EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Access to safe medicines Where is the link with the European Medicines Agency?

3rd EFIM Day – 17 March 2017 - Brussels

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An agency of the European Union

The request

- Access to new medicines among internists in Europe
  - How to balance access and cost-effectiveness (particularly in light of new premium-priced biologicals)?
  - How to set priorities?
- Medication errors
  - How to cope with rising frequency

My response

- Where the regulatory and clinical contexts come together
- What the Agency does and doesn't do
- Tools supporting early access
- Regulators' contribution to medicines affordability
- Risk minimisation

Where do the regulatory and clinical contexts come together?

Benefits/risks balance

Risk management and communication

Medicines information

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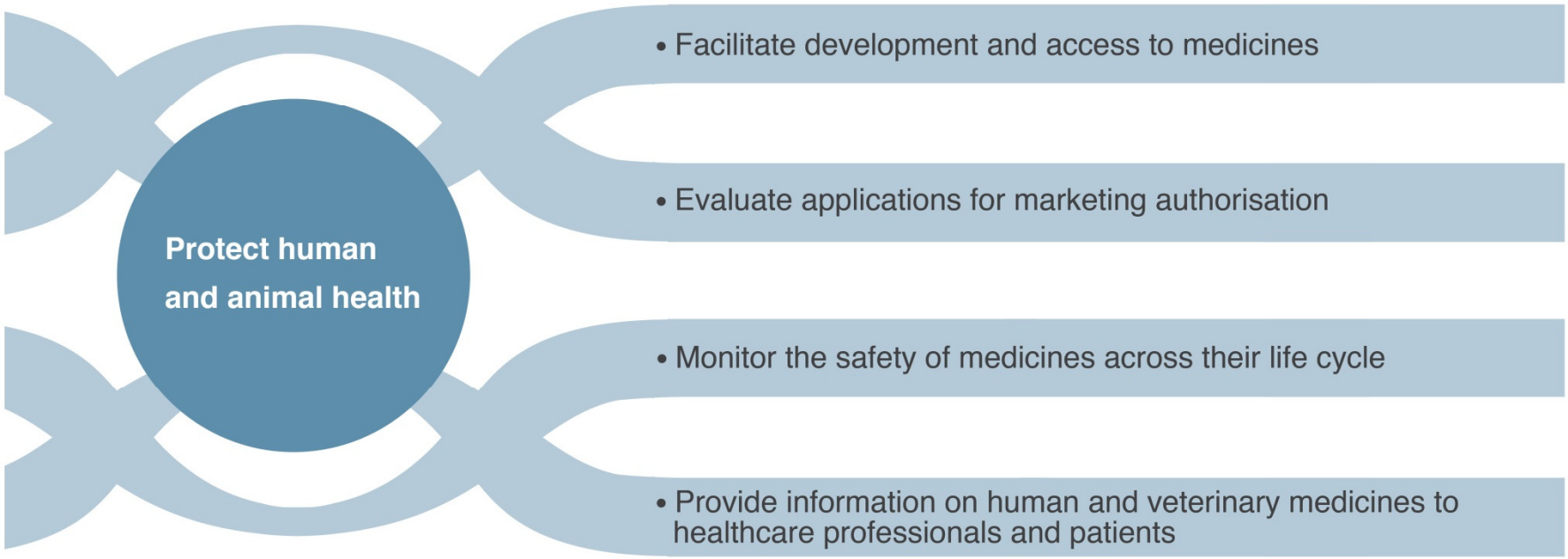
What do we do?



Achieving EMA's mission

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Foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public health in the European Union

Evidenced-based decisions

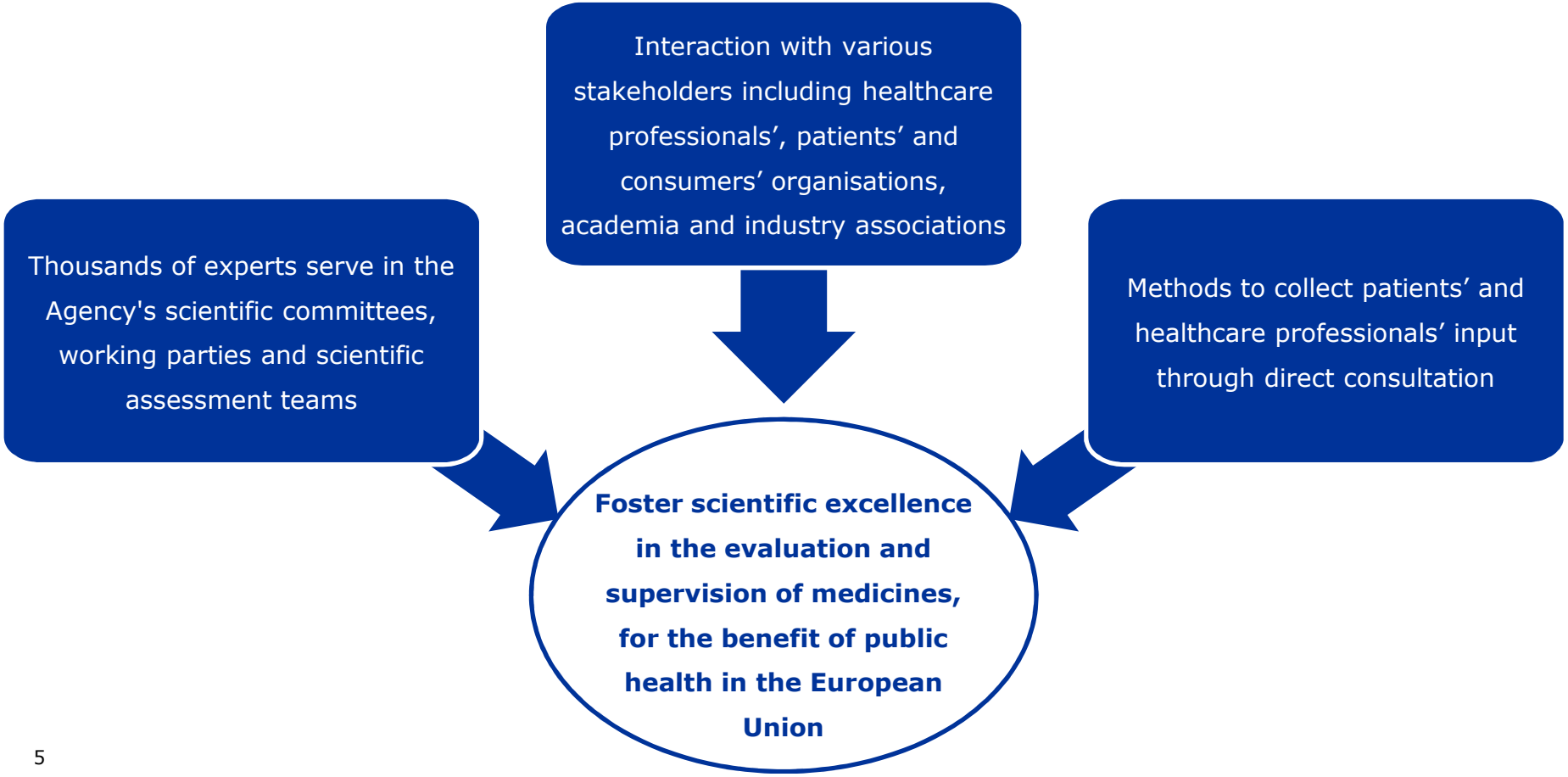
Regulatory decision-making is based on assessment of:

- Valid scientific evidence generated by marketing authorisation applicants/holders
- Data and information available from alternative sources
  - ⇨ academic studies, public authority studies (including by regulators); use of data-sources on real-life use of medicines; clinical guidelines; reports in EudraVigilance and in the scientific literature

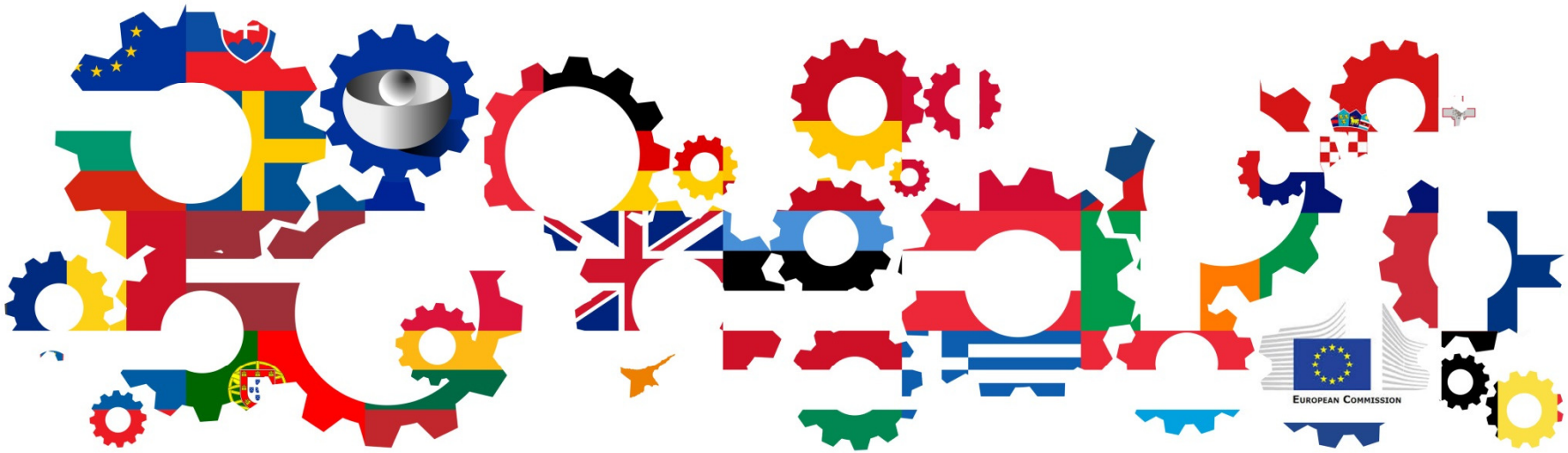
Feasible and proportionate decisions

- Incorporate clinical expertise and practical experience
- Address patient needs in real life (including values and preferences)
- Consider implementation in local healthcare contexts

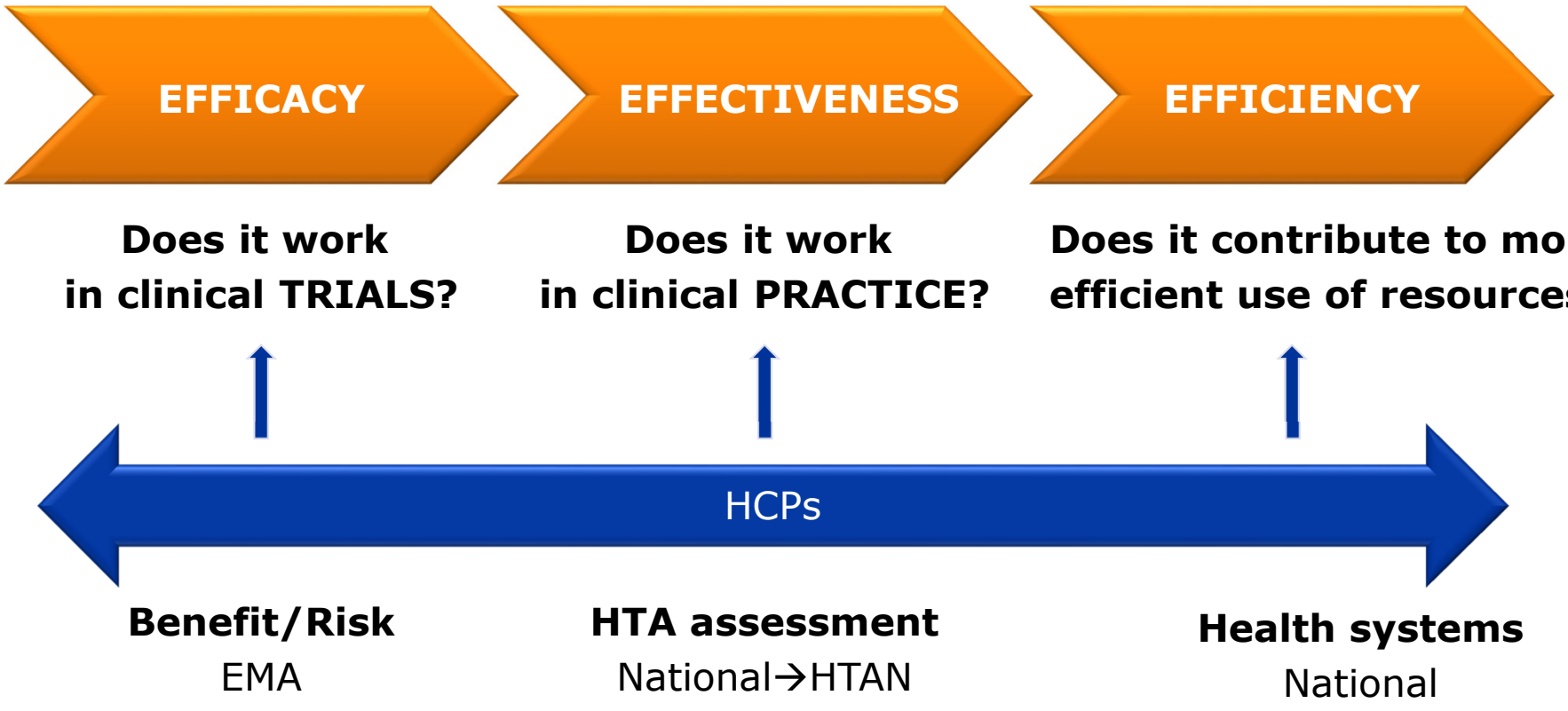
Achieving EMA's mission



The European medicines regulatory network



~ 50 national regulatory authorities European Commission European Medicines Agency


EFFICACY
EFFECTIVENESS
EFFICIENCY
Does it work in clinical TRIALS?
Does it work in clinical PRACTICE?
Does it contribute to more efficient use of resources?
HCPs
Benefit/Risk
EMA
HTA assessment
National→HTAN
Health systems
National

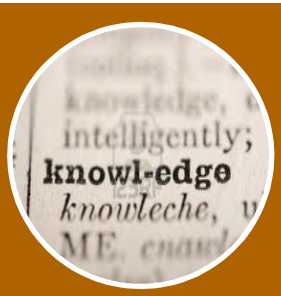
Interaction with healthcare professionals

Different roles of healthcare professionals all along the medicine's life-cycle, in the context of the patient's journey

Bring on board different fields of clinical expertise and practitioners in Europe, active within the broad spectrum of health care, including primary care

Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**

Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines



Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations

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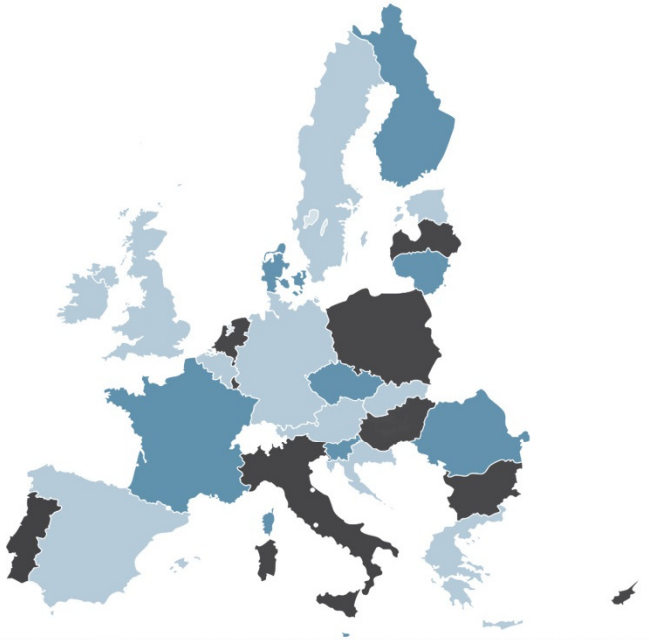
How are medicines approved?

Different authorisation routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via NCAs)

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Which medicines are approved through the centralised procedure?

- Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Officially designated 'orphan medicines' (medicines used for rare human diseases)

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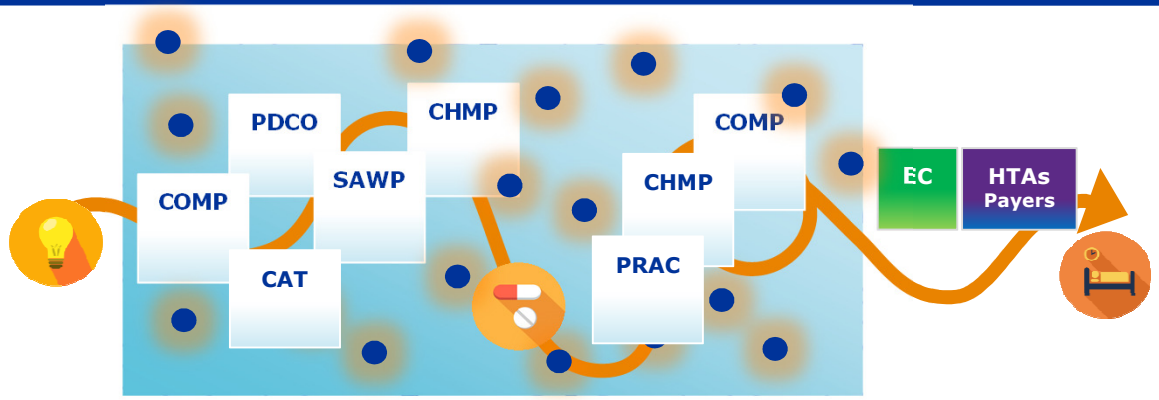
What is the benefit of the centralised procedure for EU citizens?

- Medicines are authorised for all EU citizens at the same time
- Centralised safety monitoring
- Product information available in all EU languages at the same time

An intricate regulatory environment



- Innovation task force (H&V)
- Paediatric investigation plan (PIP) (H)
- Scientific advice (H&V)
- Qualification of novel methodologies (H)
- Advanced therapy medicinal product classification (H)
- Regulatory and administrative assistance for small- and medium-sized enterprises (H&V)
- Orphan designation (including protocol assistance, fee reductions, market exclusivity) (H)

Supporting research and innovation of medicines

What we do not do

- Evaluate the initial marketing authorisation application of **all** medicines in the EU
- Evaluate applications for the **authorisation of clinical trials**
- Carry out **research or develop** medicines
- Take decisions on the **price or availability** of medicines
- Develop **treatment guidelines**
- Develop **laws** concerning medicines
- Issue **marketing authorisations**

Access to medicines

According to the authors, there are five main ways European regulators can help:

- Enable the rapid approval of generics and biosimilars, as this facilitates competition and drives down prices;
- Work to ensure 'me-too' products (medicines comparable to already approved options) continue to come on the market at reasonable speed, again to drive down prices through increased competition;

PERSPECTIVE

DRUG REGULATION AND PRICING

Drug Regulation and Pricing — Can Regulators Influence Affordability?

Hans-Georg Eichler, M.D., Hugo Hurts, M.Sc., Karl Broich, M.D., and Guido Rasi, M.D.

Public debate in the 1990s over drugs' clinical toxicity has given way to concerns about their financial toxicity. Although drug regulators aren't supposed to be concerned with pricing, they've been drawn into an acrimonious debate over the cost of medicines.

At the European Medicines Agency (EMA), we often hear conflicting arguments: high and inflexible regulatory standards drive up the cost of pharmaceutical research and development (R&D), thereby increasing drug prices; regulators license products even when the data are insufficient for assessing their value and allow drug makers to overcharge; more generics, biosimilars, and me-too drugs are needed to create a dynamic market that will keep prices down; me-too drugs should be discouraged, since they offer no added benefit to patients and lead to overutilization and higher spending; and regulators shouldn't allow drugs on the market that no one can afford.

So are regulators responsible for high drug prices? The short answer is yes and no. Before drug regulatory agencies existed, all sorts of "remedies" were sold on street corners — sometimes for a penny. But even if high prices weren't always an issue, concerns about product quality, safety, and lack of efficacy created a need for regulation. In the ensuing decades, regulatory agencies have developed sophisticated evidence standards to ensure that approved drugs have favorable benefit-risk profiles. Regulators have, for example, developed rigorous standards for the generation and analysis of clinical trial data and for acceptable trial endpoints and study designs. Regulatory requirements have undoubtedly made pharmaceutical R&D expensive.

At the same time, a regulatory seal of approval is the most important distinguishing factor that allows drug developers to charge high prices for products. Without evidence that has been vetted by regulators, why would anyone pay more for any drug than they would for, say, a dietary supplement? If we eliminated regulation, the current biopharmaceutical business model would collapse — and so would science-based drug development. Without a requirement for regulatory approval, companies would have no incentive to conduct expensive clinical trials of their products. Lowering regulatory standards would be unwise for both patients and organizations that invest in pharmaceutical R&D. Robust regulation improves public health and creates economic value.

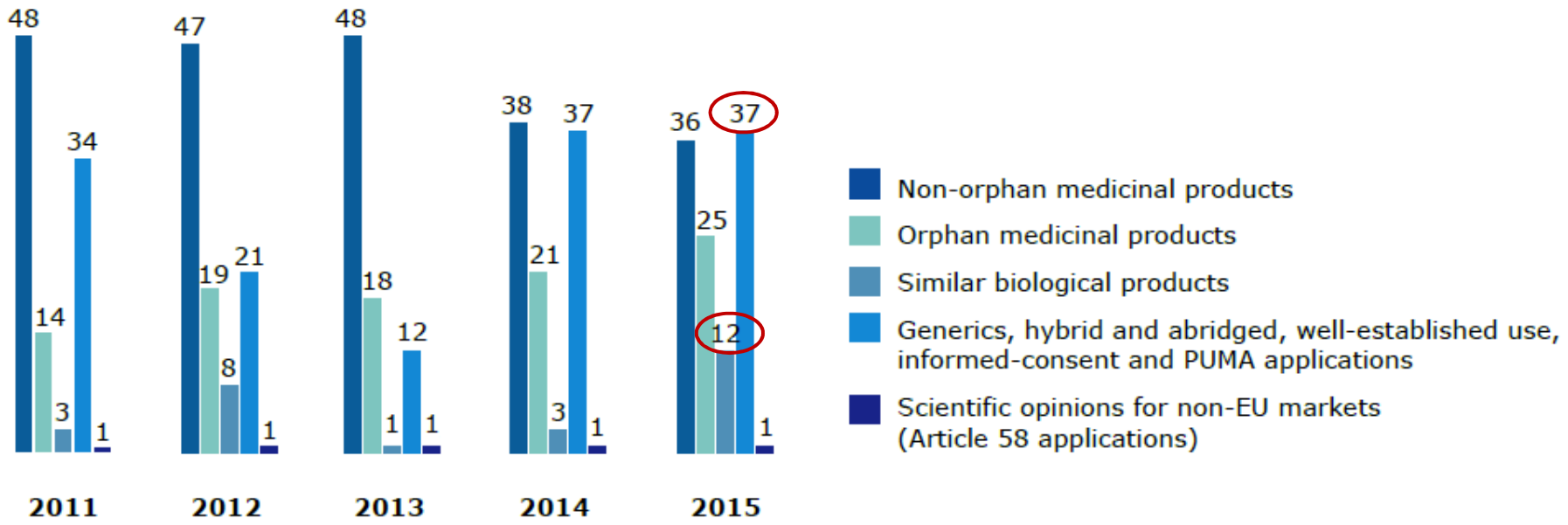
But the fact that regulation drives up R&D costs doesn't mean it's the only factor contributing to high prices — or even the most important one. Nor can we conclude the converse — that if only the high cost of R&D (driven by regulations) could be reduced, then prices would automatically drop. Even pharmaceutical executives admit that this assumption is naïve; companies tend to charge whatever the market will bear. Any belief in a correlation between R&D costs and market price was dispelled during the recent debate over the price of the new hepatitis C drug Sovaldi.[1]

Regulators should not, for the sake of affordability, yield to pressure to lower standards. But it's also inappropriate for them to be oblivious to the growing budget pains caused by newly authorized products. We believe there are several ways regulators can contribute to keeping drug spending sustainable, at least in the European Union (EU). (We recognize that some of these steps may not be readily implementable in the United States, owing to its legislative framework.)

First, by rapidly approving generics and biosimilars and allowing them to enter the market once patents or exclusivity periods have expired, regulators can facilitate competition, which drives down prices. Regulators could, for example, fast-track additional generic authorizations when companies are taking advantage of monopoly conditions for generic drugs.

Second, regulators can work to ensure that me-too products continue to come on the market at a reasonable speed. Some consumer advocates lament the high proportion of me-too products

INITIAL-EVALUATION APPLICATIONS BY TYPE OF APPLICATION (2011-2015)



Access to medicines

- Encourage companies to conduct clinical trials that both satisfy the needs of regulators (i.e. demonstrate quality, safety and efficacy of the medicine) as well as the health-technology-assessment bodies (i.e. support the demonstration of the value once the medicine is authorised, to guide payers in their reimbursement decisions);

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Access to medicines

- Facilitate the collection of other data that are important for payers by taking their needs into account when asking companies to conduct post-approval studies. This could for example help payers when considering outcome-focused deals that tie the price of a medicine to the result for patients;

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Access to medicines

- Support higher efficiency of research and development in the area of medicines: by fostering a better model for the development of medicines, it is expected that companies would potentially be able to reduce the price of their medicines. This could also mean reflecting on new approaches to medicines' development, such as the adaptive pathways approach that is being explored by EMA.

PERSPECTIVE

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Early access tools: Overview

PRIME

Major public health interest, unmet medical need.

Dedicated and reinforced support.

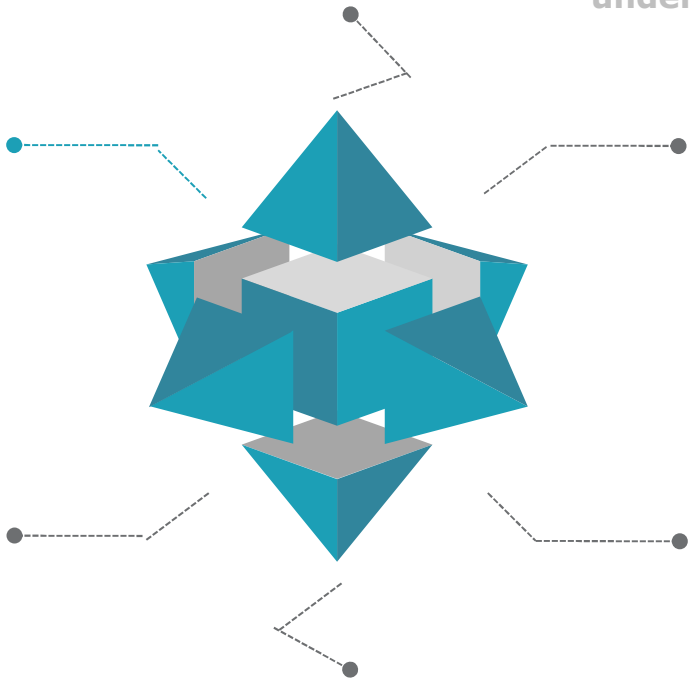
Enable accelerated assessment.

Better use of existing regulatory & procedural tools.

Accelerated Assessment

Major public health interest, unmet medical need.

Reduce assessment time to 150 days.



Other…Compassionate Use, MA under EC etc.

Adaptive Pathways

Scientific concept of development and data generation.

Iterative development with use of real-life data.

Engagement with other healthcare-decision makers.

Conditional MA

Unmet medical need, seriously debilitating or life-threatening disease, a rare disease or use in emergency situations.

Early approval of a medicine on the basis of less complete clinical data.

Parallel advice

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Early access to medicines that address specific public health needs

Accelerated assessments

Seven medicines received a recommendation for marketing authorisation following an accelerated assessment. This mechanism is reserved for medicines that have the potential to address unmet medical needs. It allows for faster assessment of eligible medicines by EMA's scientific committees (within up to 150 days rather than up to 210 days).

Cancer

Darzalex

for patients with multiple myeloma

Kisplyx

for patients with advanced renal cell carcinoma

Cabometyx

for patients with advanced renal cell carcinoma

Empliciti

for patients with multiple myeloma

Lartruvo

for patients with soft tissue sarcoma

Haematology/ Haemostaseology

Coagadex

for patients with factor X deficiency

Infections

Epclusa

for patients with chronic hepatitis C virus infection

In: Human medicines highlights 2016

Conditional marketing authorisations

Eight medicines received a recommendation for a conditional marketing authorisation, one of the possibilities in the EU to give patients early access to new medicines. This tool allows for the early approval of a medicine on the basis of less complete clinical data than normally required if the medicine addresses an urgent unmet medical need. These medicines are subject to specific post-authorisation obligations for medicines developers that aim to obtain complete data on the medicine.

Cancer

Alecensa

for patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer

Darzalex

for patients with multiple myeloma

Ninlaro

for patients with multiple myeloma

Lartruvo

for patients with soft tissue sarcoma

Venclyxto

for patients with chronic lymphocytic leukaemia

Vaccine

Pandemic influenza vaccine H5N1 MedImmune

to protect children (12 months to 18 years) against influenza during a flu pandemic

Haematology/ Haemostaseology

Zalmoxis

an advanced therapy medicine for patients receiving a haploidentical haematopoietic stem cell transplant (HSCT)

Hepatology

Ocaliva

for patients with primary biliary cholangitis

PRIME scheme - Goal & Scope

To foster the development of ***medicines with major public health interest.***

Reinforce scientific and regulatory advice

- Foster and facilitate early interaction
- Raise awareness of requirements earlier in development

Optimise development for robust data generation

- Focus efficient development
- Promote generation of robust and high quality data

Enable accelerated assessment

- Facilitated by knowledge gained throughout development
- Feedback of relevant SA aspects to CHMP

Building on existing framework;

Eligibility according to existing 'Accelerated Assessment criteria'

Justification for eligibility to PRIME

For products under development yet to be placed on the EU market

Unmet medical need

- Epidemiological data about the disease
- Description of available diagnostic, prevention and treatment options/standard of care (SOC), their effect and how medical need is not fulfilled

Potential to significantly address the unmet medical need

- Description of observed and predicted effects, clinical relevance, added value and impact
- If applicable, expected improvement over existing treatments

Data required at different stages of development

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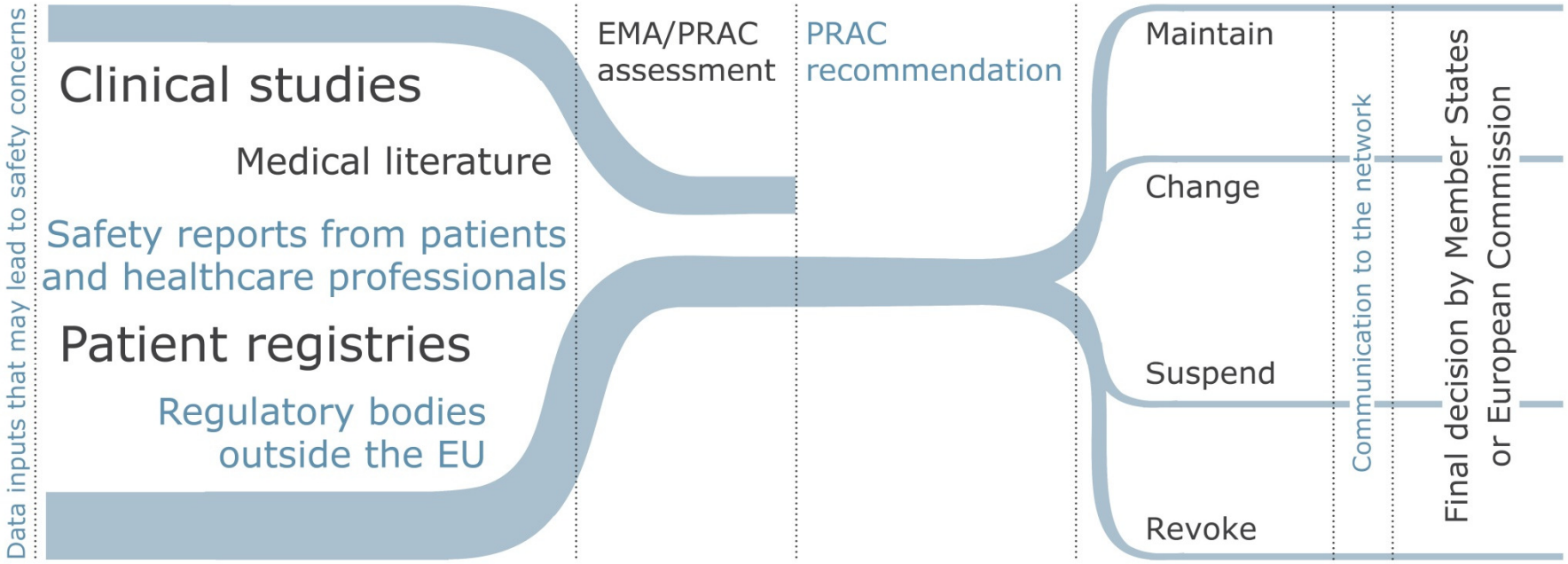
How do we monitor the safety of medicines already on the market?

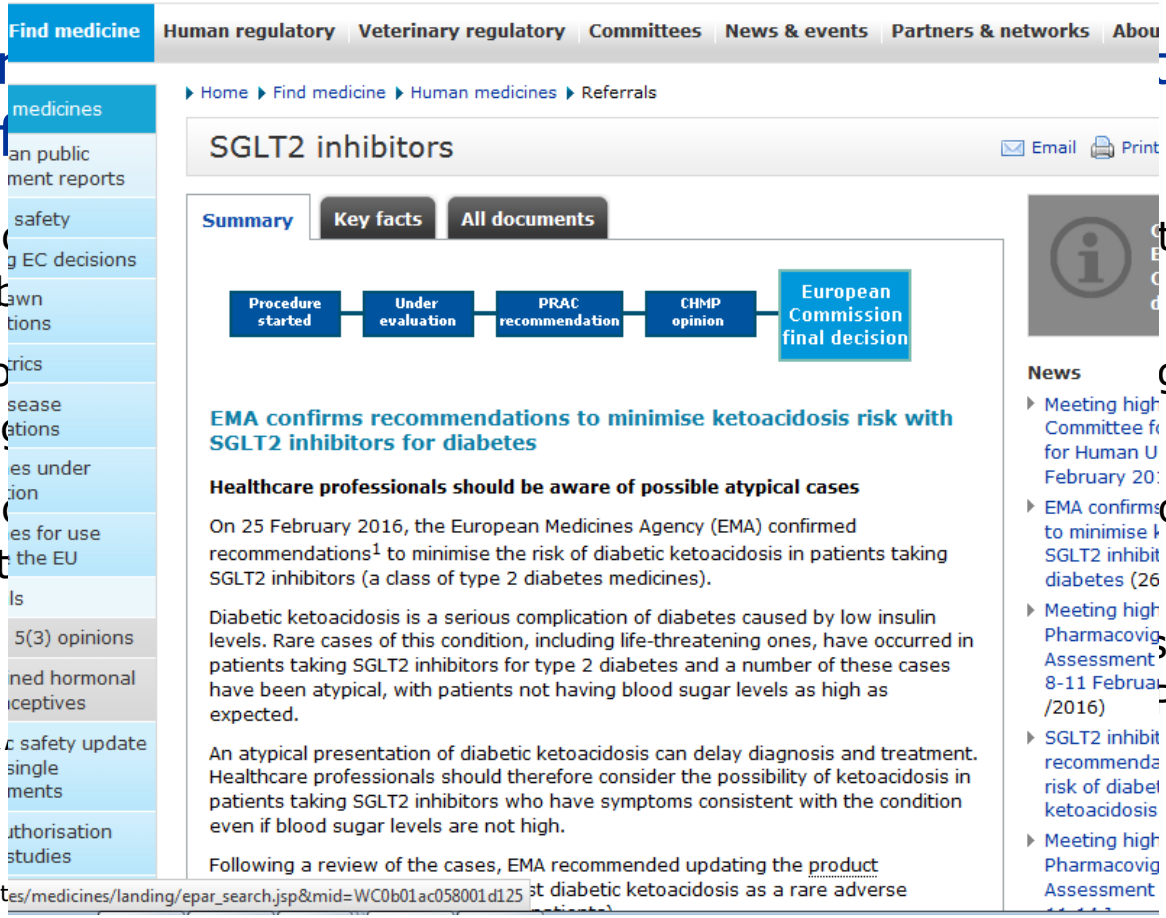


Safe use of Keppra

- Measures for use of correct dosing syringe to avoid medication errors
- Keppra (levetiracetam) to treat epilepsy in adults and children.
- In children dose depends on the child's bodyweight and age
- Cases of accidental overdose have been reported with levetiracetam oral solution; the majority of cases occurred in children aged between 6 months and 11 years.
- Most of the cases occurred when the medicine was used with a wrong dosing syringe or wrong dose measurement
- only the syringe provided with the package should be used to measure the dose of Keppra
- different medicine's cartons and labels coloured differently and clearly indicate the volume of the bottle, the volume of the dosing syringe, and the age range of the child that the medicine should be used for

Recommer…th SGLT2 inhibitors f…

- Recommen… …tients taking SGLT2 inhib…
- A number o… …g blood sugar levels as hig…
- Recommen… …ors to list diabetic ket… …1,000 patients).
- The review … …ssment Committee … …P which adopted the Agency …



Recommendations to minimise risk of PML with Tysabri

- Review of the known risk of progressive multifocal leukoencephalopathy (PML) with Tysabri (natalizumab)
- Early detection and treatment of PML when the disease is asymptomatic may improve patients' outcomes
- Full MRI scans at least once a year / patients at higher risk of PML more frequent MRI scans (e.g. every 3 to 6 months)
- Additional measures if lesions suggestive of PML are discovered
- Recommendations are based on an initial review by PRAC; CHMP confirmed them and issued its final opinion

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SCIENCE MEDICINES HEALTH

14 October 2016
EMA/668736/2016

EMA recommends measures to ensure safe use of Keppra oral solution

Medicine should only be used with dosing syringe included in the package

Several measures have been put in place to ensure that the correct dosing syringe is used to measure Keppra oral solution, and thus avoid medication errors. Keppra (levetiracetam) is a medicine used to treat epilepsy in adults and children.

In children, the dose of Keppra depends on the child's bodyweight and age, and the oral solution is the preferred formulation for use in children less than 6 years of age. The medicine is available as a 100 mg/ml solution in either a 150 or 300 ml size bottle, and it comes with a 1, 3 or 10 ml syringe.

Cases of accidental overdose have been reported with levetiracetam oral solution; the majority of cases occurred in children aged between 6 months and 11 years. Most of the cases occurred when the medicine was used with a wrong dosing syringe (e.g. a 10 ml syringe was used instead of a 1 ml one, leading to a 10-fold overdose), or because of a misunderstanding of the caregiver about how to properly measure the dose. Levetiracetam overdose often has no symptoms, but it may cause sleepiness, agitation, difficulty breathing and coma.

To avoid medication errors and the risk of overdose, parents and carers are advised that only the syringe provided with the package should be used to measure the dose of Keppra. The different medicine's cartons and labels will be coloured differently and clearly indicate the volume of the bottle, the volume of the dosing syringe, and the age range of the child that the medicine should be used for:

The package leaflet will also include clearer instructions for parents and carers in order to minimise the risk of using an incorrect dose. Parents and carers are advised always to discard the syringe once the medicine's bottle is empty.

ment(s)	Language	Publication date
ncyto: measures to avoid ation errors	(English only)	08/12/2015
jade: measures to avoid ation errors	EN = English GO	22/04/2016
rydak: compliance card to en to patients to ensure t use and avoid ation errors	(English only)	27/11/2015
ulin and a non-insulin substance: guidance on ntion of medication errors	EN = English GO	27/11/2015
ulins (high-strength): nce on prevention of ation errors	EN = English GO	27/11/2015
nsys: measures to ensure is handled and used tly	(English only)	30/11/2015
ppra: EMA recommends ures to ensure safe use of olution	(English only)	14/10/2016
xafil: EMA warns that s and oral suspension different doses and are not nangeable	(English only)	24/06/2016

How is this relevant to EFIM?

Input to/participation in general EMA activities – EFIM representatives

- EMA consultations on strategic documents, policies, projects and initiatives (written or via teleconference)
  - E.g.: Publication of clinical data; European clinical trials portal and database
- EMA workshops/conferences
  - Recent examples: ATMPs, Big data, patient registries, measuring the impact of pharmacovigilance, adaptive pathways, personalised medicine.
- EMA guidelines

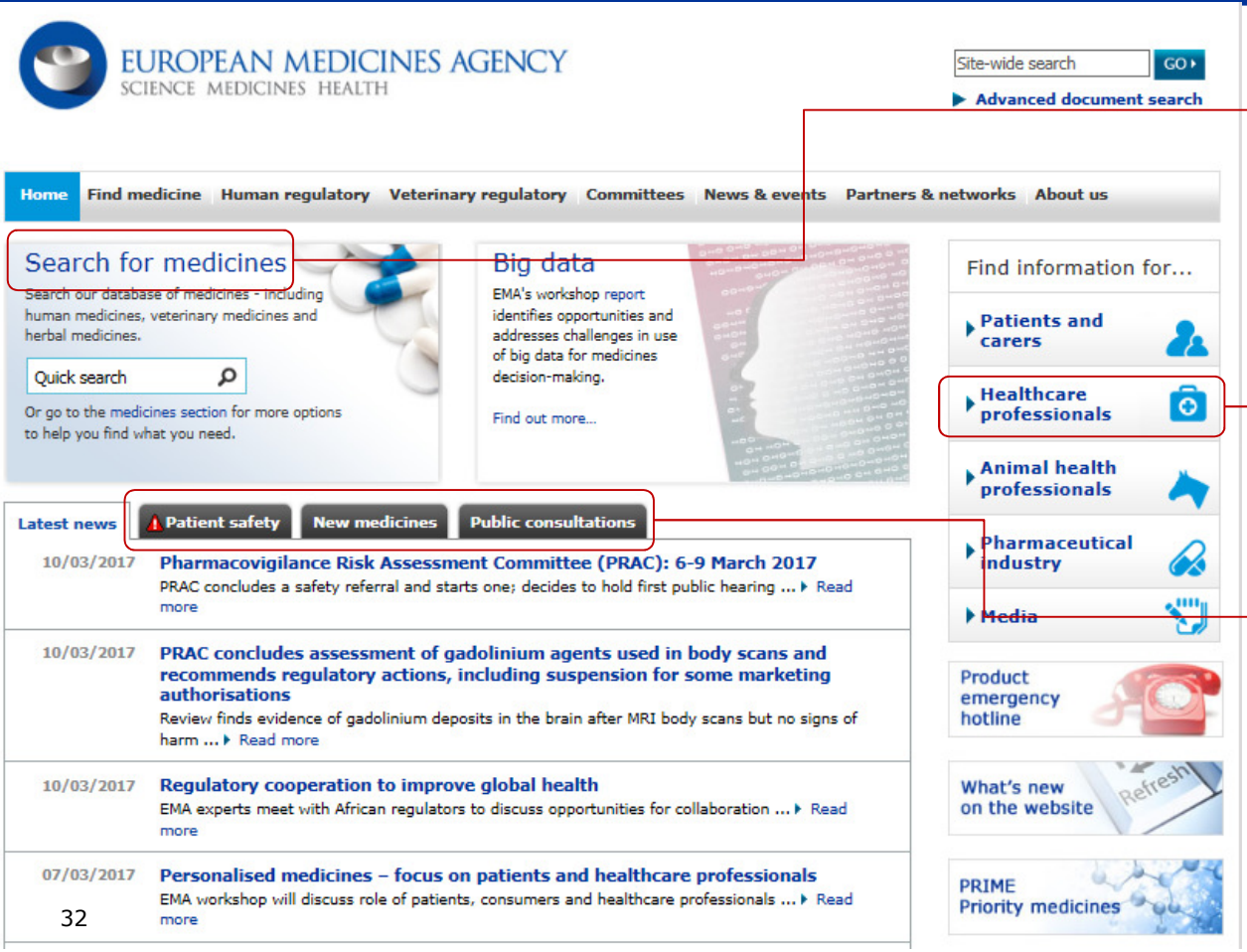
  Recent examples: Reflection Paper on the assessment of cardiovascular risk of medicinal products; Clinical evaluation of medicinal products used in weight control; Clinical investigation of medicinal products in the treatment of chronic heart failure

How is this relevant to EFIM?

Input to product-specific consultations - as individual experts (subject to confidentiality)

- Input in Scientific Advisory Groups (SAGs) and Ad-hoc expert group meetings
- Review of labelling aspects and additional risk minimisation measures including implementation
- Review of safety communications and DHPCs (including prevention of medication errors)
- Scientific Committees/Working Parties consultations (standard of care; risk minimisation measures; product information)

EFIN permanent member of 'EMA Working Party with healthcare professionals' organisations' (HCPWP)



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Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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