

Federal agency for medicines & healthcare products

**Implementation of a national Innovation Office at famhp:
current status & future action plan**

December 1st, 2016

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Head of scientific-technical advice & KM unit

1. Introduction: The EU perspective

1.1 Summary of high level objectives to stimulate pharma innovation & SME support in the EU



“Think Small First”

A Small Business Act for Europe

“The EU and Member States should make public administrations responsive to SME needs, making life as simple as possible for SMEs, notably by promoting e-government and **one-stop-shop solutions.**”

“Boosting the emergence of high growth enterprises by supporting the research and innovation capacity of SMEs, mainly through **increased coordination of national programmes and initiatives.**”

2008 - Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions



Council of Europe conclusions

(Draft conclusions on 03.11.2014 from Working Party on Pharmaceuticals and Medical Devices)

Recognises the need to

- **facilitate the translation of scientific advances** into innovative medicinal products that meet adequate regulatory standards;
- **support to early development activities**, and collaboration and dialogue between the key actors involved in the regulatory approval of medicinal products.

Urges Member states to

- explore ways to maximise the **effective use of the existing EU regulatory tools**;
- take initiatives for early patient access to innovative medicines.

Asks the EU Commission to

consider possible changes to the Regulation (EC) No 1394/2007 **to reduce regulatory burdens and increase incentives for SMEs and academics.**



Pact for Innovation (INPACT) - K4I forum of the EP

(7th European Innovation Summit 2015)

The objective of the Pact for Innovation (INPACT) is to create a space for close collaboration between key stakeholders and the European Institutions. The collaboration is meant to result in concrete solutions addressing the pressing issue of multiple barriers preventing a strong and globally competitive innovation performance in Europe at all levels: national, regional and local.

“SME instrument” (EC – Horizon 2020)

The dedicated SME instrument's supports close-to-market activities, with the aim to give a strong boost to breakthrough innovation. Highly innovative SMEs with a clear commercial ambition and a potential for high growth and internationalisation are the prime target.

3 billion € in funding over the period 2014-2020

EMA Framework of collaboration with Academia

To implement the European Council conclusion (1-12-2014) on **innovation for the benefit of the patients**:.. *“in order to stimulate development, there is a need to facilitate the translation of scientific advance into innovative medicinal products that meet regulatory standards”...*



EU innovation network (EU-IN)



- EMA ITF + 12 National innovation offices/contact points
- AIFA, BfArM, HPRA and OGYEI (HU) also starting up a national IO in Q4 2016
- Aims to share information related to innovative drug development and initiate early dialogue with developers

➔ **EU-IN = part of the EMA network strategy 2020 (objective 3) and HMA multiannual workplan (action 10 & 11)**



1.2 New initiatives: The EU Innovation Offices network (EU IN)

- NCA's innovation offices can identify local innovators, initiate early discussions with universities, consortia and local small enterprises, and prepare them so that they derive the maximum benefit from the EU supportive tools, especially scientific advice and PRIME schema.



2. The Belgian perspective:

2.1 Summary of high level objectives to stimulate (pre)clinical R&D / innovation support in Belgium

- **Federal KMO plan (feb 2015)**
Defines implementation of several KMO-support measures (eg. KMO stress test reinforcement)
- **Future Pact on medicinal products (2015):**
“Er zal een **gecentraliseerd aanspreekpunt** specifiek voor starters en KMO’s uitgebouwd worden zodat biotech spin-offs en start-ups de nodige **reglementaire ondersteuning** krijgen bij de ontwikkeling van hun activiteiten. Het FAGG zal hiervoor een **nationaal innovatie office** oprichten in een netwerk met EMA en andere nationale agentschappen”.
- **Future Pact on medical devices (2016)**



3. Current services for Innovation support provided by the STA-KM unit @ FAMHP:



- Official start: april 2009
- STA unit: has been developed towards a well recognized dept. within DGpre
- Mission: stimulate R&D, innovation and early access to new innovative medicines to the patients' benefit
- Focus: early dialogue & stakeholder engagement
- How: providing multidisciplinary scientific-regulatory guidance & expertise throughout the product lifecycle!



3.1 Core activities: STA-KM unit

1. Coordination of scientific-technical/regulatory advice requests

 special focus on one-stop shop solutions (joint advice)

2. (Admin.) support of SAWP procedures coordinated by Belgium & proactive interaction with Belgian SAWP (H/V) members

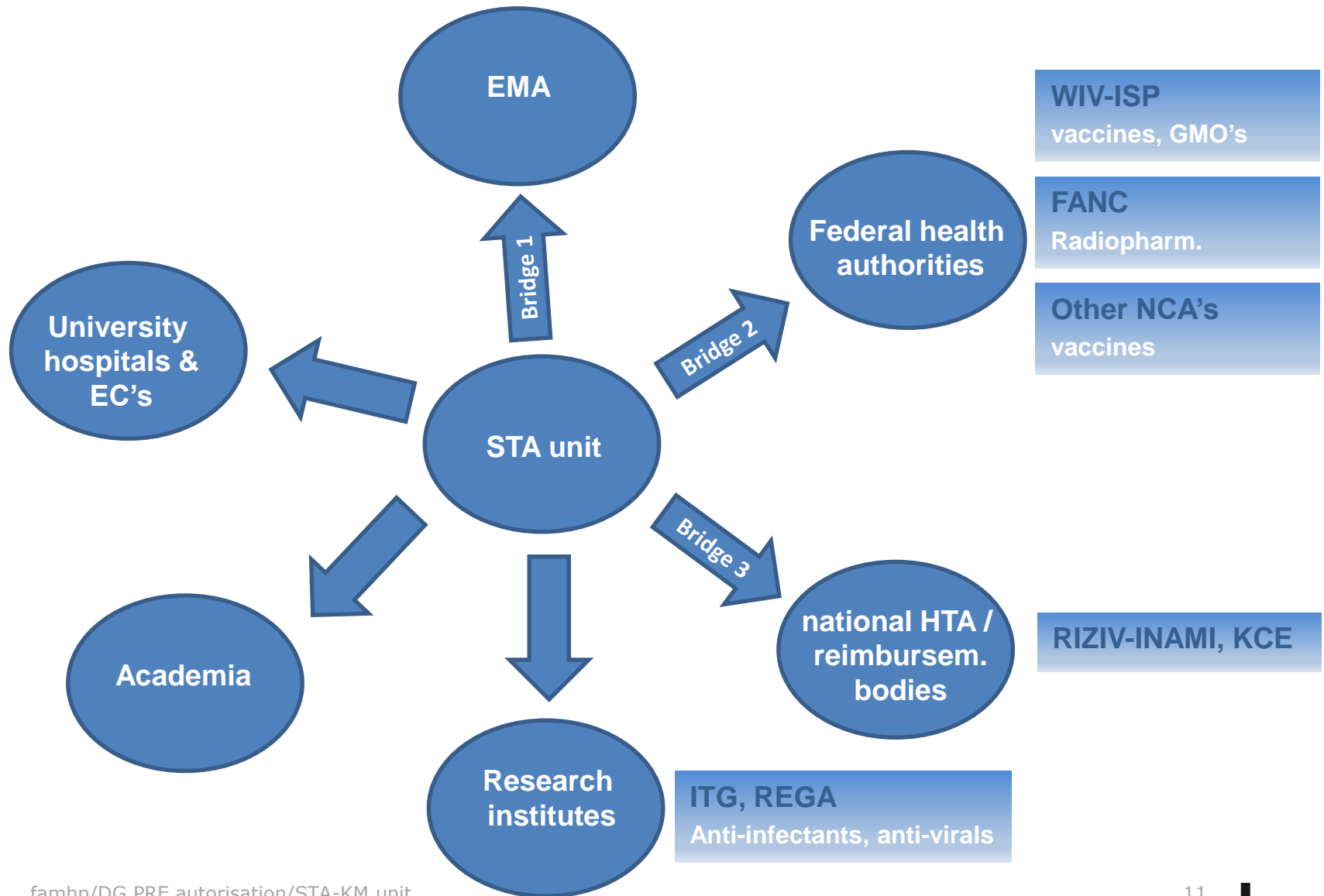
3. Networks of external expertise

famhp expert D-base: > 700 experts included (of which > 600 external)

Mainly (clinical) experts from academia / academic hospitals, other NCA's, ...



3.1 National STA: Interaction mechanisms



3.1 Core activities: STA-KM unit

4. “**horizon scanning**”: R&D developments, regulatory evolutions, rare diseases & unmet medical needs, early access mechanisms, ...

5. Coordination of:

- **Portefolio meetings:**

eg. company presentation, overview of R&D pipeline, therapeutic areas,...

- **Info meetings**

eg. R&D projects, biomarkers, biosimilars, ...

- **FAQ's**

eg. Regulatory issues, existing guidelines

= early dialogue tools prior to formal procedures !

= Free of charge, informal services



Core profile of a national Innovation Offices in the EU (EU survey 2014 results)

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LÄKEMEDELSVERKET
 MEDICAL PRODUCTS AGENCY

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 Search for medicines (Swedish) Drug or Substance [input type="text"]
 Extended search | A-Z

Website Search whole website [input type="text"]

MHRA Innovation Office

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

- Contents
- Role of the group
- Background
- Regulatory queries on regenerative

Role of the group
 The office has been set up to help enterprises (SMEs), ac

imea
 Läkemedel, utvärderings- och utvecklingscentrum för läkemedelsmyndigheten
 Finnish Medicines Agency

HEALTHCARE MARKETING AUTH. PHARMACIES SUPERVISION MEDICINES
 FOR PUBLIC ABOUT US FORMS LEGISLATION

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.



- 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

- About MPA
- Legislation
- Press Office
- Medicinal products
- Herbal Medicinal Products, Traditional Herbal Medicinal Products and Natural Remedies
- Certain medicinal products for external use
- Homeopathic medicinal products
- Cosmetic products
- Medical devices
- The Innovation Office
- More about the Innovation Office
- Newsletter Archive

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 our agency. Our goal is greater understanding of regulatory issues regarding clinical trials, pharmaceuticals, and devices.

If you have questions regarding the Innovation Office, please let us know at innovation@mpa.se.

For continuous news about regulatory issues and to subscribe to our newsletter.

The SME-Guide (only available in Swedish)
 The SME-Guide is a guide to information about drug processes and other regulatory issues. The SME-Guide assist in finding relevant information at the MPA and agencies such as the EMA and EU Commission.

Visit the SME-guide (only available in Swedish)

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

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

Paul-Ehrlich-Institut

Informationen Institut Forschung Arzneimittel Vigilanz IVD Veranstaltungen Service

Informations für Patienten und Verbraucher
 Antragssteller und Pharmazeutische Unternehmer
 Beratung
 Innovationsbüro
 Wissenschaftliche Beratung - DTKY
 Wissenschaftliche und regulatorische Beratung - GfP
 Nationale Beratung - PEI
 Scientific Advice - EMA
 Klinische Prüfungen
 Zulassung (human)
 Zulassung (veterinär)
 Genehmigungen
 Chargenprüfung (human)
 Chargenprüfung (veterinär)
 Inspektionen
 Medizinprodukte / Anlageerfüllung
 Referenzmaterial
 Elektronische Einreichung
 IVD
 Gebühren
 Ärzte und Apotheker
 Tierärzte
 Journalisten
 Heilpraktiker

Innovationsbüro
 Informelle Beratung zur Entwicklung von Arzneimitteln für neuartige Therapien (ATMP)
 E-Mail: innovation@pei.de
 Telefon: +49 6103 77-1012 oder -1034
 direkter Link: www.pei.de/innovationsbuero

Aktuelle Termine
 19.03.2015
 31. Jahrestagung Pharmazeutische Industrie

witere Informationen:
 Broschüre:
 Arzneimittel für neuartige Therapien, regulatorische Anforderungen und praktische Hinweise
 Beratungen: Rahmen und Möglichkeiten
 Orientierungssprache
 Konzept und Expertise
 Adressen und Ansprechpartner
 Entscheidungsbäume:
 Klassifizierung eines Arzneimittels als ATMP
 Voraussetzungen für die Genehmigung eines Arzneimittels nach S. 13 Abs. 1

Formulare:

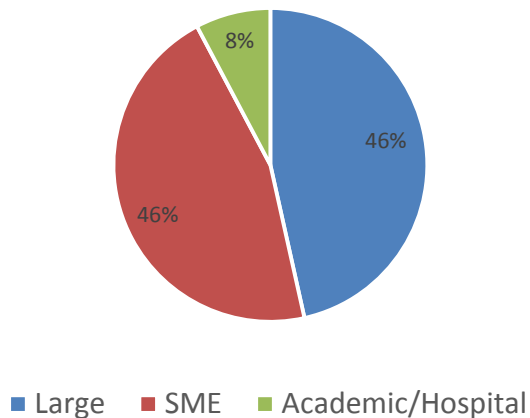


famhp/DG PRE authorisation/STA-KM unit

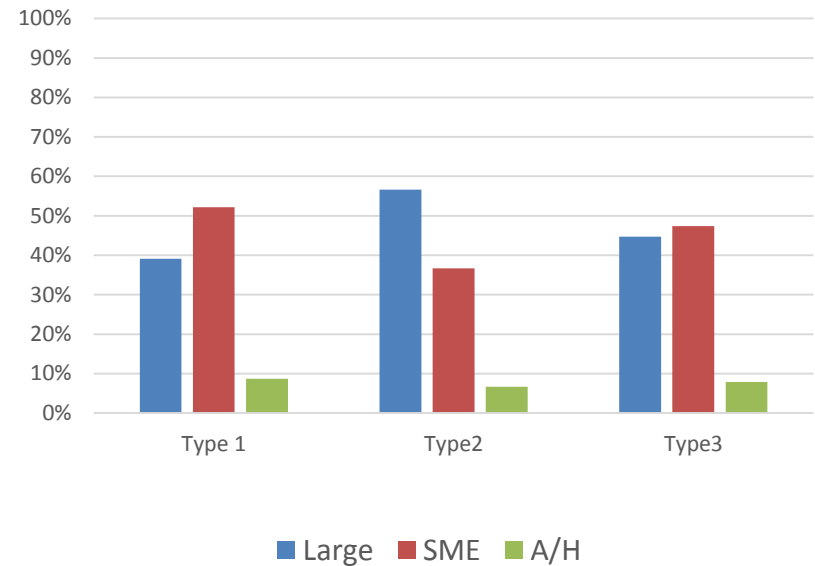


3.2 National STA: specific experience with SMEs

Type of STA applicants: 2013-2016

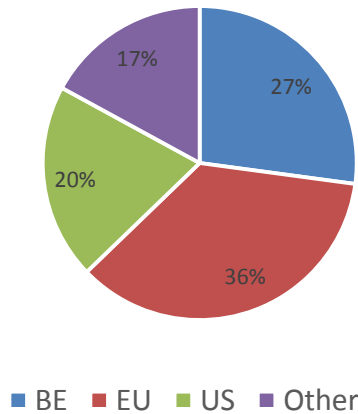


Type STA file: 2013-2016

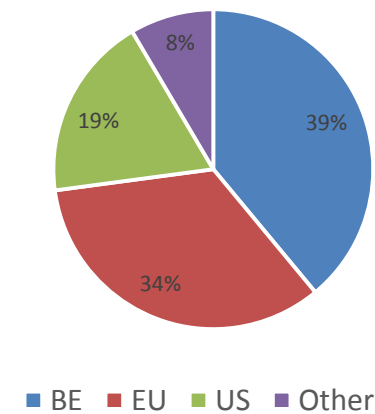


4.2 National STA: specific experience with SMEs – geographic origin of STA request

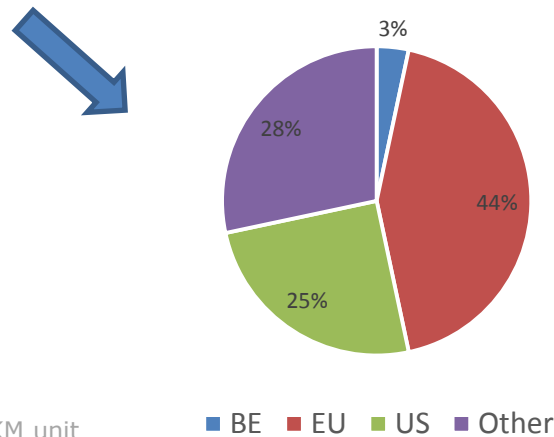
Total STA requests: 2013-2016



SME related STA requests: 2013-2016

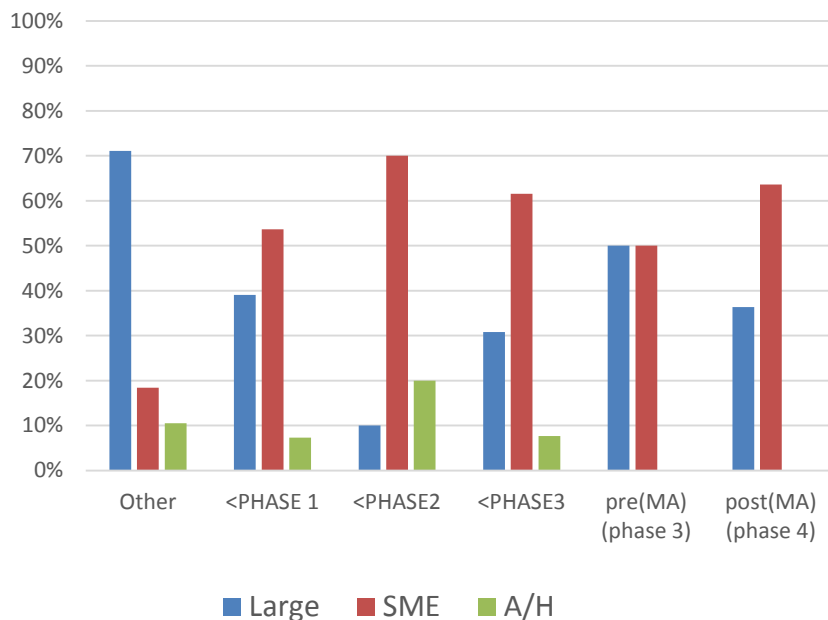


Large pharma Cy's STA requests: 2013 -2016

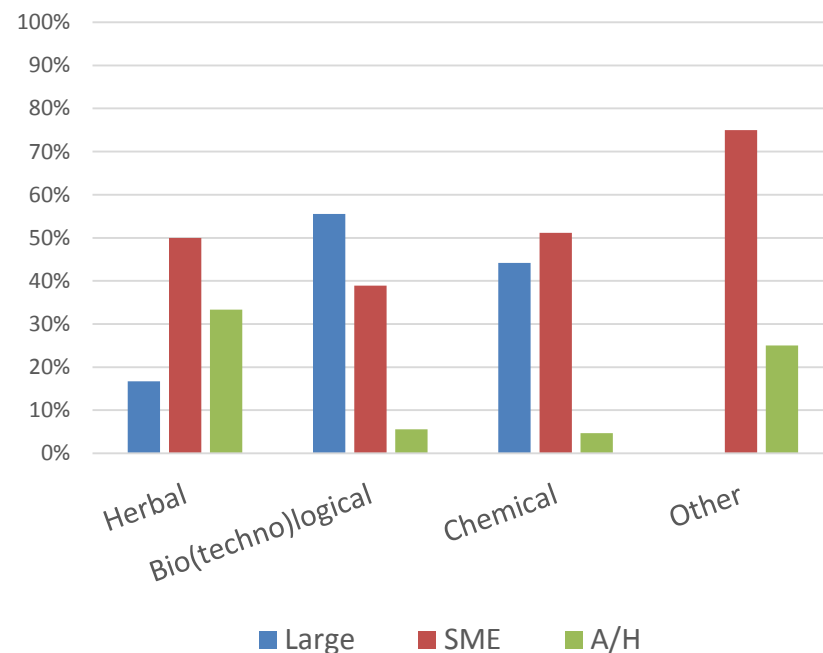


3.2 National STA: specific experience with SME's

Timing of STA request ifo development phase: 2013-2016



Product type of STA request: 2013-2016



3.3 SME & academia-related STA challenges

1. Lack of knowledge & experience

- STA procedures and opportunities not well-known
- SME incentives insufficiently known, dispersed or lacking (international - EU - national level)
- Difficulties in identifying & formulating critical STA questions
- Lack in awareness of regulatory requirements

2. Lack of resources:

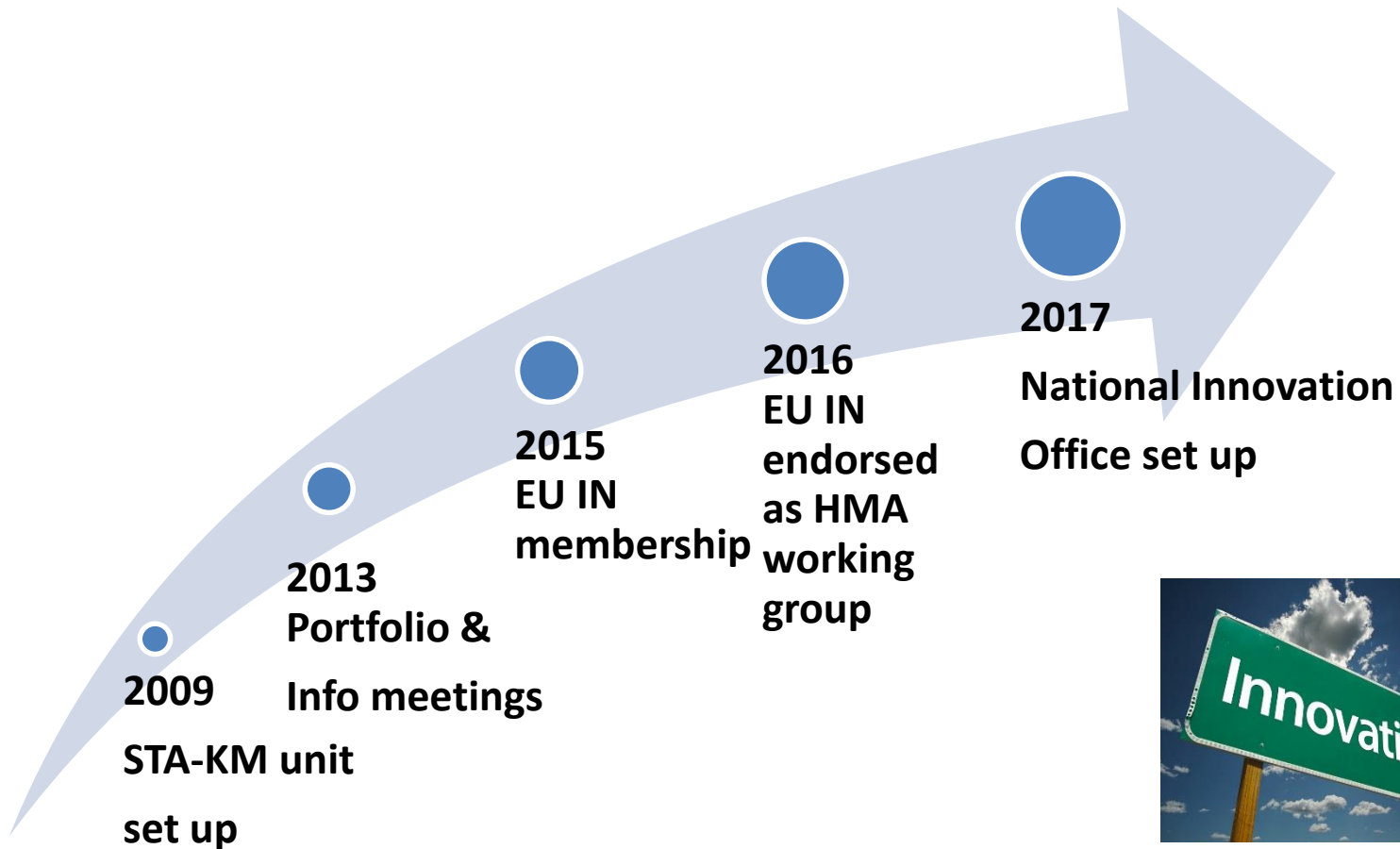
- STA fees = financial hurdle ?
- Lack in resources for proper STA file preparation

3. Different needs SME's & academia ?

= heterogenous stakeholder groups with specific needs vs large pharma sector (eg. Regulatory training, funding / STA fee reduction, ...)



4. From STA-KM unit to national Innovation Office



4.1 National Innovation Office:

3 Main pillars of future activities:

- Scientific & technical/regulatory advice:
 - optimising current services + staggered scope expansion to medical devices, IVD's and MCH
 - implementing new services
- Specific support to SME's, start-ups and academics/academic hospitals
- General innovation support
(open to all innovators / stakeholders involved in innovative R&D)



4.1 National Innovation Office:

6 Key result areas:

- Developing new types of scientific-technical/ regulatory advice & early dialogue mechanisms:
 - ➔ facilitation & acceleration of (pre)clinical R&D & early access to patients
- Promotion of innovative R&D with medicinal products & attracting new R&D to belgium
- Developing specific support mechanisms for SME's and academia and SME friendly policy @ famhp



4.1 National Innovation Office:

6 Key result areas:

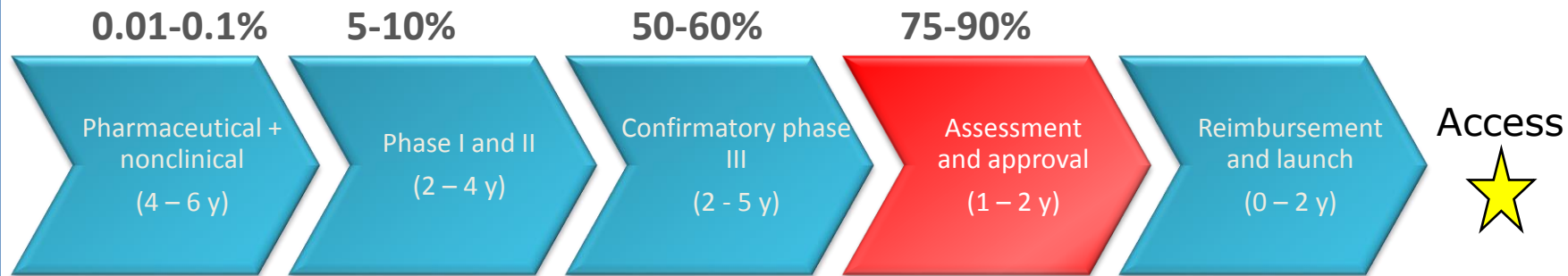
- Information & communication:
National IO = central entry port & knowledge centre at famhp for innovators
= central interface & facilitator for
(re)directing innovators to other national & EU
authorities, service providers, initiatives
- Training & sensibilisation
(eg. Regulatory topics, upcoming regulations &
guidelines, ...)
- Policy support ifo farma-related innovations &
SME/academic support



4.2 National Innovation Office: a starting point

The typical long route of medicines to patients

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



ITF

PRIME

EMA/CHMP scientific advice

National Scientific Advice

National innovation office



4.3 National Innovation Office: Next steps

Key priorities towards 2017:


- Recruitment of 1 FTE project collaborator
- Communication: SME specific website, symposia
- STA procedures:
 - optimisation of joint STA-HTA advice
 - scope extension: medical devices & DDCP's
 - investigating new types of STA
- STA fees revision & feasibility study for fee reduction system for eg. SME's & academia (cfr. ZBB project 2017)
➔ for budget 2019 ?

Sustainability of national Innovation Office (investment fund ?)



4.3 National Innovation Office: Next steps

Key priorities towards 2017:

- Cartography of clinical research from SME's, academic spin-offs, clin. res centres, ...
- Promote national IO as central contact point for innovators & interface  knowledge gathering
- Active involvement @ EU IN & follow-up of best practices of EU IN members in line with the core activities from the national IO's (EU survey 2014)
- Training workshops: eg. CTR



4.3 national Innovation Office: Next steps

Initial scope (project phase I):

- Product types: eg. for human use
 - medicinal products
 - medical therapies
- Non-Product related topics:
eg. new platform technologies, innovative clinical trial designs/concepts
- Stakeholder types: mainly
SME's, academic spin-offs, academic research centres/hospitals




criteria for access to specific national IO services to be defined! (eg. STA fee reductions)



4.3 National Innovation Office: Next steps

Organisational set-up

- Implementation of the national IO is foreseen:
 - within DGpre marketing autorisation as a separate entity
 - at the level of the current STA-KM unit
 - with partially dedicated staff,
 - with a specific website (including SME specific area)  maximal visibility
 - the previous « KMO loket » project is being retaken within the current national IO project



STA info & national IO guidance at FAGG website

The screenshot shows the FAMHP website interface. The main navigation bar includes 'Human medicines', 'Veterinary medicines', 'Information for the public', and 'Notification of adverse reactions or incidents'. The 'Human medicines' section is active. The breadcrumb trail is: Home > Human medicines > Medicines > Medicines > Scientific-technical advice. The 'Scientific-technical advice' page lists several sub-topics: Introduction, Procedures, Regulation, Fees, FAQ's, Workshops and Training, and National Innovation Office: consultation procedure. The last item is circled in red. On the right side, there are three promotional boxes: '5-year celebrations at famhp!', 'Notification of adverse reactions or incidents', and 'PIL and SPC of a medicine'. The browser's address bar shows the URL: https://www.fagg-afmps.be/en/human_use/me. The taskbar at the bottom shows various application icons and the system clock indicating 11:21 on 14/10/2016.

http://www.fagg-afmps.be/en/human_use/medicines/medicines/scientific_technical_advice/



Contact

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Backup slides



2.2 New initiatives:

Mission of the EU-IN

The objective of the EU Innovation Network is to facilitate the development of innovative medicines by addressing gaps in early regulatory support to innovation by:

- **making the regulatory support available at national and EU level more visible and attractive** to innovators since early stage;
- **reinforcing dialogue** with innovators with a wider EU exposure of identified issues;
- providing a **platform for regulators to share and improve the flow of knowledge** from early stage innovators (with their agreement) to NCAs and to EMA scientific committees;



2.2 New initiatives:

Mission of the EU-IN

- **identifying and encouraging sponsors** of promising drug development projects, including combination products and advanced therapy medicinal products, **to move into the next appropriate regulatory level** for national and EU advice and evaluation;
- **actively contributing to and integrating into relevant EU initiatives** enabling innovative medicines development and access to patients.



2.2 New initiatives:



Mandate of the EU-IN

(adopted by HMA : 6th sept 2016)

- The EU-IN develops an **annual work plan** to be agreed upon by the EMA and the HMAs.
- The EU-IN provides the EMA and the HMA with **an annual update** of the activities undertaken.
- **Support the EU-NTC** in identifying areas for training ensuring capability of the network
- **Discuss best practices**
- **Establishment of innovation contacts points/offices** in more regulatory agencies.
- **Horizon scanning** for HMA and EMA:
New emerging science and technology



3.3 SME & academia-related STA challenges & needs

- Need to come early in development starting with general R&D project outline before entering formal procedures (eg. STA, CTA)
 cfr. relevant for public funded trials
- Need for STA pre-submission guidance if first time
- Need for regulatory guidance
- Fear of disclosing key info in an open manner to allow proper advice from famhp
- consider upfront the need & funding in the R&D project for seeking follow-up advice
 Impact on succes rate on future filing of eg. CTA, UMN, MAA but also requests for project funding (BE and EU level)!



A large, stylized graphic of a human eye is centered on the page. The eye is composed of several overlapping, semi-transparent shapes in shades of light blue and grey. The iris is a light blue circle with a white pupil and a grey ring. The eyelids are represented by grey, curved shapes at the top and bottom. A dark blue horizontal bar is superimposed over the center of the eye, containing white text.

**Your medicines and health products
are our concern!**