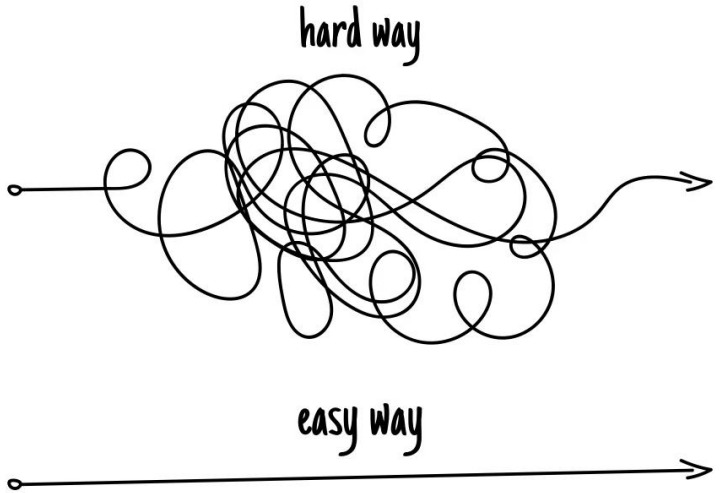
No hay una relación unilateral entre dos partes sino una relación multilateral entre múltiples partes



No todas las partes están en el mismo momento del ciclo

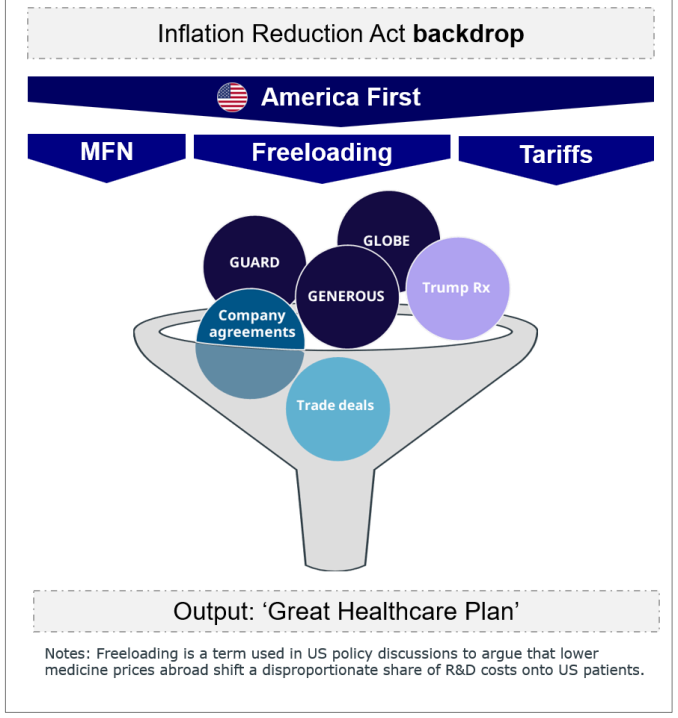
Tensiones entre lo local y lo global (con todos sus grises)

Fragmentación excesiva y no siempre coherente

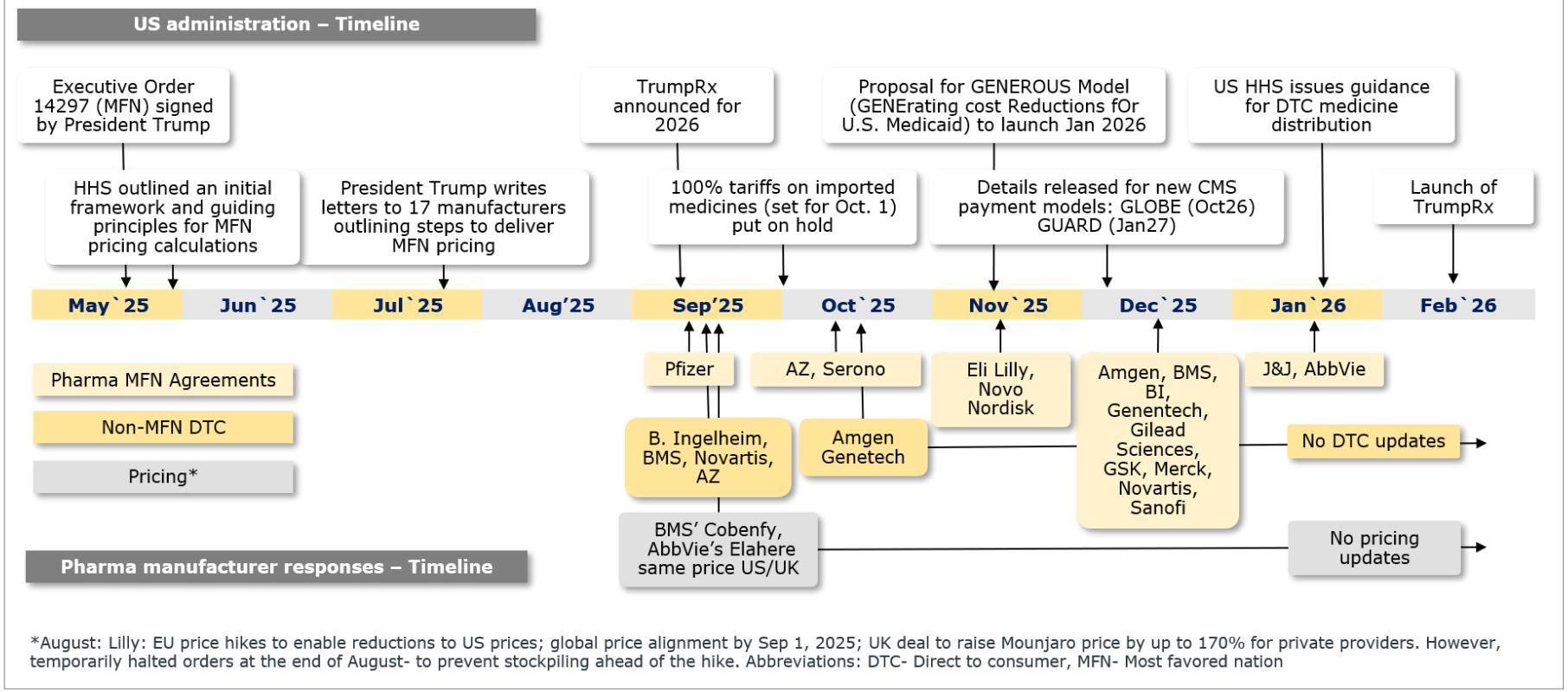


Paradigmas y procedimientos que tienden a la complejidad como solución

Multiple overlapping initiatives have been announced or proposed in recent months by the US Administration



Notes: Freeloading is a term used in US policy discussions to argue that lower medicine prices abroad shift a disproportionate share of R&D costs onto US patients.



*August: Lilly: EU price hikes to enable reductions to US prices; global price alignment by Sep 1, 2025; UK deal to raise Mounjaro price by up to 170% for private providers. However, temporarily halted orders at the end of August- to prevent stockpiling ahead of the hike. Abbreviations: DTC- Direct to consumer, MFN- Most favored nation

The deals: Multiple overlapping initiatives, details not yet in place. Some are voluntary. Challenges can be expected. Long implementation cycles

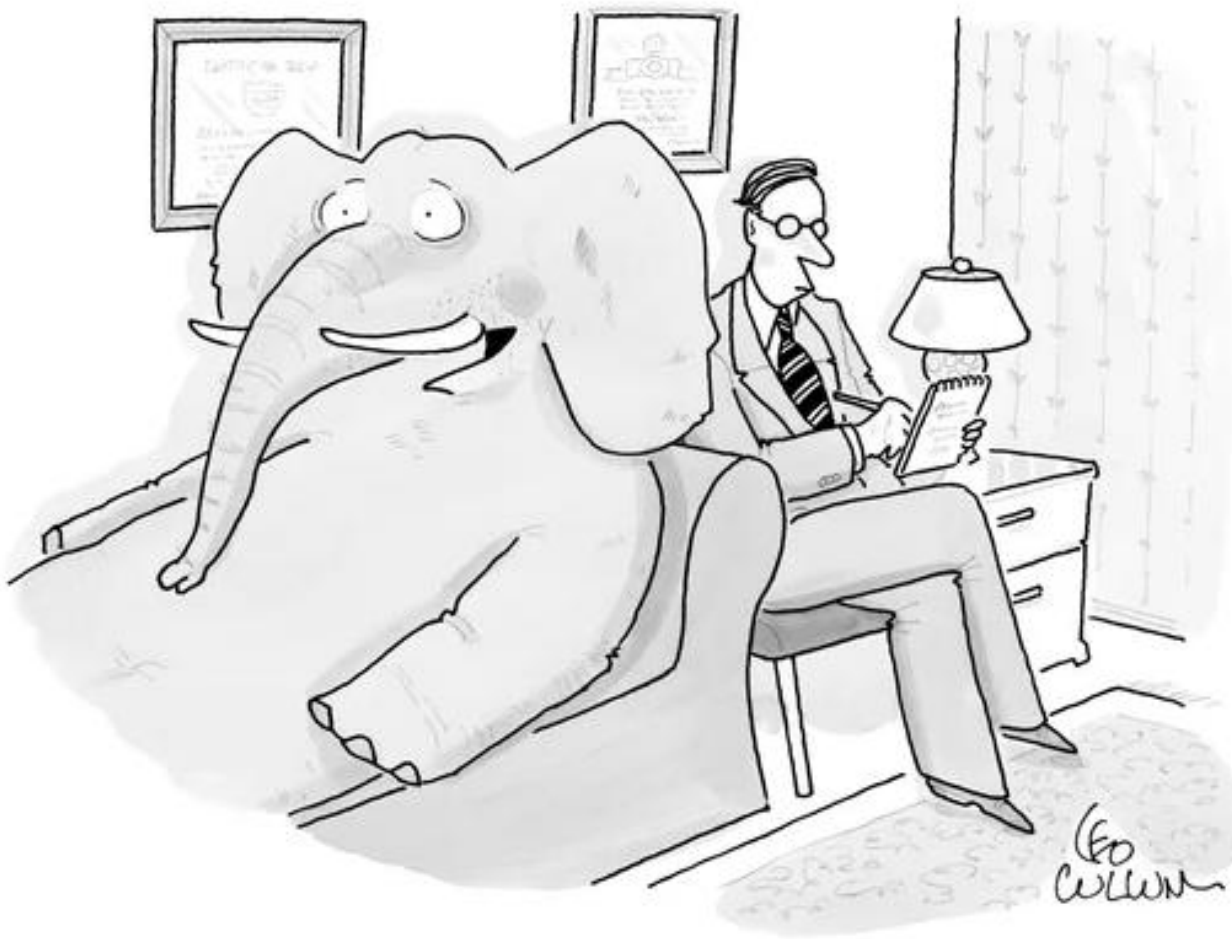
Policy shift: Federal government is determining a "Maximum Fair Price (MFN)" for expanding number of high sales pharmaceuticals. Divergent pricing between U.S. and other comparable high-income countries "unacceptable". Pilot initiatives to explicitly link prices in U.S. to prices ex-U.S.

Drug prices + Add to myFT

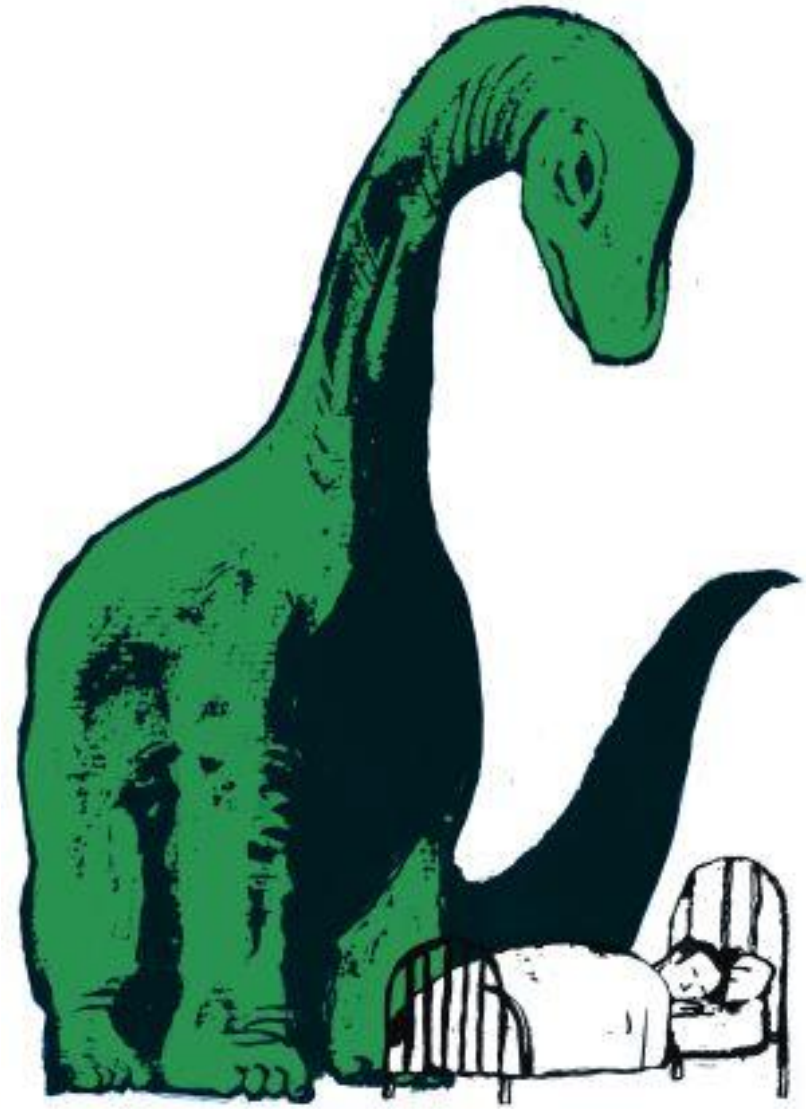
US launches trade investigation into Germany's spending on new medicines

So-called Section 301 probe escalates Washington's drug pricing war with Europe

US Trade Representative Jamieson Greer has called recent German legislation a 'serious step backwards' © David Paul Morris/Bloomberg



"I'm right there in the room, and no one even acknowledges me."

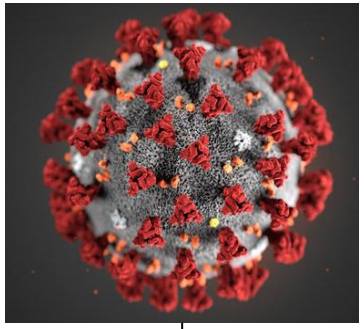


Council of the EU

PRESS
EN

PRESS RELEASE
350/16
17/06/2016

Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States



2016 | 1017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026

La legislación de la UE se mueve...

- Pharma Package
- IVDR (In Vitro Diagnostic Regulation 2017/746)
- MDR (Medical Devices Regulation 2017/745)
- Critical Medicines Act
- Reglamento de Ensayos Clínicos (CTR 536/2014)
- Biotech Act
- HTA Regulation (2021/2282)

about MFN

The MFN debate is not merely about price levels but about fundamentally different health system models. Europe combines value-based assessment, broad access, and regulatory coherence, resulting in a volume-driven and stable pharmaceutical market where predictability helps sustain industry revenues despite lower unit prices.

Europe and the U.S. face the same structural challenge

Both EU countries and the US are working to curb the sustained growth of pharmaceutical expenditure while preserving innovation and access. In this context, the U.S. introduced the Most Favored Nations (MFN) policy, proposing international price referencing—including European prices—to lower drug costs for American patients.

The MFN debate rests on two contested assumptions

First, that the return on investment gap between the U.S. and the EU implies that pharmaceutical **companies are "underpaid" outside the U.S**. Second, that **comparing pharmaceutical expenditure as a percentage of GDP accurately reflects price differences**, when in fact it conflates demographics, utilization rates, system design, and standards of care.

European systems are not simply "lower-priced," but structurally different

Europe relies on value-based assessment and cost-effectiveness analysis (HTA), leading to more selective and protocol-driven use of medicines. Lower expenditure often reflects policy choices, evidence-based prescribing, and structured care pathways—including substitution with non-pharmaceutical interventions where appropriate.

Higher spending does not automatically mean better outcomes

Indicators such as avoidable mortality suggest that European systems, despite lower per capita spending, achieve outcomes comparable to—or in some cases better than—the United States. System organization and care coordination are critical determinants.

Industry reactions to U.S. price reductions are not linear

The assumption that lowering U.S. prices would necessarily require higher prices in Europe or reduced innovation is based on a static view of revenue. In reality, **price, volume, and access interact dynamically**: **lower prices may expand treated populations and partially or fully offset revenue reductions.**

Europe as a pharmaceutical market: scale, stability, predictability

From a demographic perspective, the EU+EEA (~455 million people) exceeds the U.S. population (~335 million) and offers near-universal coverage (≈98–100%). While unit prices may be lower, broad coverage and stable reimbursement mechanisms create a large, predictable, and structurally reliable market.

a) Regulatory EU vs. US approval timelines

Products typically take longer to obtain marketing authorization in the EU than in the US. Key drivers of delay are industry strategies with priority review or accelerated approval more widely used in the US vs. the EU (most likely impacted by subsequent access policies)

b) Post-authorization: Time to initiate P&R

After approval, companies often delay initiating P&R procedures in the EU, varying by country and strategy. Reasons include the need to prepare country-specific value dossiers and HTA submissions, sequencing strategy across markets (launch order optimization), or internal alignment on pricing corridors and evidence packages

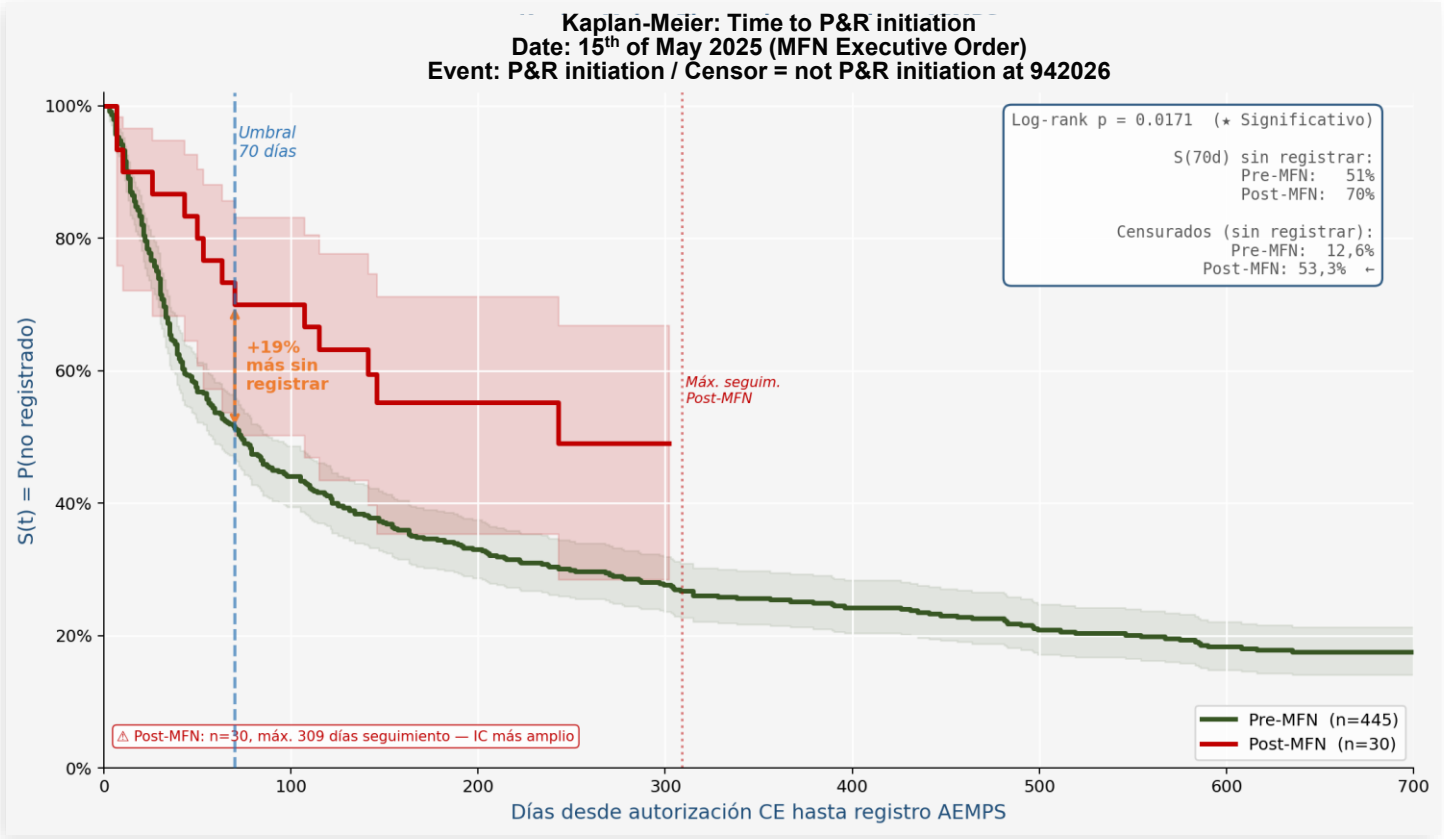
c) Duration of the P&R process itself

MFN policies can influence both timing and complexity of P&R negotiations.

Observed effects: (i) delays in initiating or progressing negotiations to avoid triggering low reference prices, (ii) increased strategic sequencing of launches across countries, (iii) greater negotiation complexity, requiring tighter control of price disclosure and agreements

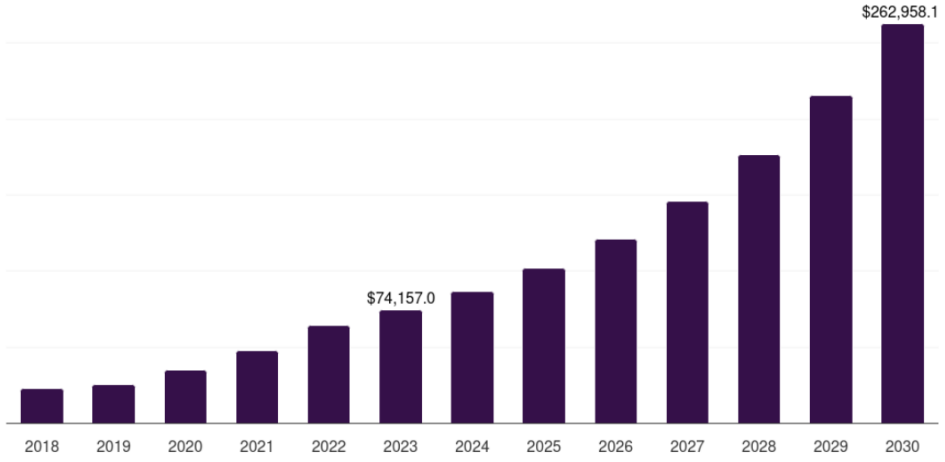
Potential outcomes: (i) higher initial list prices in some markets to protect global price corridors, (ii) or conversely, restricted access / delayed launches to manage international reference pricing risk

Overall, MFN contributes to slower, more complex, and more strategically constrained P&R processes



Post-MFN (15/05/2025) analysis: 53% of medicines authorized did not initiated P&R procedures in Spain (vs. 13% historically). When compared within the same time window, the percentage of medicines without initiating P&R procedures changed from 9% (2023) and 16% (2022) to 53% in 2025. Log-rank test confirmed a statistically significant difference (p = 0,017) even with such a low numbers.

China biotechnology market, 2018-2030 (US$M)



Chinese companies

U.S. licensers

Distracted by the US, Surpassed by China

Europe Is Watching Washington While China Is Building the Future

While Europe remains largely focused on responding to U.S. protectionist measures and managing transatlantic trade tensions, China continues to execute a long-term industrial strategy that is rapidly strengthening its position across biopharmaceutical innovation, clinical development, and advanced manufacturing.

Regulatory Fine-Tuning Cannot Substitute for Industrial Ambition

The European debate remains heavily centred on regulatory incentives and legislative reforms, whereas its main competitors are deploying comprehensive industrial policies supported by substantial public investment, strategic coordination, and a clear commitment to technological leadership

China Has Moved from Manufacturing Hub to Innovation Powerhouse

The growing ability of Chinese companies to generate innovative assets, attract global clinical development programmes, and out-license novel therapies to Western pharmaceutical companies illustrates that competition has moved well beyond low-cost manufacturing and into the highest-value segments of the pharmaceutical value chain.

Regulatory Activity Is Not a Growth Strategy

There is a risk that Europe mistakes regulatory activity for industrial strategy. New frameworks, action plans, and incentive schemes will struggle to reverse the continent's relative decline unless they are accompanied by meaningful investment, deeper capital markets, and conditions that enable companies to scale and remain globally competitive.

The Real Strategic Challenge Lies to the East

In an increasingly fragmented geopolitical environment, the challenge is no longer simply how to respond to U.S. trade policies, but how to prevent the centre of gravity of pharmaceutical and biotechnology innovation from shifting decisively towards Asia while Europe continues to rely primarily on incremental policy adjustments.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Commission

European Commission

HMA
Heads of Medicines Agencies

HAG
HEADS OF HTA AGENCIES GROUP

NCAPR

R&D

Pharma Industry, developers, distributors

Regulatory bodies

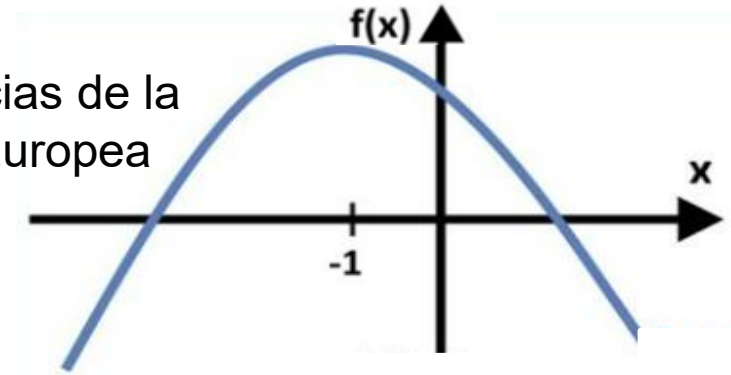
HTA bodies

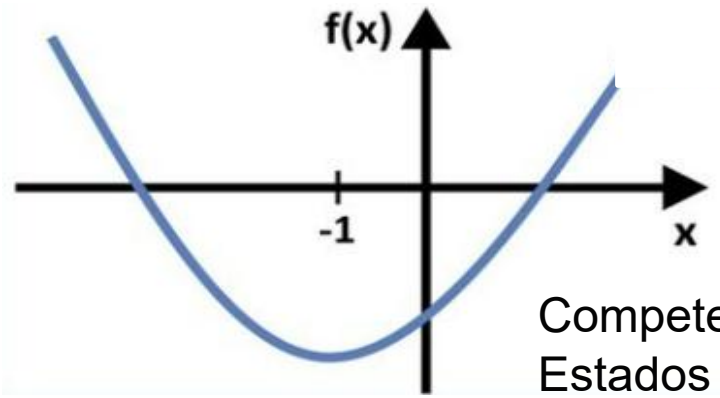
Payers/Buyers

NHS

Patients

Competencias de la Comisión Europea





Competencias de los Estados Miembros

Economic growth
Employment
Geopolitical influence

VALUE

R&D

Pharma Industry, developers, distributors

Access
Knowledge
Industrial investment

VALUE

Regulatory excellence

VALUE

Regulatory bodies

HTA bodies

Better NHS performance

VALUE

Payers/Buyers

NHS

Patients

VALUE

Prevention
Health
QoL
Productivity

VALUE

NHS Excellence
R&D Incentives
Industrial incentives
Tax incentives

VALUE

Price (x volumes)
Procurement

Push Incentives

Regulatory excellence

Pull Incentives

R&D

Pharma Industry, developers, distributors

Regulatory bodies

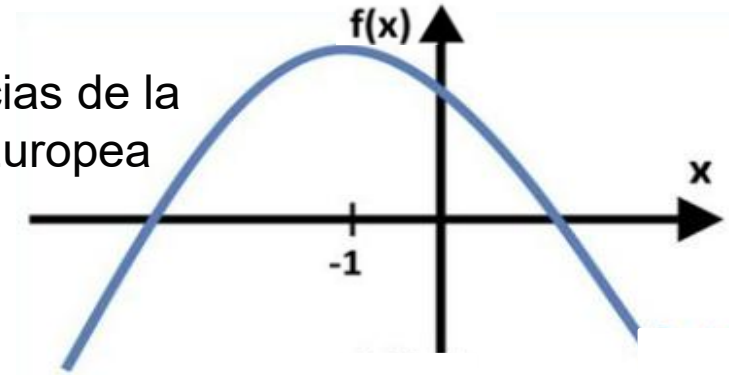
HTA bodies

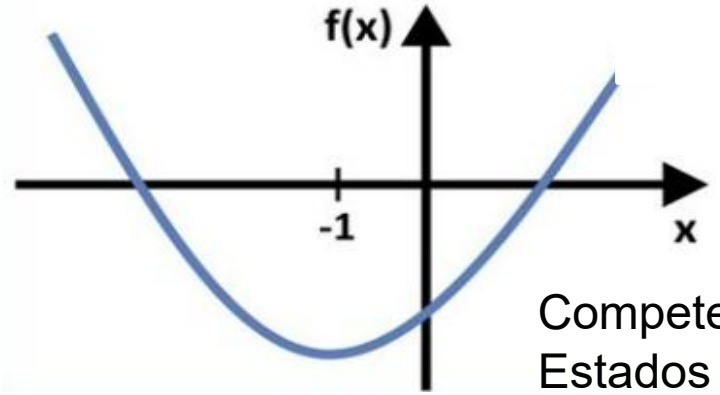
Payers/Buyers

NHS

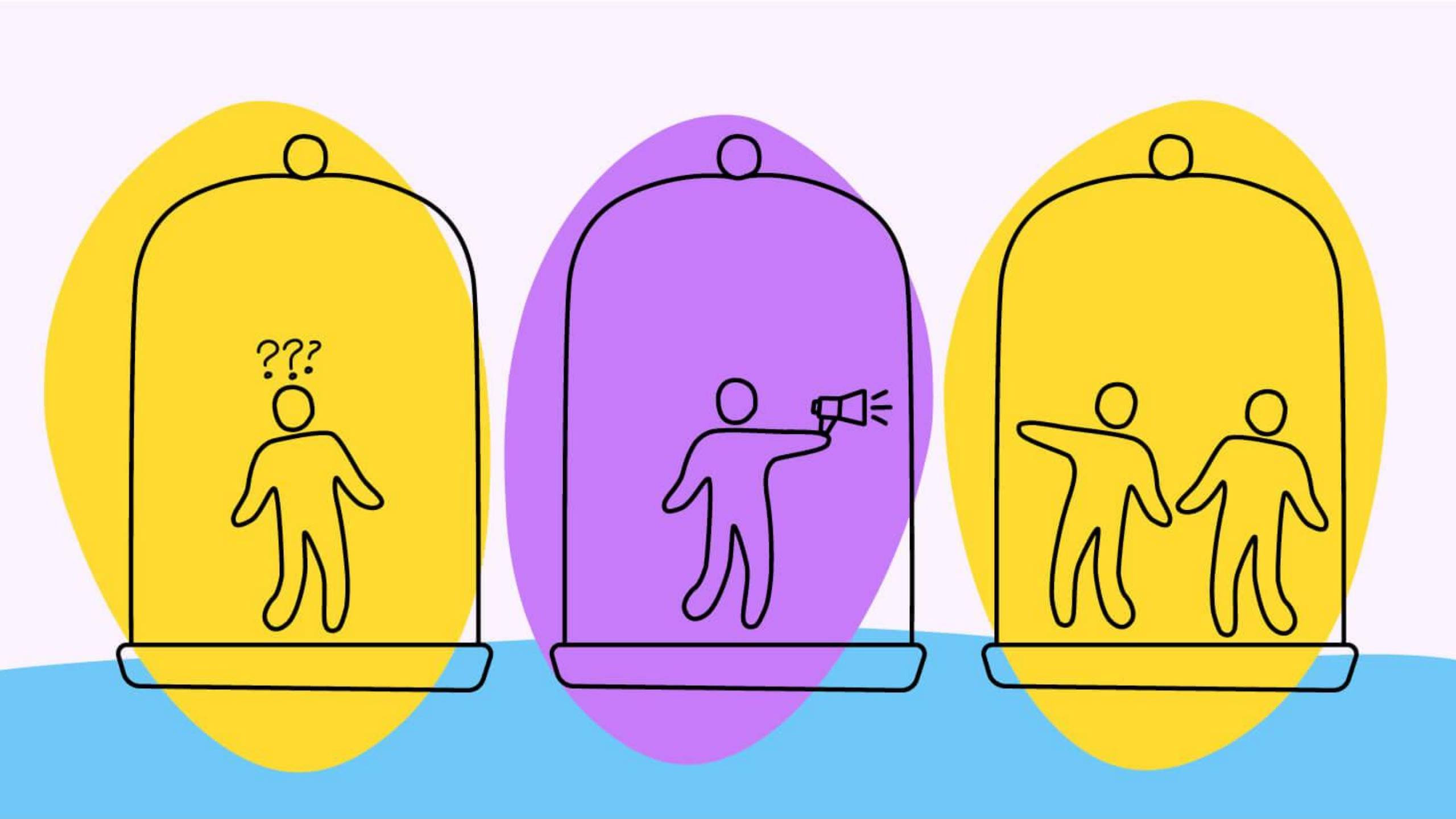
Patients

Competencias de la Comisión Europea





Competencias de los Estados Miembros



Juguemos a encontrar las diferencias

- En España se matriculan anualmente alrededor de **1 millón de turismos nuevos**.
- Las adquisiciones realizadas por administraciones públicas (Estado, CCAA, ayuntamientos, policía, guardia civil, empresas públicas, etc.) suelen representar del orden del **2%-5% del mercado**, dependiendo del año y de los ciclos de renovación de flotas.
- Es decir, más del **95% del mercado del automóvil es privado** (particulares, empresas y renting privado). La demanda pública existe, pero no determina la estructura competitiva del sector.
- En automoción, la política industrial y la regulación son mucho más importantes que la contratación pública.

- En España el gasto farmacéutico total se sitúa en torno a **28.000-30.000 millones de euros anuales**.
- De esa cifra, la parte financiada por el SNS supera ampliamente los **23.000 millones de euros**.
- Aproximadamente **70%-80% del mercado farmacéutico español está financiado o comprado por el sector público**.
- Además, en muchos segmentos, el comprador es prácticamente **único**: el sistema público.
- En el sector farmacéutico, la contratación pública, la financiación pública y las decisiones de precio y reembolso son elementos constitutivos del propio mercado.

Estrategia de la Industria Farmacéutica 2024-2028

GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD | MINISTERIO DE HACIENDA | MINISTERIO DE INDUSTRIA Y TURISMO | MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

Estrategia de la Industria Farmacéutica 2024-2028

GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD | MINISTERIO DE HACIENDA | MINISTERIO DE INDUSTRIA Y TURISMO | MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

Publicada el 10 de diciembre de 2024

En Consejo de Estado.
Pendiente segunda vuelta Consejo de Ministros

Ley de los Medicamentos y Productos Sanitarios

RD de evaluación de tecnologías sanitarias

Publicado el 27 de mayo de 2026

RD de financiación y precio de medicamentos

Trámite de audiencia pública iniciado 19 de junio de 2026

Estrategia de la Industria Farmacéutica 2024-2028

GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD | MINISTERIO DE HACIENDA | MINISTERIO DE INDUSTRIA Y TURISMO | MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

Ley de los Medicamentos y Productos Sanitarios

a) gravedad, duración y secuelas de las patologías (…), así como la carga de enfermedad asociada. b) necesidades específicas de determinados colectivos, (…). c) valor terapéutico y social del medicamento, considerando su beneficio clínico incremental, la mejora en resultados en salud, calidad de vida, adherencia terapéutica u otros (…). d) La relación coste-efectividad, coste-utilidad u otras evaluaciones económicas, (…) impacto presupuestario (…). e) alternativas terapéuticas. f) innovación del medicamento, (…) AMR, así como mecanismos de acción, tecnologías o abordajes clínicos novedosos. g) contribución del medicamento a la sostenibilidad y resiliencia del SNS, competencia, diversificación y seguridad del suministro, la multiplicidad de indicaciones autorizadas, las combinaciones terapéuticas obligadas. h) contribución del medicamento a objetivos de interés general, incluyendo su impacto en la generación de renta y actividad económica, productividad, autonomía estratégica, investigación clínica y preclínica, desarrollo e innovación biomédica vinculada al SNS, así como la reducción del impacto medioambiental.

RD de evaluación de tecnologías sanitarias

Artículo 22. Instrucciones para la evaluación de las tecnologías sanitarias en España.
1. El Ministerio de Sanidad, publicará las directrices, modelo de expediente y guías metodológicas y de procedimiento (…)
2. Para la elaboración y modificación de este cuerpo documental, que tendrá el carácter de documento vivo, se seguirá un procedimiento participativo, deliberativo y transparente (…).

Directrices de implementación

- Evaluación Económica
- Impacto presupuestario
- Incertidumbre
- Combinaciones
- Financiación

RD de financiación y precio de medicamentos

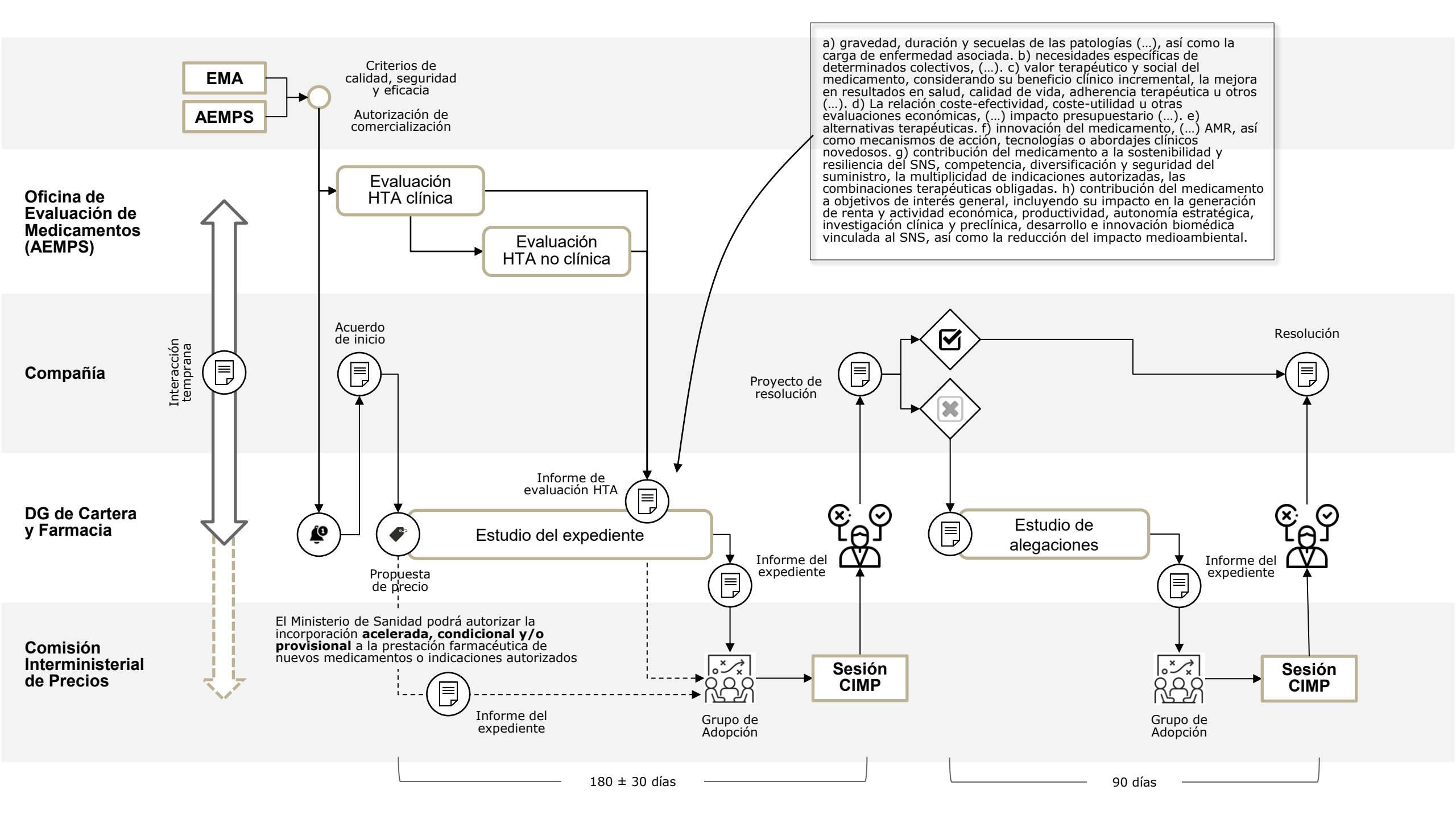
Artículo 7. *Criterios para la financiación pública de los medicamentos*
a)
b)
c)
n) (…).

Gestión de la información y los datos

- SI nacional de consumo de medicamentos y productos sanitarios
- VALTERMED
- BIFAP

Planes en marcha o nuevos

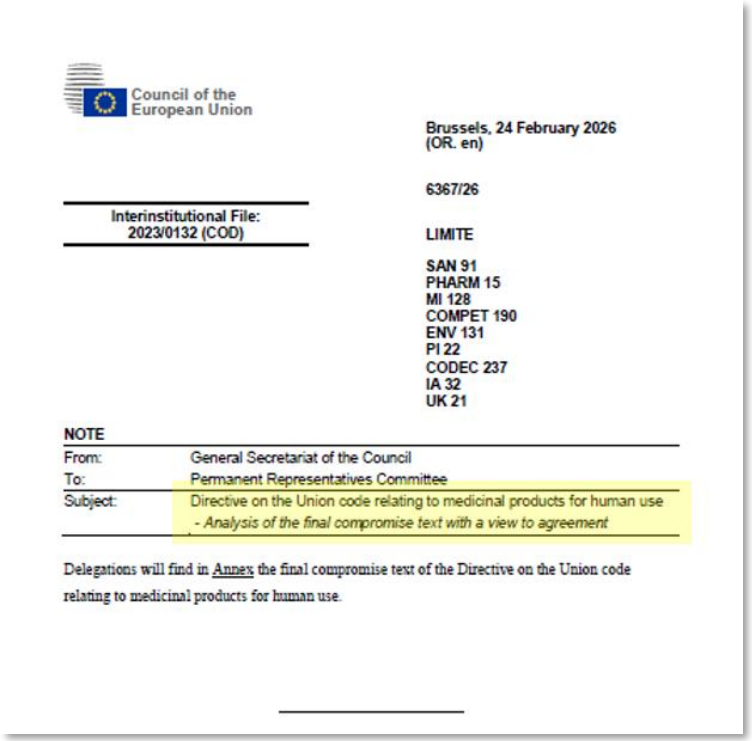
- PROFARMA
- Genéricos y Biosimilares
- Biomarcadores
- Modelos de Gestión


EMA
AEMPS
Criterios de calidad, seguridad y eficacia
Autorización de comercialización
Oficina de Evaluación de Medicamentos (AEMPS)
Evaluación HTA clínica
Evaluación HTA no clínica
a) gravedad, duración y secuelas de las patologías (…), así como la carga de enfermedad asociada. b) necesidades específicas de determinados colectivos, (…). c) valor terapéutico y social del medicamento, considerando su beneficio clínico incremental, la mejora en resultados en salud, calidad de vida, adherencia terapéutica u otros (…). d) La relación coste-efectividad, coste-utilidad u otras evaluaciones económicas, (…) impacto presupuestario (…). e) alternativas terapéuticas. f) innovación del medicamento, (…) AMR, así como mecanismos de acción, tecnologías o abordajes clínicos novedosos. g) contribución del medicamento a la sostenibilidad y resiliencia del SNS, competencia, diversificación y seguridad del suministro, la multiplicidad de indicaciones autorizadas, las combinaciones terapéuticas obligadas. h) contribución del medicamento a objetivos de interés general, incluyendo su impacto en la generación de renta y actividad económica, productividad, autonomía estratégica, investigación clínica y preclínica, desarrollo e innovación biomédica vinculada al SNS, así como la reducción del impacto medioambiental.
Compañía
Interacción temprana
Acuerdo de inicio
Proyecto de resolución
Resolución
DG de Cartera y Farmacia
Informe de evaluación HTA
Estudio del expediente
Propuesta de precio
Informe del expediente
Estudio de alegaciones
Informe del expediente
Comisión Interministerial de Precios
El Ministerio de Sanidad podrá autorizar la incorporación **acelerada, condicional y/o provisional** a la prestación farmacéutica de nuevos medicamentos o indicaciones autorizados
Informe del expediente
Grupo de Adopción
Sesión CIMP
Grupo de Adopción
Sesión CIMP
180 ± 30 días
90 días

2016 | 1017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026

La legislación de la UE se mueve…

- Pharma Package
- IVDR (In Vitro Diagnostic Regulation 2017/746)
- MDR (Medical Devices Regulation 2017/745)
- Critical Medicines Act
- Reglamento de Ensayos Clínicos (CTR 536/2014)
- Biotech Act
- HTA Regulation (2021/2282)



Council of the European Union

Brussels, 24 February 2026
(OR. en)

6367/26

Interinstitutional File:
2023/0132 (COD)

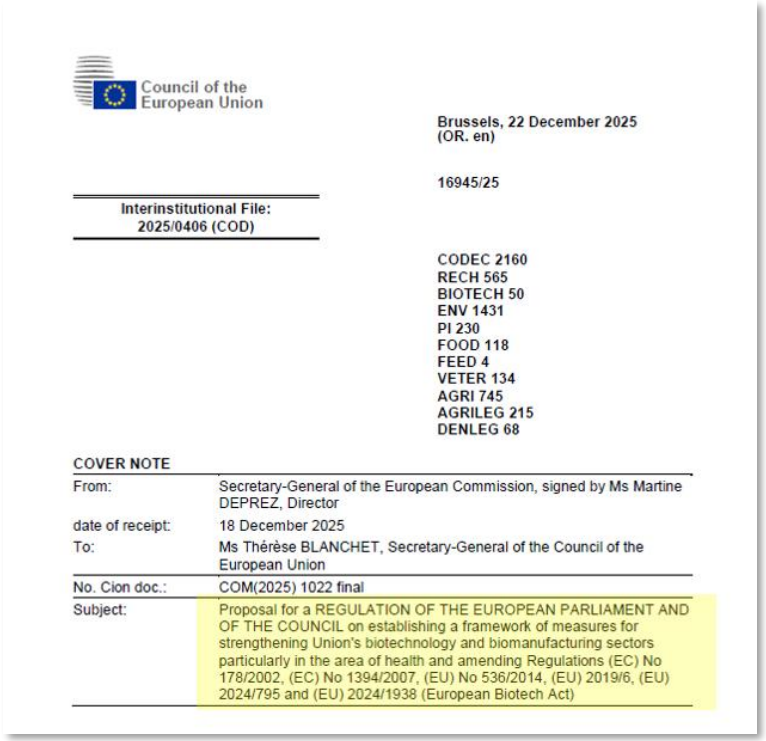
LIMITE

SAN 91
PHARM 15
MI 128
COMPET 190
ENV 131
PI 22
CODEC 237
IA 32
UK 21

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Directive on the Union code relating to medicinal products for human use *- Analysis of the final compromise text with a view to agreement*

Delegations will find in Annex the final compromise text of the Directive on the Union code relating to medicinal products for human use.



Council of the European Union

Brussels, 22 December 2025
(OR. en)

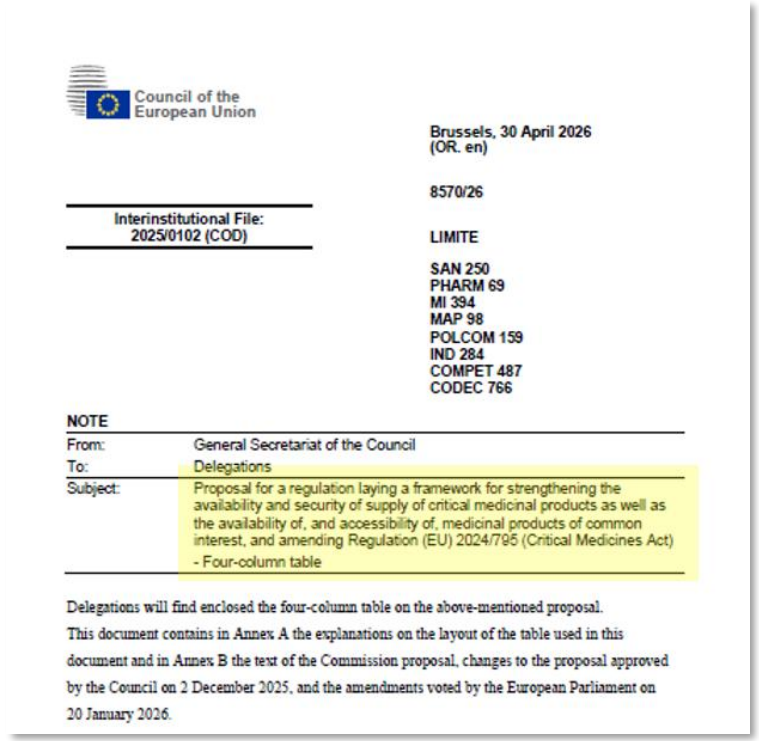
16945/25

Interinstitutional File:
2025/0406 (COD)

CODEC 2160
RECH 565
BIOTECH 50
ENV 1431
PI 230
FOOD 118
FEED 4
VETER 134
AGRI 745
AGRILEG 215
DENLEG 68

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	18 December 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 1022 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)



Council of the European Union

Brussels, 30 April 2026
(OR. en)

8570/26

Interinstitutional File:
2025/0102 (COD)

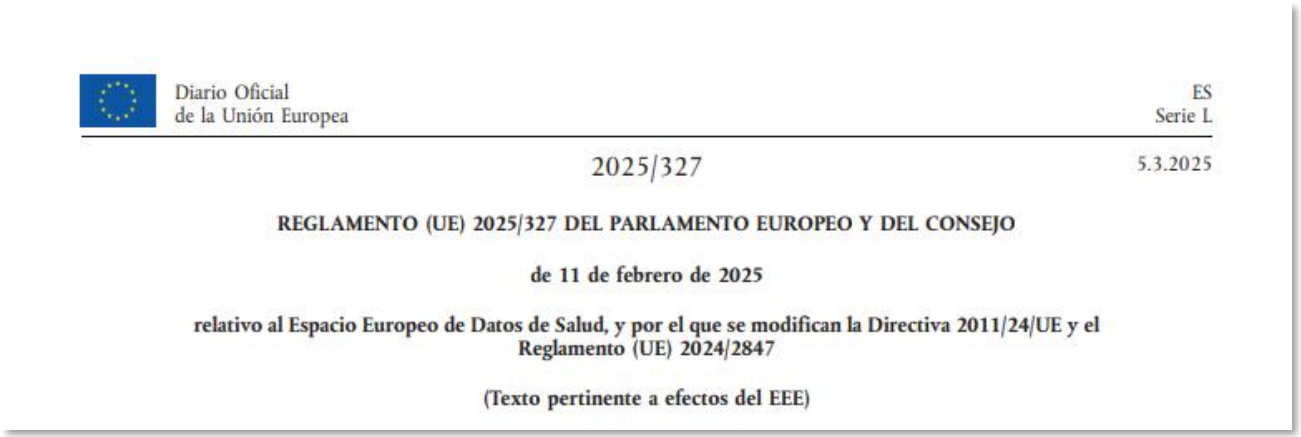
LIMITE

SAN 250
PHARM 69
MI 394
MAP 98
POLCOM 159
IND 284
COMPET 487
CODEC 766

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Four-column table

Delegations will find enclosed the four-column table on the above-mentioned proposal.
This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, changes to the proposal approved by the Council on 2 December 2025, and the amendments voted by the European Parliament on 20 January 2026.



Diario Oficial
de la Unión Europea

ES
Serie L

2025/327

5.3.2025

REGLAMENTO (UE) 2025/327 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 11 de febrero de 2025

relativo al Espacio Europeo de Datos de Salud, y por el que se modifican la Directiva 2011/24/UE y el Reglamento (UE) 2024/2847

(Texto pertinente a efectos del EEE)

Más allá de la reforma regulatoria y la política industrial, el Espacio Europeo de Datos de Salud (EHDS) tiene el potencial de transformar radicalmente el ecosistema de las ciencias de la vida. Al facilitar el acceso seguro, interoperable y a gran escala a los datos sanitarios en todos los Estados miembros, el EHDS podría mejorar significativamente la investigación clínica, acelerar la generación de evidencia, optimizar el reclutamiento de pacientes y fortalecer el atractivo de Europa.

"There are only two kinds of countries in Europe: small countries, and countries that have not yet realised they are small"

— *Paul-Henri Spaak*
— *Jean-Claude Juncker*
— *Josep Borrell*
— *Vytenis Andriukaitis*

Europe accounts for roughly 7% of the world's population and remains one of the largest economic blocs, but its relative weight in the global economy is set to decline steadily over the coming decades.

In a world increasingly shaped by continental-scale competition, no European country, regardless of its size, can compete alone with the economic, technological, and industrial power of the United States or China.

This reality is particularly evident in the pharmaceutical and biotechnology sectors, where innovation ecosystems, capital markets, data resources, manufacturing capacity, and industrial policy are becoming key determinants of competitiveness.

While Europe often focuses on refining regulatory frameworks and responding to transatlantic trade tensions, China continues to build scale through coordinated industrial policies, strategic investment, and long-term technological planning.

The central question is therefore not whether Europe needs **more regulation or more incentives**, but whether it is prepared to act with the scale, speed, and ambition required to remain a leading pharmaceutical and biotechnology power.

NCAPR
National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers

NCAPR Background paper

The European pharmaceutical market beyond pricing: Stable, predictable, innovative and socially grounded

Final version
15 April 2026

10. Conclusion

Europe is a valuable market for pharmaceutical innovation.

European countries prioritise universal access, clinical value and long-term sustainability, ensuring that valuable therapies reach patients efficiently. The strong and unbiased regulatory framework, supported by evidence-based market access through HTA's, creates a climate where innovation is both rewarded and aligned with health goals. With nearly 450 million citizens insured by universal health coverage, Europe offers pharmaceutical companies a high-volume market, in which reimbursement decisions are transparent and predictable.

Europe continues to improve on delivering access to fast and proven care.

Countries focus on the triad of timely access, quality and efficiency. This has prompted initiatives such as EMA's PRIME program, early scientific consultations and horizon scanning, joint clinical assessments and national efforts to optimise treatment protocols and real-world evidence generation. The strong research infrastructure is supported by EU programs such as Horizon Europe and by public-private partnerships. Legislative changes such as the HTA Regulation, European Health Data Space, and the anticipated Biotech act, show Europe's efforts to balance innovation and ensuring sustainable access.

Europe is profitable, health-oriented and open for dialogue.

Europe makes up for a significant part of global pharmaceutical revenues, where payers have a high willingness to pay for fast access to truly innovative products. Although there is a strong tradition of independent and thorough procedures and decisions, there is room for stakeholders to interact, share ideas and help improve legislation so that it benefits all stakeholders.

A holistic look at the pharmaceutical market shows that Europe remains an attractive and resilient market for the pharmaceutical industry, now and in the future.

Federal Ministry of Health

MINISTÈRE
DE LA SANTÉ, DES FAMILLES,
DE L'AUTONOMIE
ET DES PERSONNES HANDICAPÉES
Liberté
Égalité
Fraternité

Joint Declaration on Strengthening the Pharmaceutical Industry in Europe between the Federal Ministry of Health of the Federal Republic of Germany and the Ministry of Health, Families, Autonomy and Persons with Disabilities of the French Republic

1. Strengthening the EU as a location for clinical research
2. Easing the market launch of new medicinal products by harmonising the benefit assessment
3. Strengthening security of supply and the industrial base
4. Balancing environmental regulation with safeguarding attractiveness for pharmaceutical companies
5. Improving the protection of intellectual property
6. Addressing global tensions: immediate measures

Beneluxa
Initiative on Pharmaceutical Policy

10 June 2026 - Statement of the Beneluxa Initiative on a more unified European approach to Pricing and Reimbursement of pharmaceutical products

Countries in the European Union and the European Economic Area differ in how they organise, insure and provide health care. Yet there is one important unifying factor: access to health care is broadly considered to be a social right[1]. With patients' interests and social accountability in mind, their citizens can rely on universal health care systems that have delivered health outcomes ranking amongst the best in the world[2].

The Beneluxa Initiative has explored the opportunities and challenges in European collaboration since 2015. We therefore welcome collaborative approaches by Member States to address shared structural challenges within a European framework rather than through uncoordinated individual national responses, while still respecting national competences. Support from the European Commission in facilitating continued dialogue and collaborative working would enhance the ability of Member States to achieve this. This approach endorses Europe as an attractive location that guarantees legal stability and safeguards scientific advancement. This is a goal we share.

In turbulent geopolitical times, we believe that the current developments in the pharmaceutical system require unity and coordination to safeguard long-term affordable pharmaceutical care for European patients, while providing a strong and targeted approach to innovation in Europe.

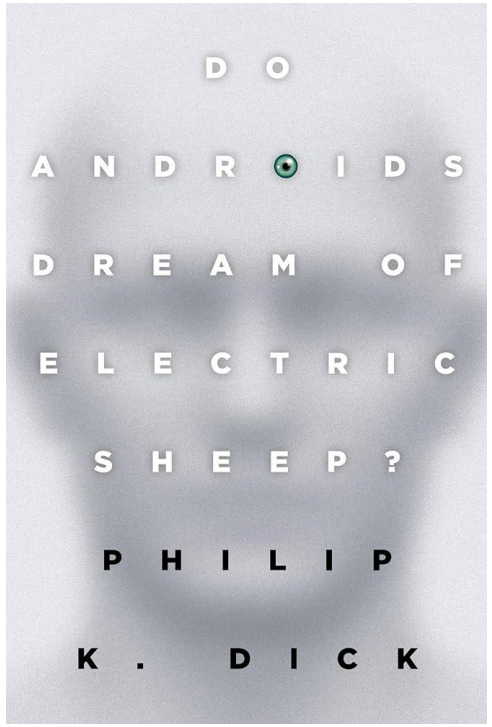
Although Europe remains an attractive economic and innovative place for the pharmaceutical sector, recent geopolitical developments have highlighted more fundamental challenges in pharmaceutical policy across Europe. These challenges require a fundamental review.

System optimisation

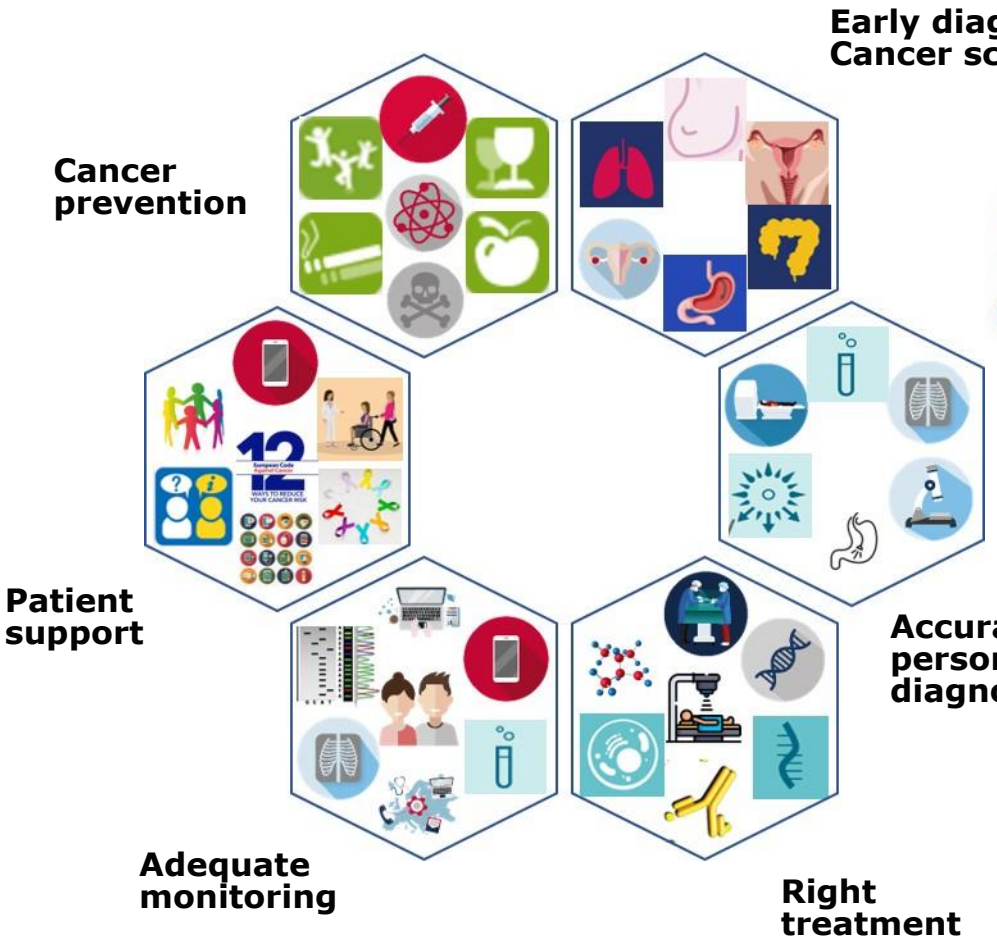
We believe that there is an opportunity for deeper cooperation to further strengthen and support the way in which pricing and reimbursement is carried out in Europe. European health care systems fundamentally distinguish between economic and health care outcomes. Medical interventions are assessed on the impact they have on population health, rather than their economic impact alone. Maintaining this strong, science-based approach, while fully respecting national competences, joint efforts could aid in reducing lead times to new, valuable products. Among others, increased information sharing, quickly expanding the uptake of HTA-R outcomes and streamlining P&R procedures on a mutually agreed collaborative basis, should ultimately lead to a more unified European approach to pricing and reimbursement of new treatments. Collaborative approaches on pricing and purchasing, including those facilitated by the Critical Medicines Act, should be explored. In

[1] European Social Charter of the Council of Europe, art. 11
[2] Background paper on the European pharmaceutical market (April 2026), Network of Competent Authorities on Pricing and Reimbursement (NCAPR)

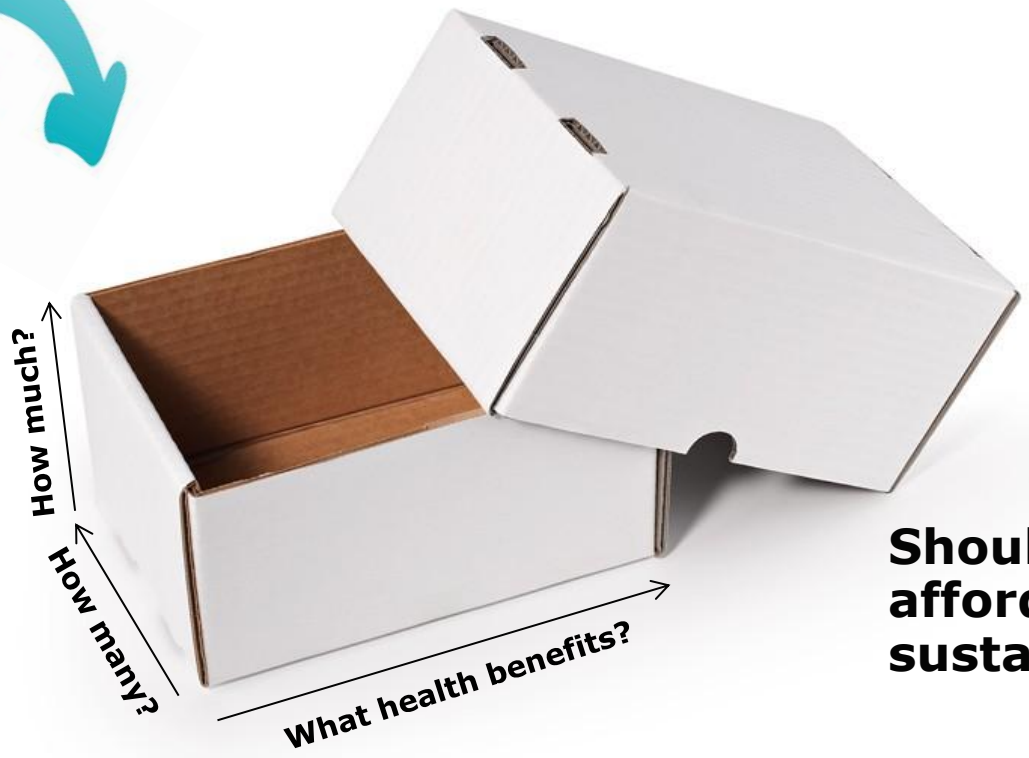
What do buyers dream of?



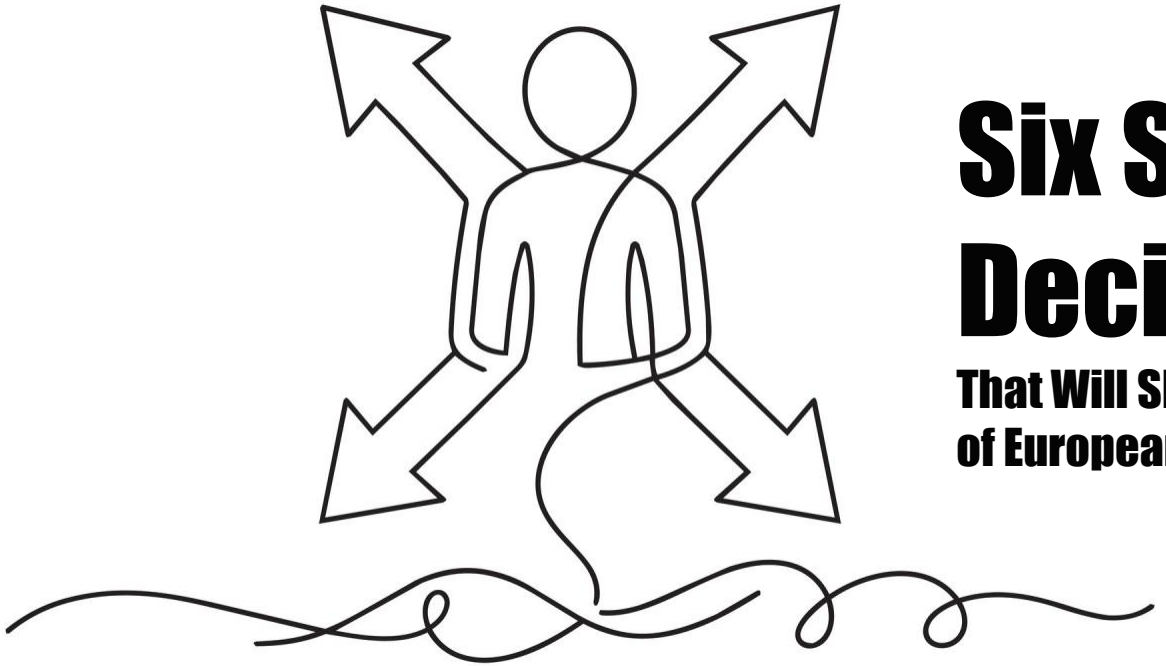
What are we pulling from when we fill the box?



The box for the provision of health services



Should be affordable and sustainable



Six Strategic Decisions

That Will Shape the Future of European Healthcare

"Made in Europe" y contratación pública estratégica

El debate no es solo sanitario, sino geopolítico (AMR, CMA y Biotech act).

- Dar más peso en las licitaciones públicas a la producción europea.
- Introducir criterios de "seguridad de suministro" además del precio.
- Favorecer proveedores con fabricación en Europa.
- Crear capacidades productivas estratégicas para medicamentos críticos.

La pregunta de fondo es: ¿Debe Europa pagar más por un medicamento fabricado en Europa si eso reduce el riesgo de desabastecimiento?

Reforma del SPC

Este es probablemente uno de los asuntos más sensibles y de posición más dispar.

Es el incentivo más potente de la Biotech act, pero no deja de ser una surrogada del acceso que se sitúa, además, muy al final de la vida comercial del producto (cuando el valor del incentivo es menor).

La extensión de la protección retrasa la competencia y, necesariamente, incrementan el gasto sanitario.

No está ligada a elementos ortodoxos de la HTA de medicamentos (ensayos clínicos, producción en Europa, nuevo principio activo, nuevo mecanismo de acción)

Probablemente es solo mejor que no hacer nada.

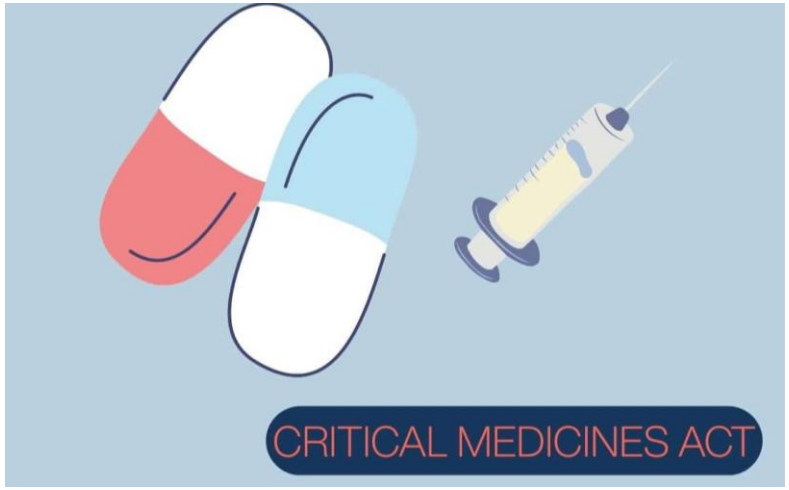
Incentivos “push” en Europa

Europa reconoce que tiene buena ciencia, pero le cuesta transformar investigación en empresas globales.

Por ello el debate se centra en:

- Mayor participación del Banco Europeo de Inversiones en biotecnología.
- Fondos específicos para escalado industrial.
- Financiación de fabricación.
- Apoyo a terapias avanzadas y producción de medicamentos críticos.

Muchos informes europeos señalan que EEUU financia mejor el paso de la investigación al mercado y que Europa pierde empresas innovadoras en fases de crecimiento.



Orientación de la CMA

La verdadera discusión es sobre si Europa está dispuesta a sacrificar parte de la eficiencia basada en precios para comprar resiliencia, soberanía industrial y capacidad productiva propia.

¿Cómo definir “producción europea” para que el sistema sea real?

Compras conjuntas: ¿más Europa o más soberanía nacional?

¿Quién –y cómo- financia la reindustrialización? Y si se financia, ¿servirá si luego no se compra?

El Critical Medicines Act es menos una ley farmacéutica que una ley de política industrial aplicada a la salud, ¿se puede hacer sin los pagadores?

Reequilibrio del sistema farmacéutico

¿Cómo reforzar los incentivos a la innovación al mismo tiempo que se promueve una mayor competencia y se garantiza la sostenibilidad?.

¿Cómo afecta la competencia entre innovadores a la entrada de biosimilares?

¿Cómo recuperar los precios de medicamentos de alto valor sin incrementar el gasto farmacéutico?

El debate trasciende lo estrictamente sanitario. La política farmacéutica se integra progresivamente con la política industrial, la ciencia y la innovación, y la gestión de cadenas de suministro.

Y, en este contexto, ¿hacia dónde va la HTA?

Europa debe hacer un esfuerzo por identificar quienes son sus actores y cómo se reparten los papeles

Solo hay dos elementos decisorios, la autorización de comercialización y la decisión de financiación

La HTA “procedimental” debe proporcionar la información relevante que estos decisores le pidan

Atención a la nueva posición de FR y DE y cómo afecta al statu quo actual

El nuevo equilibrio farmacéutico europeo ya no es solo sanitario, es también industrial

Cada decisión sobre acceso o precio es una decisión sobre dónde se produce, quién innova y quién pierde capacidad productiva. La política de salud no es neutral.

La sostenibilidad no puede evaluarse solo en términos de gasto sanitario, sino de inversión sistémica

Si Europa quiere resiliencia y capacidad productiva, estos objetivos deben reconocerse explícitamente en los presupuestos sanitarios, evitando que se carguen de forma implícita o fragmentada en otras partidas.

Integración y transversalidad

La estrategia de la industria farmaceutica española ofrece un modelo en el que se puede mirar Europa

Thanks for your attention

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