European Federation of Pharmaceutical Industries and Associations

Perspectivas empresariales sobre las propuestas de regulacion europea de la industria farmacéutica

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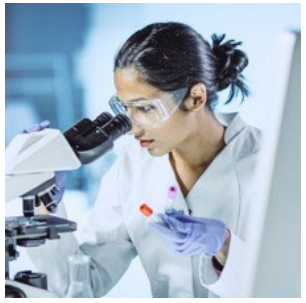



Madrid, 25 April 2024

IMAGINE that patients in Spain/Europe are amongst the first to benefit from cutting edge solutions because medical innovation is created here.

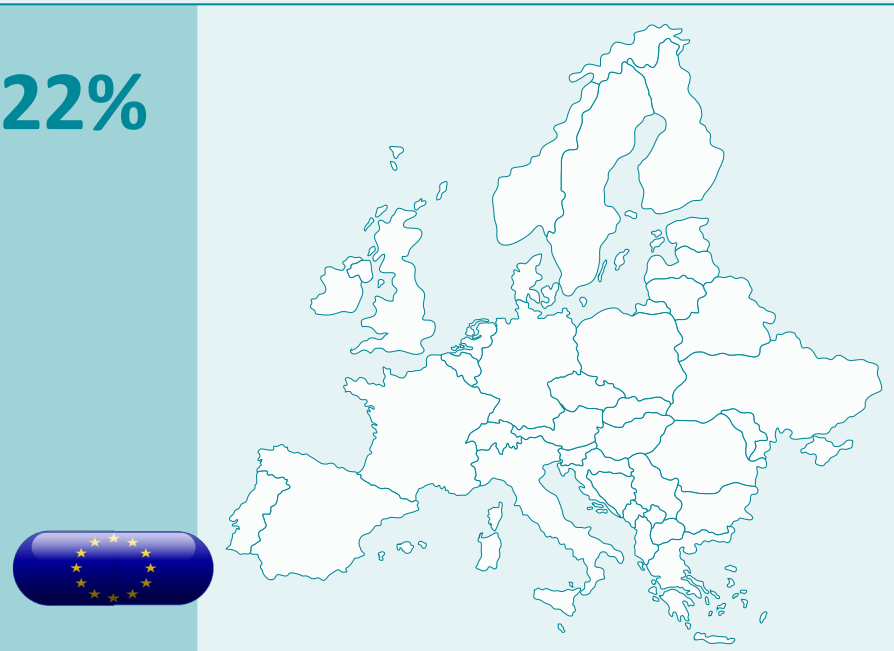
It matters where new solutions (innovations) are developed

- **For Patients: their needs, early access**
- **For Healthcare Systems: capacity and capability building**
- **For Research: translational research ecosystem**
- **For the Economy: trade balance, high added value jobs**

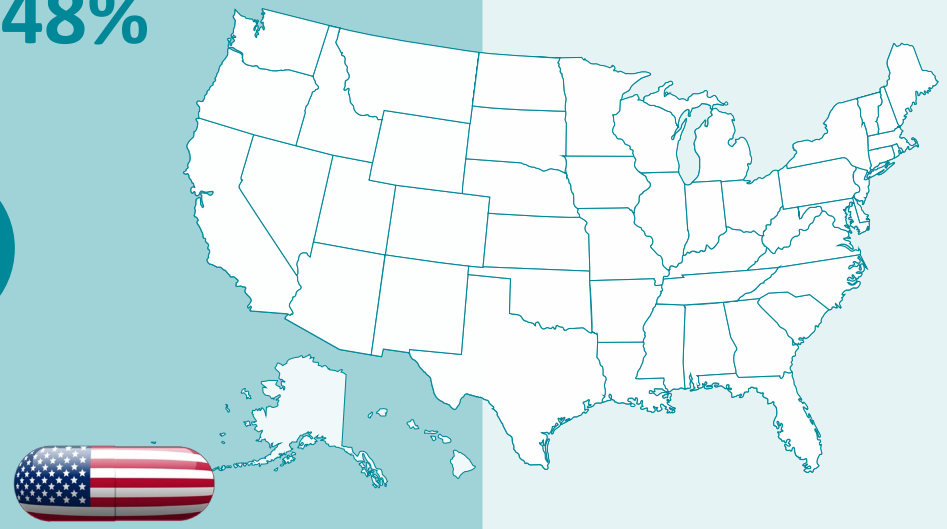
Baseline: Most new therapies are no longer developed in Europe…

WHERE NEW TREATMENTS ORIGINATE

22%



48%



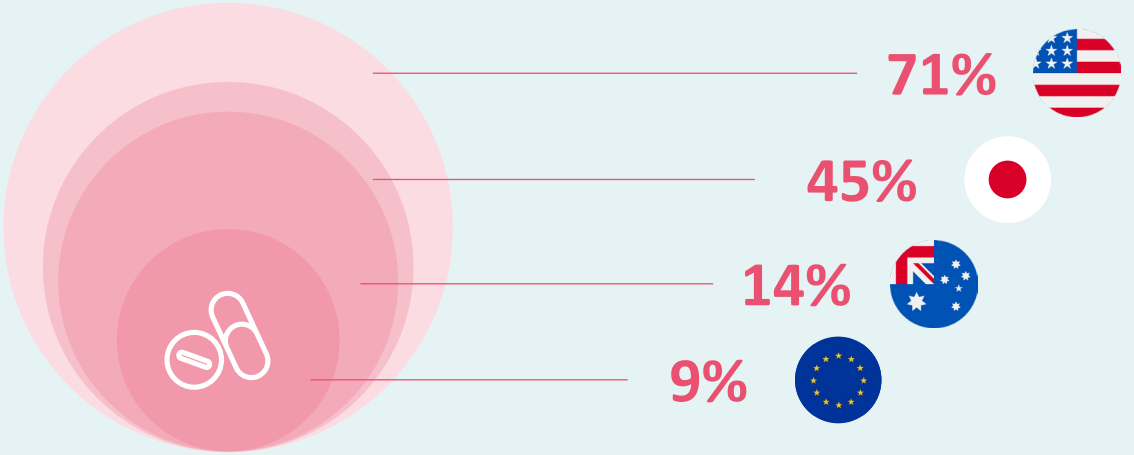
…putting Europe’s strategic autonomy in a societally high-value sector at risk

The European regulatory system is slower than others

Europe is the slowest in the region to approve new medicines in comparison to the US, Japan, Canada and Australia

New therapies approved via expedited reviews in 2021

When compared to other regions of the world, in 2021 the EMA had an extremely low percentage of new active substances approved via expedited reviews



SOURCE: https://cirsci.org/wp-content/uploads/dlm_uploads/2022/06/CIRS-RD-Briefing-85-6-agencies-v2.3.pdf

Why should Europe strengthen its regulatory framework?

Agile, competitive and world-class regulatory system which embraces advances in science, technology and medicines and offers long term perspectives and certainty to investors

Science is evolving faster than before:

The next-generation biotherapeutics make around 10% of the total late-stage R&D pipelines. They have more than doubled in number over the past three years as new pathways for disease treatment and cure evolve

20% of approved products are now combination products, composed of both a medicine and a medical device

The EU is facing fierce competition from other regions to attract 'first wave' new products launches

What's the impact?

The impact of these trends is delayed access to innovative treatments for European patients. And for patients, every day counts

How to tackle that?

Through future proofing regulatory processes, adequate RDP protection, and consistency of other measures with innovation and access objectives

Graph source: CIRS, 2021

Boston invests since 1970 – all ingredients in one place

Intellectual Capital

Cultivating emerging research. Steering emerging inventions.

Growth Capital

Fostering seed-stage companies. Scaling growing businesses.

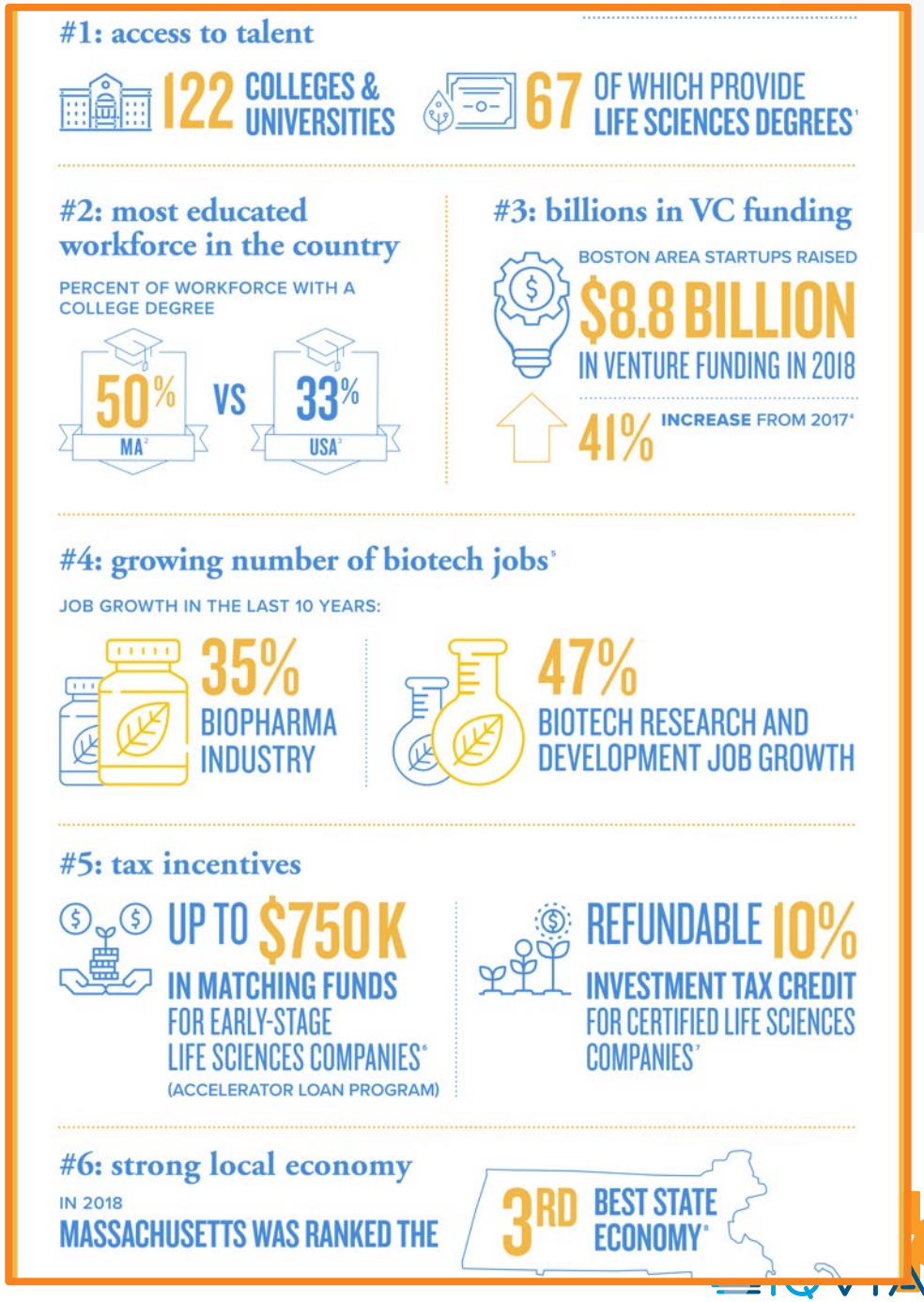
Innovation Capital

Investing in infrastructure. Orienting for innovation.

Human Capital

Strengthening networked connections. Fortifying diversity of talent.

Source: https://fivethirtyeight.com/sponsored/massachusetts-biotech/



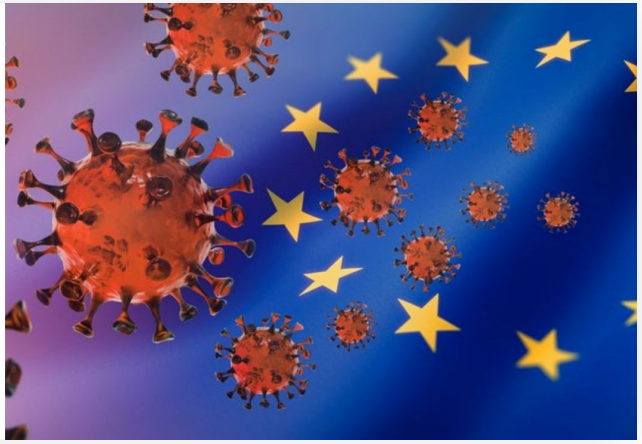
Major revision of EU pharmaceutical laws upcoming and healthcare high up on the Brussels political agenda – how did we get here?

2016

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

2020

COVID-19, war, inflation and energy crisis



November 2020

Pharmaceutical Strategy for Europe

2023

Revision of the EU general pharmaceutical legislation and the orphan and paediatric regulations

Reform of the EU Pharmaceutical Legislation having 6 Key political objectives

No Single Market
Access

Shortages and security of supply
Availability

Budgets
Affordability

Competitive
Regulatory framework

Checking
Environmental sustainability

Combatting
AMR

Single market of medicines in the EU

European Commission

A once in a generation opportunity to upgrade the EU regulatory system and ensure that Europe bridges the gap with other regions and comes back as a world leader in biopharmaceutical innovation to the benefit of European patients

Directive and regulation: what does each cover?

DIRECTIVE

Environmental measures
- Specific requirements for antimicrobials
- Guidance for Environmental Risk Assessments (ERA) for older products
- ERA scope extended to cover the entire life cycle of medicines

Paediatric medicines
- ONLY: Paediatric use marketing authorization procedure

Unmet Medical Need

Regulatory Data Protection (duration, conditionalities, obligations)

Electronic product information

Market Exclusivity for orphan drugs

Transparency

Bolar exemption

REGULATION

Environmental measures
- ERA scope extended to cover the entire life cycle of medicines
- Marketing authorisation refusal in case of ERA requirements not being addressed
- Specific requirements for products containing GMO
- ERA scope extended to cover the entire life cycle of medicines

Paediatric medicines

Assessment and decision timeline

Scientific advice (PRIME)

Security of supply and shortages

European Medicines Agency

Orphan Medicinal Drugs/high unmet medical need

Antimicrobial Resistance

Regulatory sandboxes

EU Commission legislative proposal

Topic areas under discussion

Incentives for innovation
Reduction of regulatory data protection

Future proofing the EU regulatory system
Adapted regulatory framework
for selected technologies

AMR
Holistic approach with measures on
incentives, access, regulatory, environment

Addressing environmental challenges
Include assessment ERA of
manufacturing into MA dossier

Competition: generic, biosimilar entry
Broaden Bolar exemption

Quality & manufacturing
Extended scope of mandatory
inspections and stronger EMA role

Security of supply
Increased obligation for MAH to ensure
appropriate and continued supplies

OMP & Paediatric
OMP: reduction of incentives
PAED: increased obligations and penalties

UMN
Introduction of a narrow
definition of unmet medical need

Pharmaceutical
Regulation and
Directive

EFPIA's perspective on the Commission's proposed measures

Needing further consideration to close the gap

- Regulatory Data Protection
- Market Exclusivity provisions for orphan drugs
- Unmet Medical Need definition and criteria
- Bolar exemption
- Paediatric medicines PIPs
- Environmental risk assessment

Heading in the right direction / almost there

- Regulatory sandboxes
- Electronic product information
- Assessment and decision timeline
- Scientific advice (PRIME)
- Security of supply and shortages
- European Medicines Agency re-structure
- Antimicrobial Resistance Transferable Exclusivity Vouchers

Impact of EC proposals

Refusal of a Marketing Authorisation

Medicines with excellent efficacy proven by clinical trials would not be authorised in Europe, or their continued availability will be compromised affecting treatment journey

Include manufacturing in the environmental risk assessment of antimicrobials

Questionable feasibility. Application one-size-fits-all standards even when local conditions do not require that will unnecesarily disrupt production and supply in Europe of any anti-infective

Prioritisation of ERA for legacy active pharmaceutical ingredients

Appropriate prioritisation of substance will help manage resources for evaluation of legacy products

Increased interlinkage across non-pharma legislations

Application of One Substance One Assessment and application of other sectorial norms to medicines will disrupt production and supply in Europe

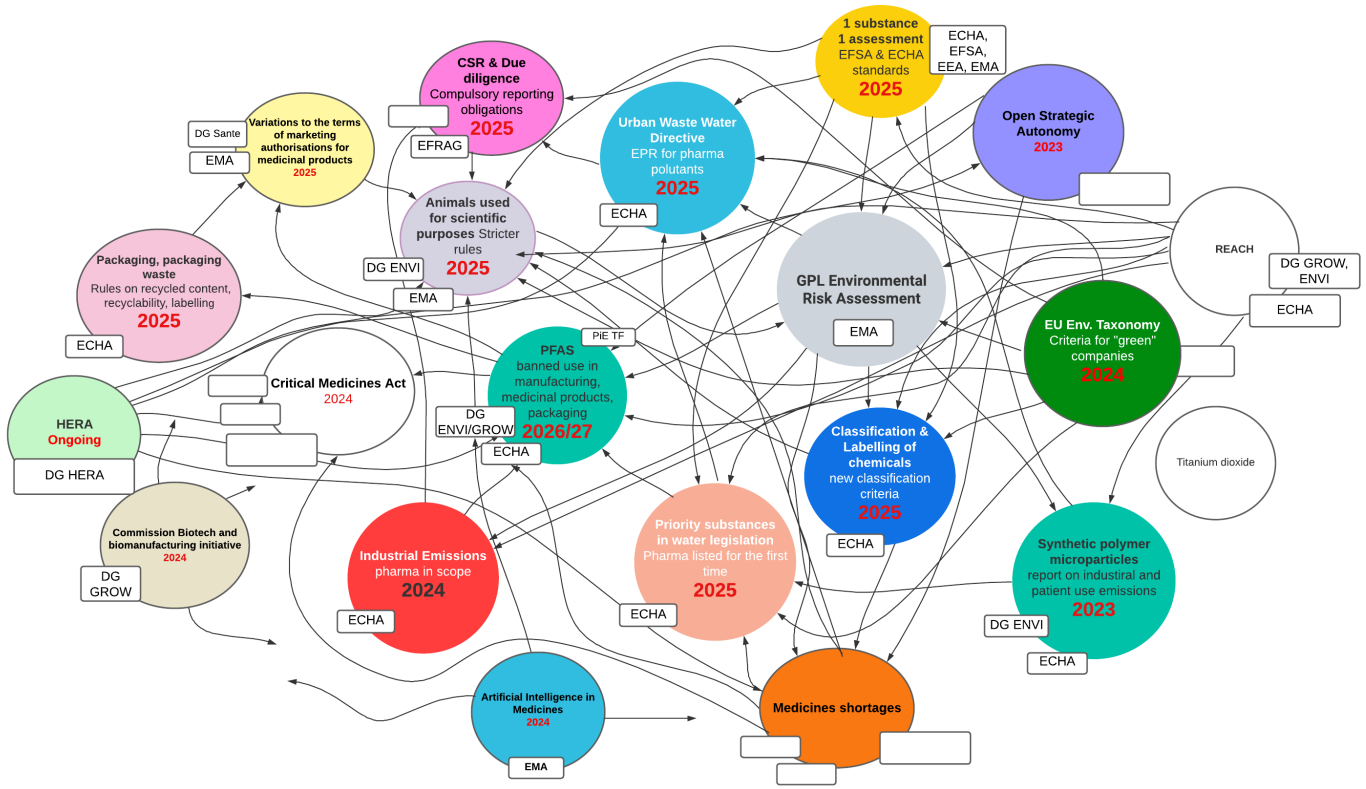
Medicines identified as environmental hazards to be subject to prescription only

Use of common painkillers or antibacterial substances (even disinfectants) may require doctors visit and impact on cost and access to healthcare

Pharmaceutical legislation is just one piece in the puzzle

Interplay between pharma, chemical, food and environmental legislation - uncertainty & disruptions

- **It is more complicated for innovators and regulators to navigate the landscape (multiple interplays and moving targets)**
- **EMA is not always in the lead, even if the B/R evalution of medicinal products is impacted**
- **Practical impact ranges from acceptable admin burden to unnacceptable disruption of decision-making, operations and supply**

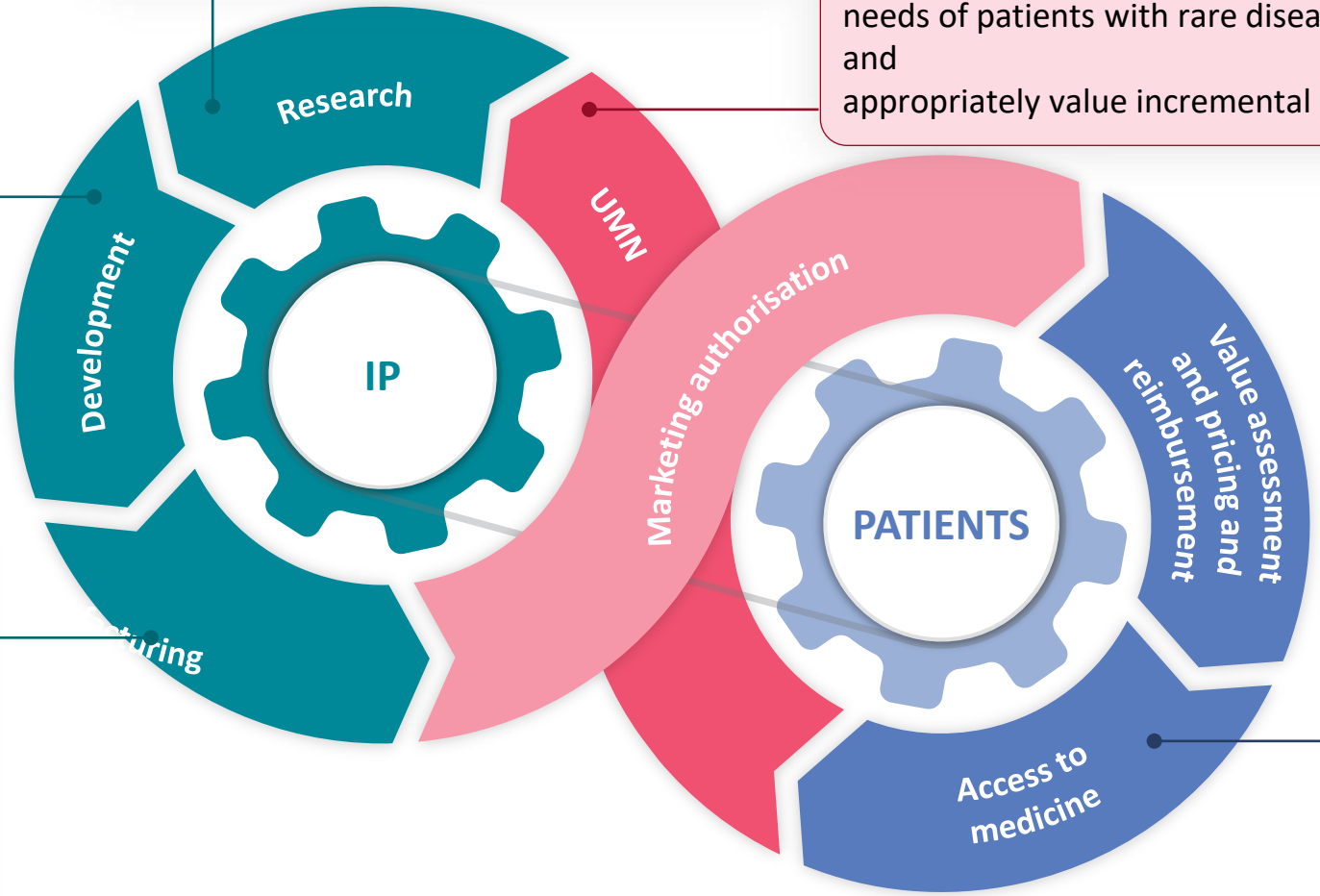


The Right Balance

Strengthen, rather than cut, the region's RDP baseline as well as creating separate incentives to drive innovation and meet health care challenges such as AMR

Include a patient-centred, broad definition of unmet medical need that would incentivise avenues of research to meet the needs of patients with rare diseases and chronic conditions, and
appropriately value incremental innovation

Optimise the regulatory framework and ensure maximum use of expedited pathways in support of patient needs



Ensure that supply chain and environmental requirements are proportionate and fit for purpose, to best support our shared objectives of increasing supply of medicines and reducing our sector's environmental impact

Jointly address barriers and delays to access based on a shared understanding of the evidence generated by the recently published Industry European Access Hurdles Portal

Take home messages

Europe needs globally competitive regulatory system that can keep pace with science and technology evolution and supports future innovations

Many of the Commission and EU Parliament proposals align with this aspiration and intent to simplify, accelerate, optimise regulatory processes

To bring Europe on the R&D map and balance access and competitiveness, adjustments are needed to incentives proposals.