



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU scientific regulatory support mechanisms and initiatives for innovation in drug development: the EMA perspective

FAMHP Workshop, Brussels, 2nd May 2016

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An agency of the European Union





Acknowledgments

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Agenda

- 1 European Medicines Agency: introduction
- 2 The EMA Innovation Task Force
- 3 The EMA SME office
- 4 Priority Medicines (PRIME) initiative
- 5 The European Innovation offices Network



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EMA in the EU

Who do we work for?



over **500** million people living in the European Union

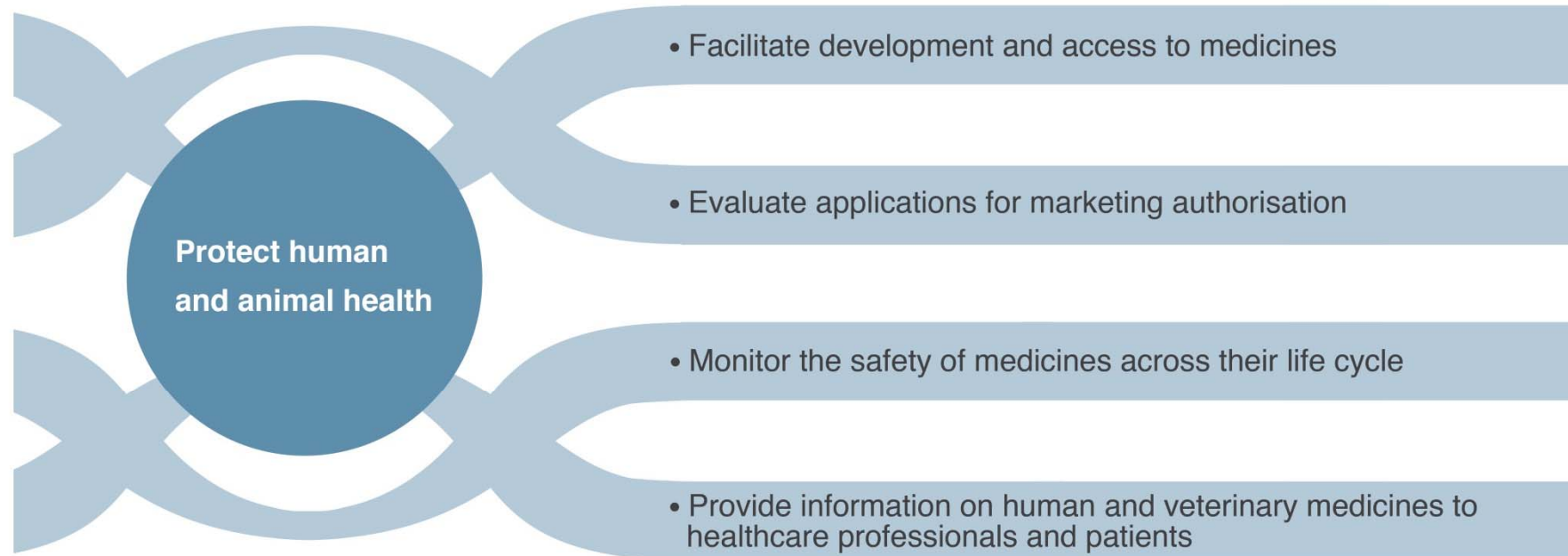
28 member states

27% of global sales of medicines

24 official languages



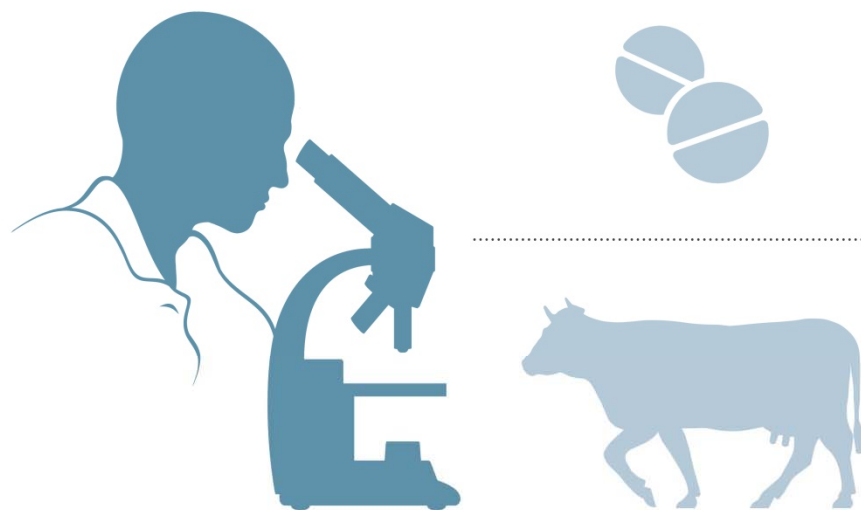
What do we do?





Who we are

~4000 Scientific experts from right across Europe



1995 EMA established to evaluate medicines for use in the EU

7 Scientific committees

CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC

28 Working parties

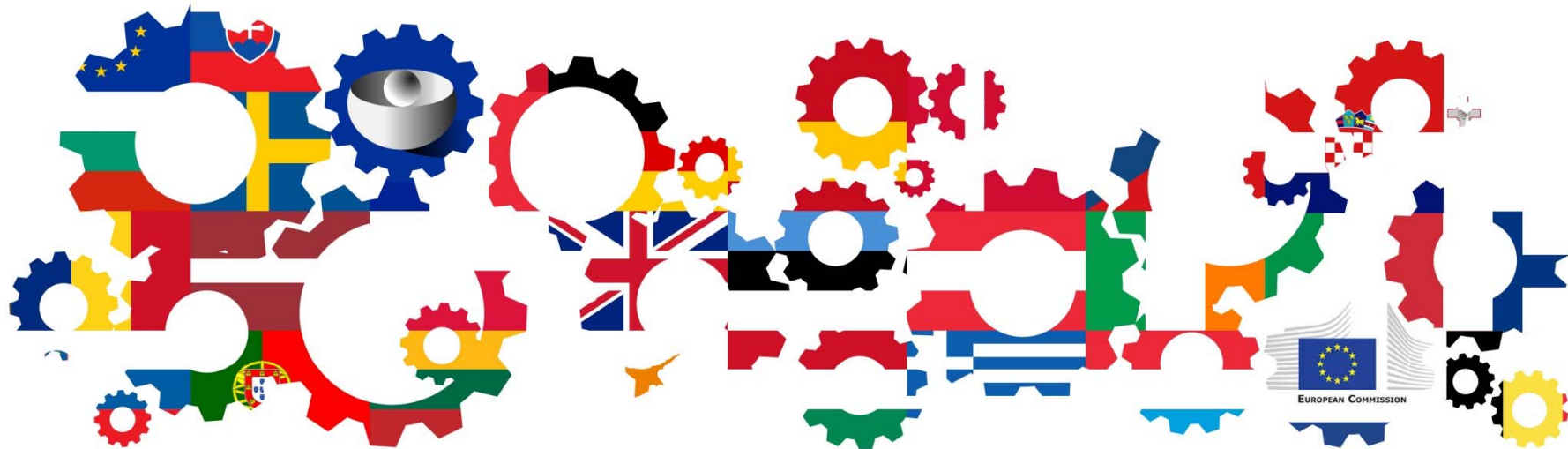
over **1000** marketing authorisations recommended



~ **890** Staff members



The European medicines regulatory network



~ 50 national regulatory authorities

European Commission

European Medicines Agency



How is EMA organised?



National competent authorities
~4000 European experts



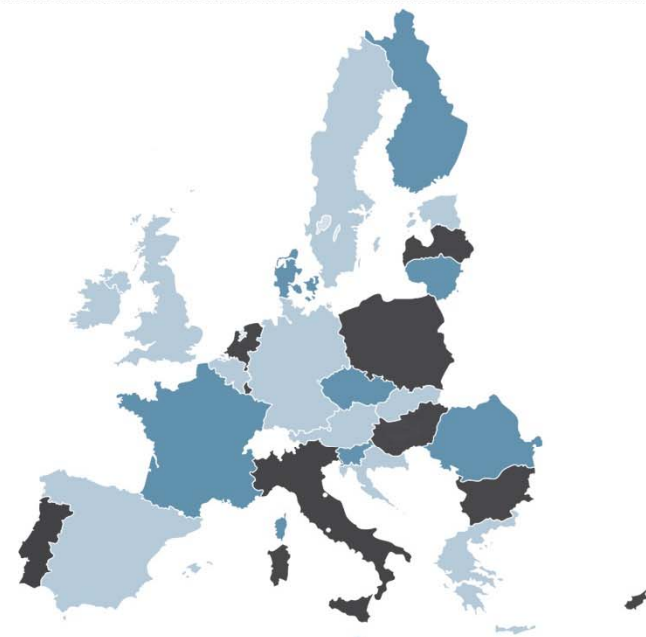


How are medicines approved?

Different authorisation routes: one set of common rules



Centralised procedure (via EMA)



National procedures (via NCAs)



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)



Supporting research and innovation of medicines

Pre-authorisation

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)

Marketing authorisation application evaluation

Post-authorisation (When a medicine is available on the market)

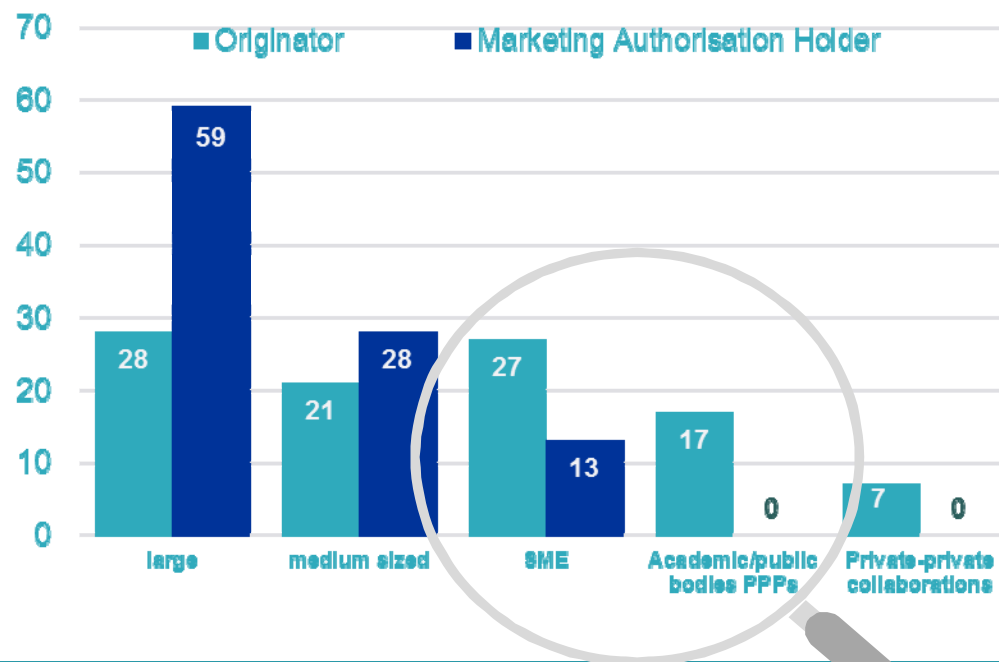


Innovation: origins of new medicines



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*



EU 2010-2012

*

- Of 94 novel *authorised* medicinal products:
- Large majority marketed by large or intermediate sized companies.
 - SMEs and academia at the origin of innovation.



Advancing public health

Innovation in healthcare brings new opportunities to treat certain diseases and is essential to advancing public health. Noteworthy therapeutic innovations in 2015 included:



Cancer

Blincyto - directing the immune system towards cancer cells
Farydak - regulating the activity of genes
Imlygic - using genetically engineered virus to kill cancer cells
Opdivo, Nivolumab BMS and Keytruda - increasing the capacity of the immune system

Cardiovascular

Entresto - dual action to treat heart failure
Repatha and Praluent - monoclonal antibodies to treat hypercholesterolemia

Haematology

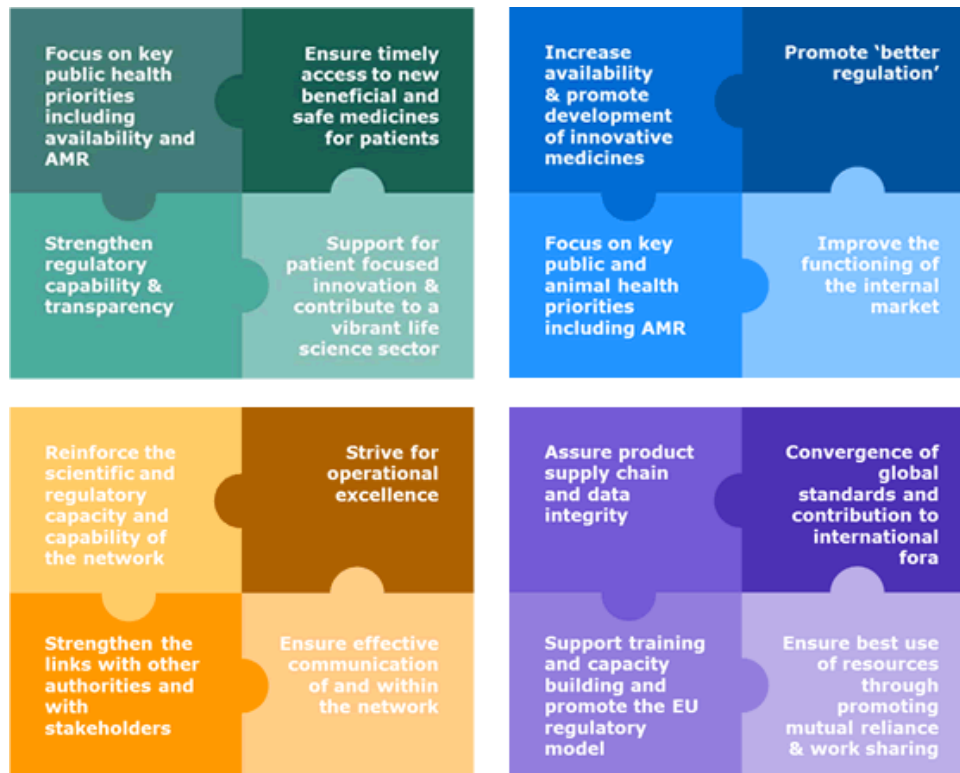
Praxbind - targeted neutralisation of the anticoagulant effect of Pradaxa

Neurology

Wakix - action on histamine H3 receptors to treat narcolepsy



EU Medicines Agencies Network Strategy to 2020



Includes objectives to:

- Support for patient focused innovation and contribute to a vibrant life science sector in Europe
- Greater collaboration across network to support innovation
- Consider further regulatory incentives for innovation, particularly in certain areas of public health need



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Multidisciplinary platform for preparatory dialogue and orientation on innovative methods, technologies and medicines



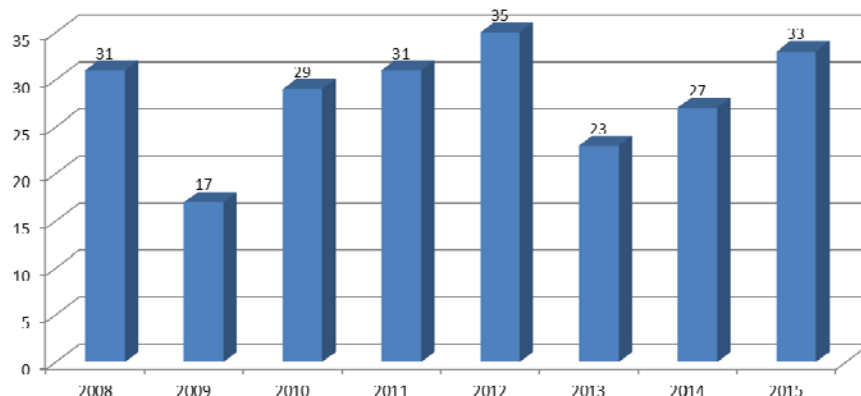
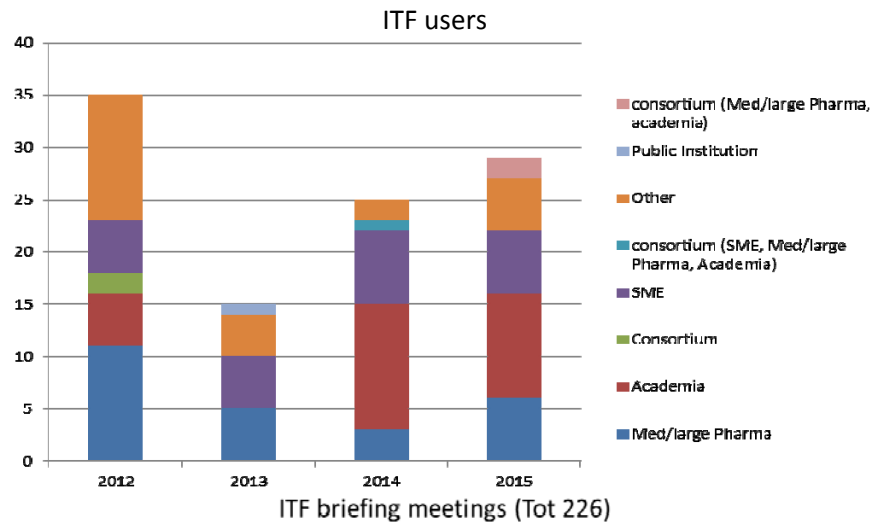
16 FAMHP workshop, 2 May 2016

- Early dialogue on scientific, legal and regulatory issues
- Address the impact of emerging therapies and technologies on current regulatory system
- Identify the need for specialised expertise at an early stage
- Provide advice on the eligibility to Agency procedures relating to research and development, e.g. borderline products
- Increase awareness and learning in emerging therapies and technologies at the Agency

EMA ITF briefing meetings



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- Informal exchange of information and provision of guidance early in the development process.
- Discussions led by experts from the Agency's network, working parties and committees
- Complement and reinforce existing formal regulatory procedures, such as (ATMP) classification and certification, designation of orphan medicinal products and scientific advice.



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The EMA SME Office



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SME Office launch

December 2005.

A single interface

"One-stop-shop."

Assistance to SMEs

Regulatory, administrative and procedural support.

Facilitates communication

Of SMEs in veterinary and human pharma sector.

Coordinating & networking

Working closely with EU.

SME Office
tailoring assistance to SMEs

“A strategic regulatory toolbox to promote innovation and development of new medicines by SMEs.”



- 1 Validation of SMEs status
- 2 Regulatory Assistance
- 3 Fee Incentives
- 4 Translation Assistance
- 5 Training and Awareness





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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'



Features of the PRIME scheme

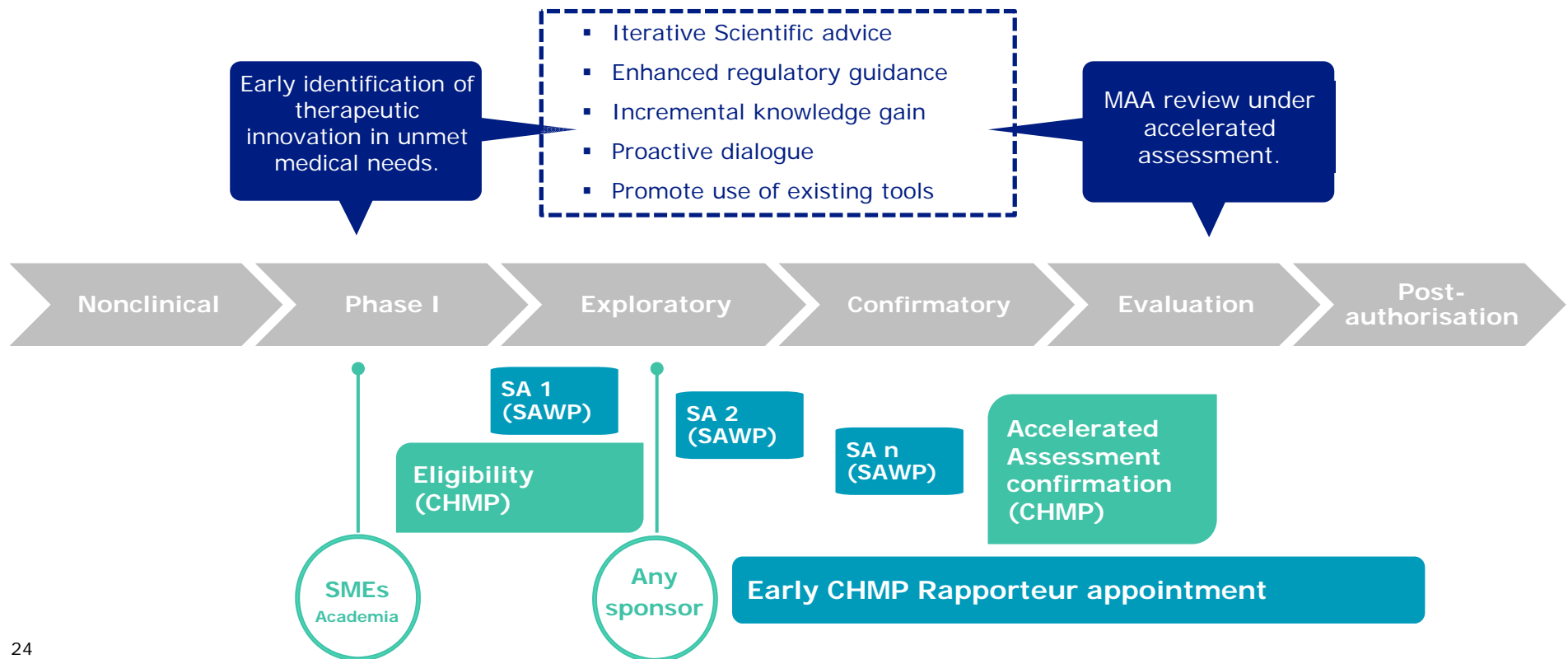
Early access tool, supporting patient access to innovative medicines.



- **Written confirmation of PRIME eligibility** and potential for accelerated assessment;
- **Early CHMP Rapporteur appointment** during development;
- **Kick off meeting** with multidisciplinary expertise from EU network;
- **Enhanced scientific advice** at key development milestones/decision points;
- **EMA dedicated contact point**;
- **Fee incentives** for SMEs and academics on Scientific Advice requests.



Overview of PRIME scheme





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

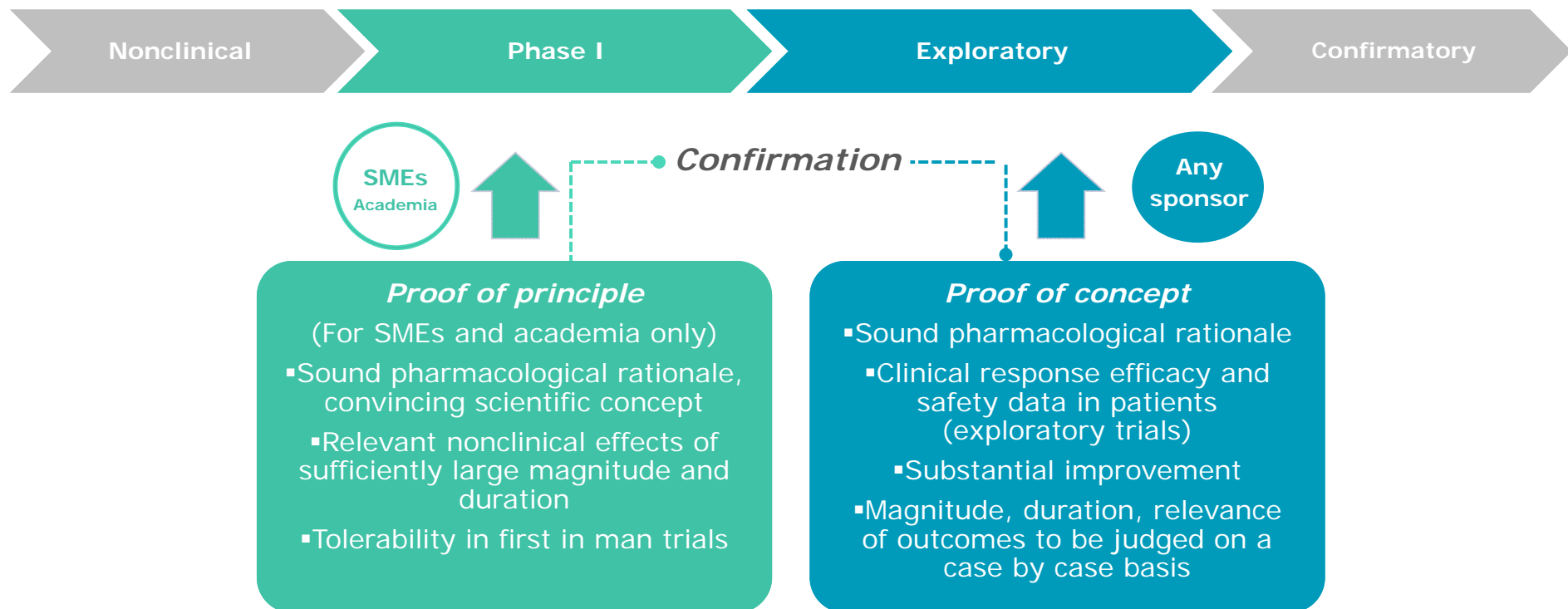
Potential to significantly address the unmet medical need

- 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



Entry points PRIME eligibility and required evidence





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EU innovation network (EU-IN)



EMA ITF + 12 National innovation offices/contact points

Regular teleconferences

Aims to share information related to innovative drug development and initiate early dialogue with developers

Supporting Innovation in the EU NCAs



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- Certain medicinal products for external use
- Homeopathic medicinal products
- Cosmetic products
- Medical devices
- The Innovation Office
- More about the Innovation Office

Home /

Welcome to the Innovation Office

The Innovation Office has been founded to support innovators in academia and industry. We provide assistance on regulatory issues as well as assist you in your research. Our goal is greater understanding of regulatory issues as well as assist you in your research. Our goal is greater understanding of regulatory issues as well as assist you in your research.

If you have questions regarding the Innovation Office, please let us know at innovation@mpa.se. For continuous news about regulatory issues and subscribe to our newsletter.

The SME-Guide (only available in Swedish)

The SME-Guide is a guide to information about the Innovation Office. It is available in Swedish, English and German.

Contact the Innovation Office
Telephone: +46 (0) 18 17 46 00
E-mail: innovation@mpa.se

MHRA Innovation Office

MHRA Innovation Office helps organisations that are developing medical devices or using novel manufacturing processes so they can progress their products or technologies.

Contents

Role of the group

Fimea Läkemedelstillsättnings- och kvalitetsmyndigheten
Säkerhets- och utvecklingscentret för läkemedelsområdet
Finnish Medicines Agency

HEALTHCARE MARKETING AUTH. PHARMACIES SUPERVISION
FOR PUBLIC ABOUT US FORMS

Designer drugs to be covered under the Narcotics Act

New psychoactive substances, or designer drugs, will be moved from the Medicines Act to the Narcotics Act. Read more.



News

17.6.2015
Regulation concerning the marketing authorisation for medicinal products to be updated

22.5.2015
Are bosonilars interchangeable?

15.8.2015
Fimea switches over to new financial and HR processes and information systems on 1 October 2015

13.4.2015
New decree on fees and price list for services priced according to commercial criteria into force on 1 April 2015

Show all

Shortcuts

- Classification and list of medicines
- Clinical drug trials
- Electronic submissions
- European Pharmacopoeia
- Fees
- Forms
- Frequently asked questions
- Good Laboratory Practice (GLP)
- Reporting of adverse reactions

Role of the group

The office

Paul Ehrlich-Institut

Informationen Institut Forschung Arzneimittel Vigilanz IVD Veranstaltungen Service

Informationen für
Patienten und Verbraucher
Antragsteller und Pharmazeutische Unternehmer
Beratung
Innovationsbüro
Wissenschaftliche Beratung - DTK
Wissenschaftliche und Regulatorische Beratung - DZP
Nationale Beratung - PEI
Scientific Advice - EMA
Klinische Prüfungen
Zulassung (human)
Zulassung (veterinär)
Genehmigungen
Chargenprüfung (human)
Chargenprüfung (veterinär)
Inspektionen
Hilfspflichten / Anzeigepflichten
Arzneimittel
Elektronische Einreichung
PEI International
Gehühren
Ärzte und Apotheker
Therapie
Journalisten
Hilfspflichten
Datenangebote
Sitemap
Qualitätskriterien
Datenschutzklärung

Innovationsbüro
Informelle Beratung zur Entwicklung von Arzneimitteln für neuartige Therapien (ATMP)
E-Mail: innovation@pei.de
Telefon: +49 6183 77 1012 oder - 1034
direkter Link: www.pei.de/innovationsbuero

Beratungsangebot
Adressaten
Kontakt
Regulatorische Beratung
Koordination der wissenschaftlichen Beratung
Regionale Ziele
Externe Fragestellungen
Glossar
Rechtsvorschriften
Weitere Informationen

Große Fortschritte in der Biotechnologie führten zur Entwicklung neuartiger Therapien, wie Gentherapie, somatische Zelltherapie und Tissue-Engineering. Diese bieten neue Möglichkeiten der Behandlung von schweremgenen Erbkrankungen und Funktionsstörungen des menschlichen Körpers. Aufgrund ihrer Neuheit und Komplexität erregen für sog. Advanced Therapy Medicinal Products (ATMP) spezielle, auf europäischer Ebene harmonisierte Vorschriften.

Unternehmen, die Arzneimittel für neuartige Therapien entwickeln, erhalten im Innovationsbüro am Paul Ehrlich-Institut die Möglichkeit der regulatorischen und wissenschaftlichen Beratung. Es wurde eingerichtet als zentrale Anlaufstelle für Firmenfragen und strebt eine "All-in-one-Lösung" an in Form der Koordination übergreifender Anfragen sowie Bildung einer Brücke zu EMA, KCS-Zentren, IQWiG und GfA.

Beratungsangebot

- Ansprechpartner für allgemeine regulatorische Fragestellungen für die Entwicklung von ATMP
- Ansprechpartner für die Koordination von wissenschaftlichen Beratungen
- Ansprechpartner für die deutschen Zentren der Gesundheitsforschung "Deutsches Konsortium für Translationale Krebsforschung (DKTK)" und "Deutsches Zentrum für Neurodegenerative Erkrankungen (DZNE)"

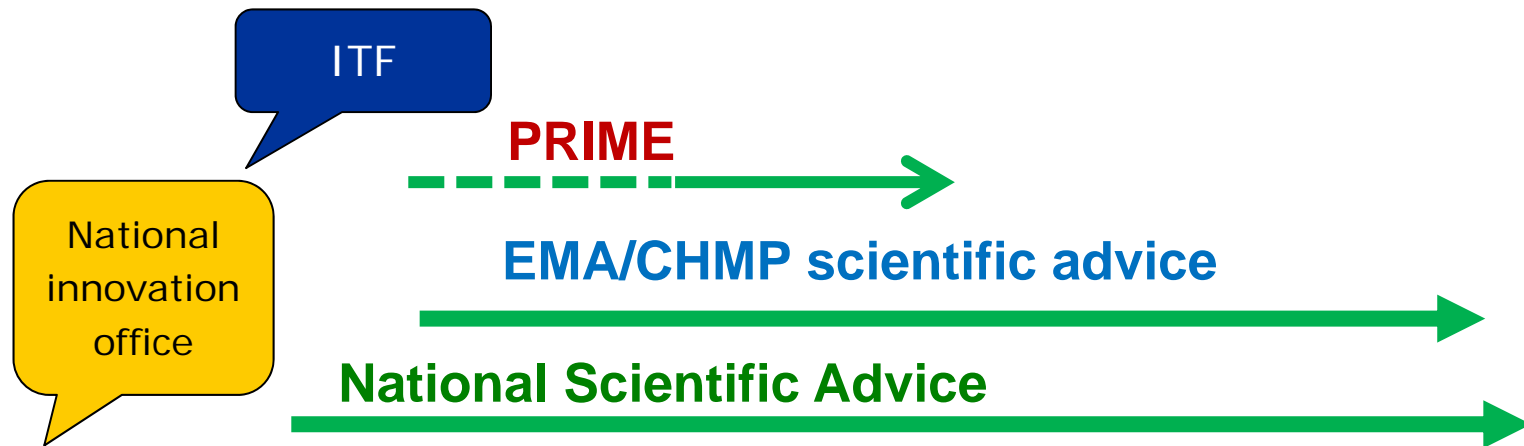
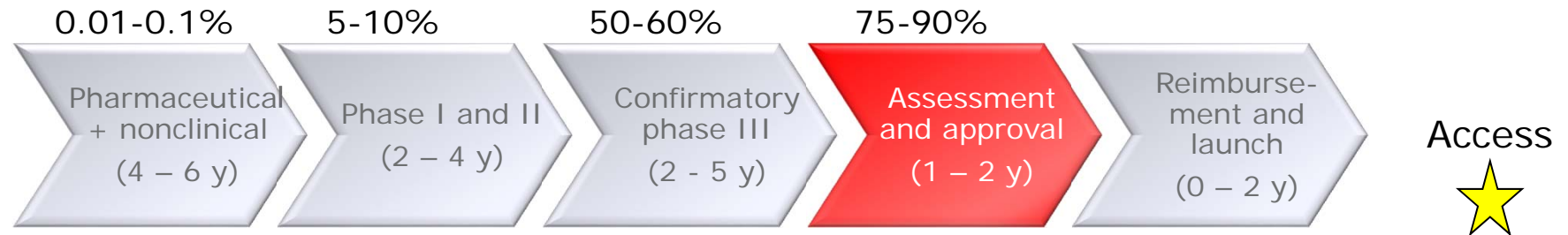
The core profile of an innovation office

Target group	Hospitals units Start-ups SMEs
Target products	Chemical medicines Biological medicines + vaccines ATMPs Medical devices
Focus	Quality / viral safety Preclinical Clinical Regulatory
Services	A f2f meeting: Simple advice, referral to scientific advice or other competence Other information: website, Interaction with other stakeholders of innovation



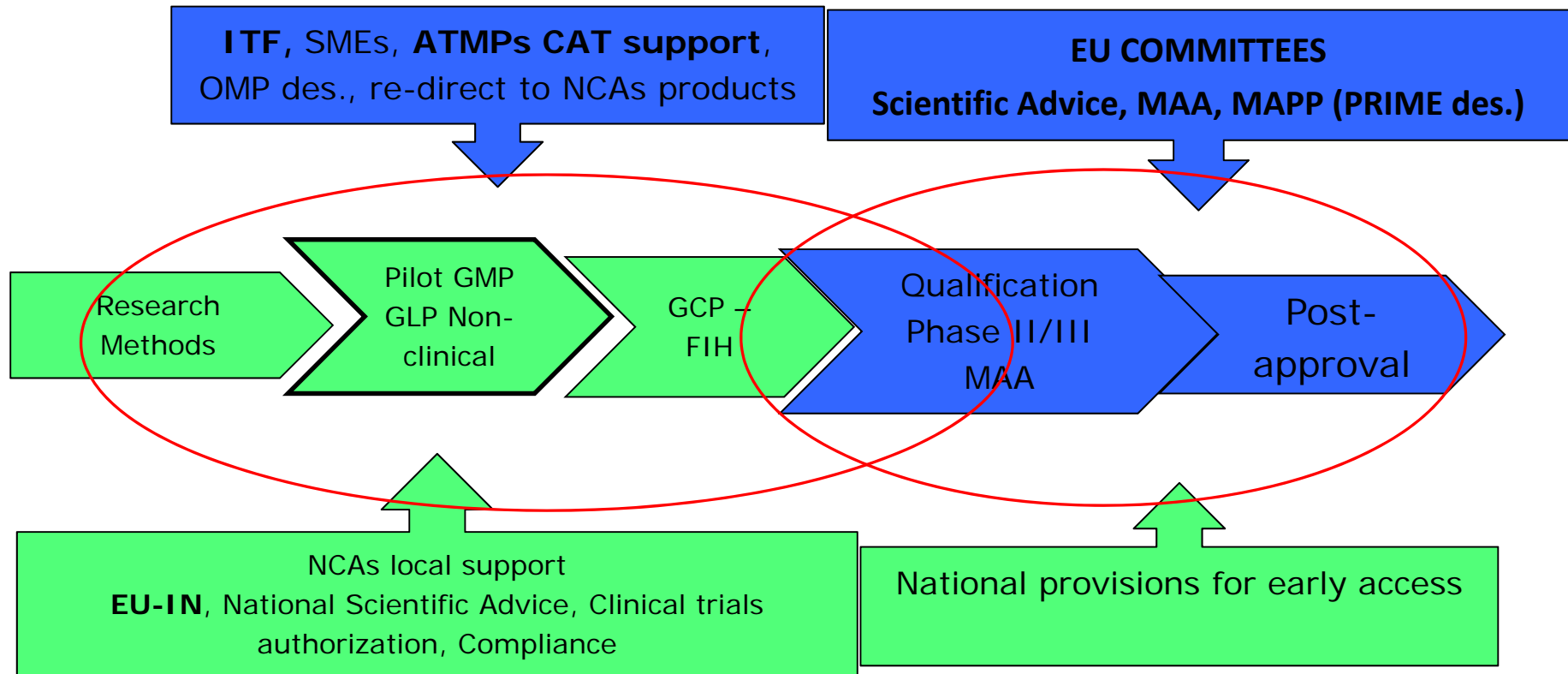
The typical long route of medicines to patients

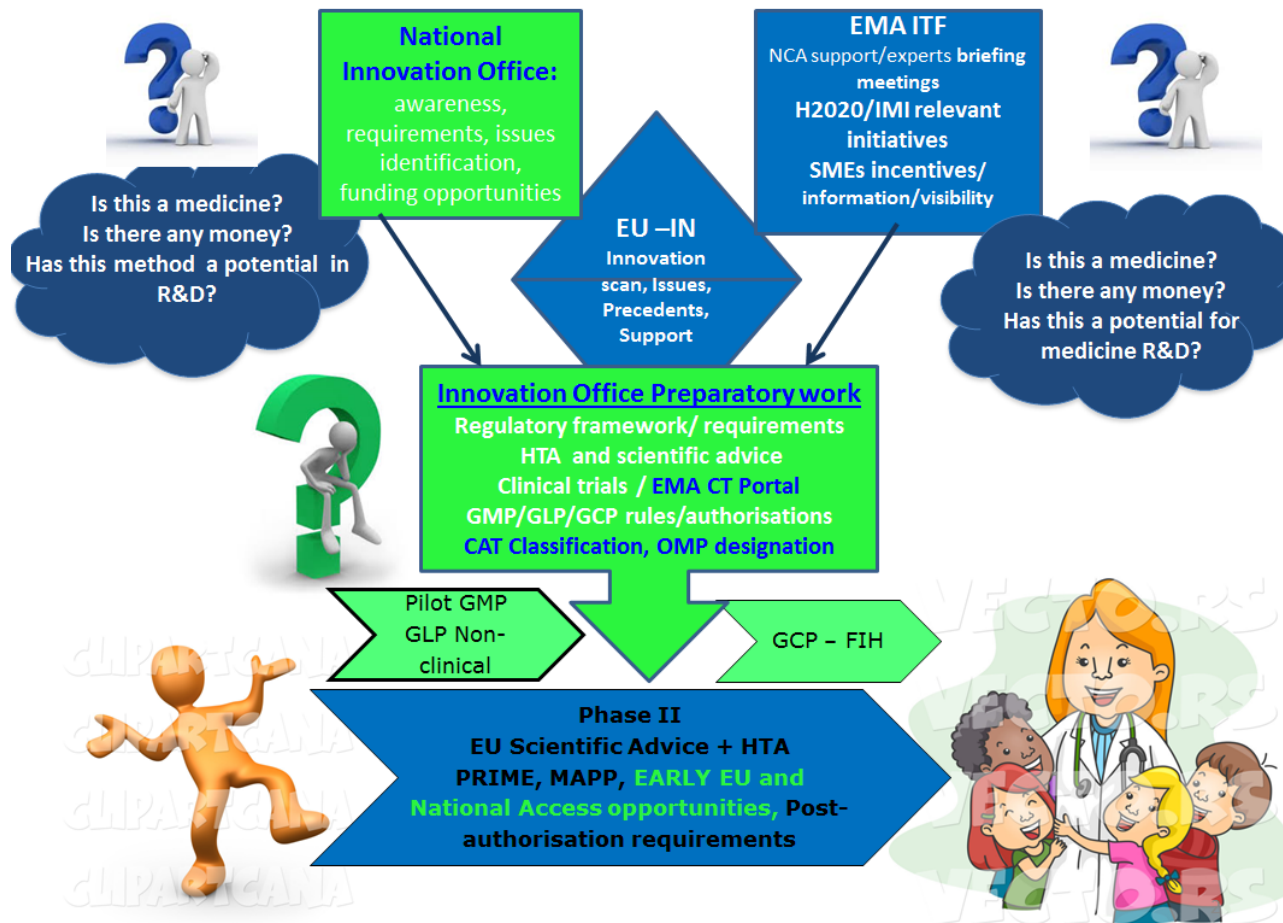
Chance of reaching access for a product entering the development phase:





For an EU seamless support to Innovation







Collaboration across EU network to support innovation





Thank you for your attention

Further information

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