EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strengthening the Network – Goals of EMA and National Competent Authorities

DGRA – 19 annual congress
23 May 2019

Presented by Professor Guido Rasi
Executive Director - European Medicines Agency

An agency of the European Union

The European medicines regulatory network

50 national regulatory authorities European Commission European Medicines Agency

EU Medicines Agencies Network Strategy 2020 - Focus

- More support is needed for generics and biosimilars.
- Innovation is extremely important and needs to be supported but should not be the only focus of the Strategy.
- Timely access to medicines should be addressed for all medicines and not only innovative. Reduction of regulatory burden should be addressed for all medicines.

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EMA and the European medicines regulatory network

28
Working parties

7 Scientific committees
CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC

Over
1000
Marketing authorisations receomended

1995
EMA established to evaluate Medicines for use in the EU

4000
scientific experts from right across Europe

860
Staff members

Performance and achievements 2016

Staff

860 EMA

4000 scientific experts

Products

81 positive opinions

27 New active substances

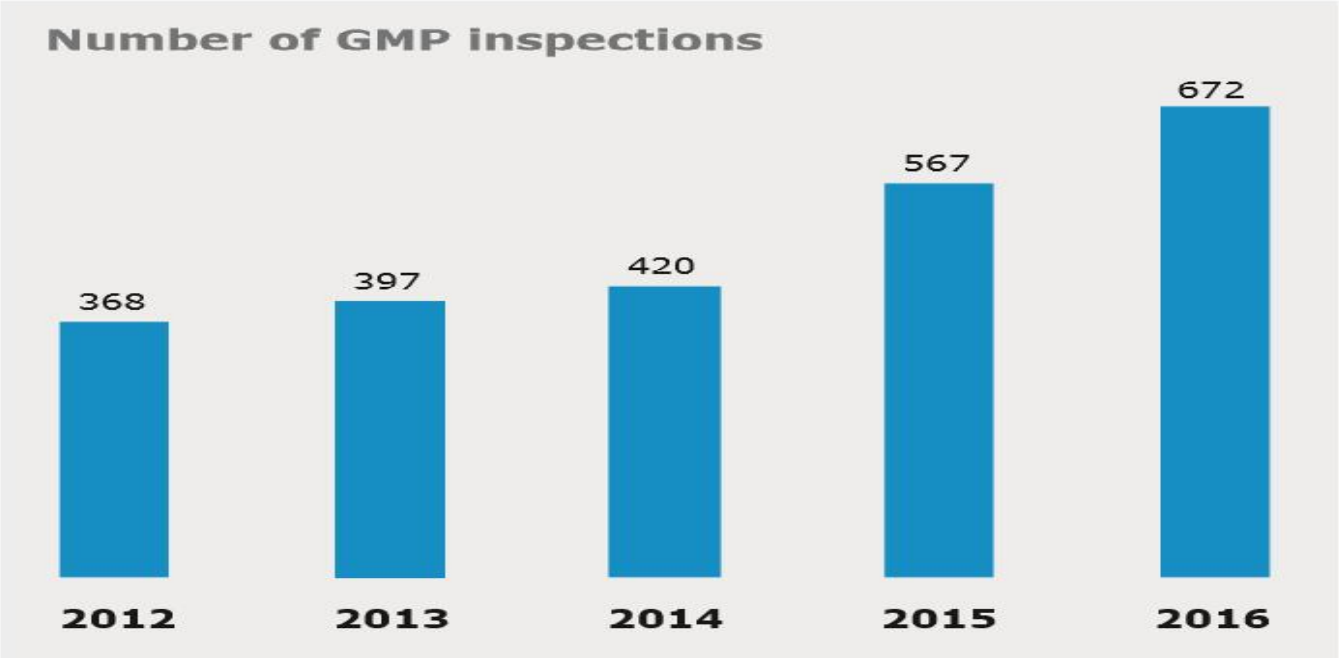
PSURs/PSUSAs

751 PSURs&PSUSAs procedures started in 2016

791 PSURs&PSUSAs procedures finalised in 2016

GMP inspections

The number of GMP inspections requests increased by 18.5% in 2016, linked to the growing number of centrally authorised products.



Regulatory challenges and how to address them

Sustainability

- Health systems (medicines cost, NCAs/EMA)
- R & D (patient access to innovation, Europe competitiveness)

Quality

- Scientific opinions (complexity)
- Medicines (safety, efficacy, availability)

...and how to address them

- Increase attractiveness, competiveness (SME office, PRIME, Regulatory Sciences)
- Initiatives for timely access (ITF, PRIME, Adaptive Pathways)
- Work load (re)distribution
- Strengthen the network through initiatives (MNAT, EU NTC)

Timely access

- ITF-EU Innovavation Network
- PRIME
- Scientific Advise
- Adaptive pathways

Innovation across the product lifecycle

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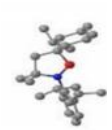

Clinical development

Pharm | Non-clinical | I | II | III | MAA | Post-mkt

*EU-Innovation Network

PRIME Scheme

Adaptive pathways

Scientific Advice / Protocol Assistance

Innovation Task Force (ITF)

* Qualification biomarkers/methods

* Parallel SA with FDA

* Parallel SA with HTA's

Paediatric Investigation Plans

Business Pipeline Meetings

Orphan Designation

Academic Office

ATMP Classification

Certification

SME Office

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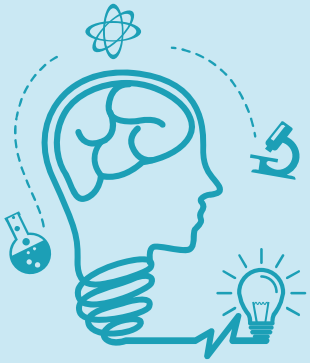
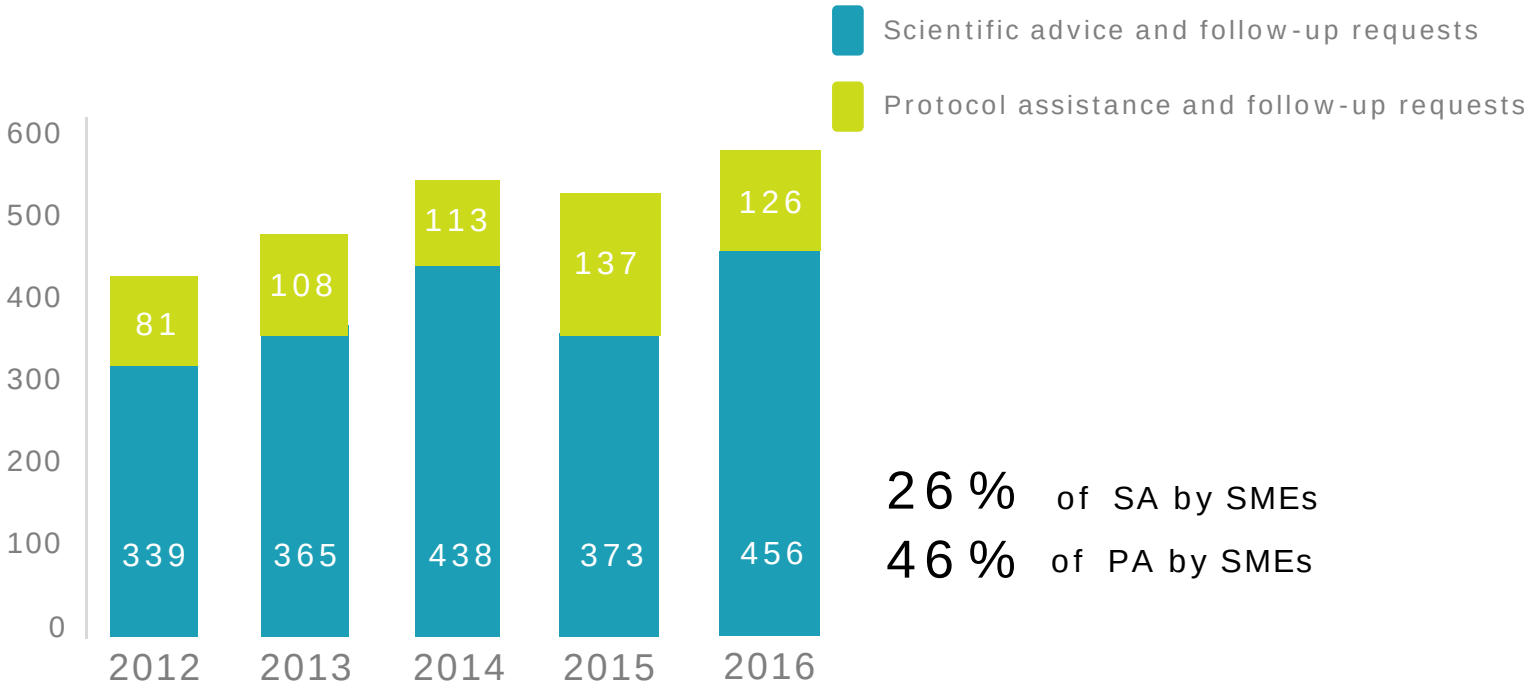
Scientific Advice – Protocol Assistance



Human medicines

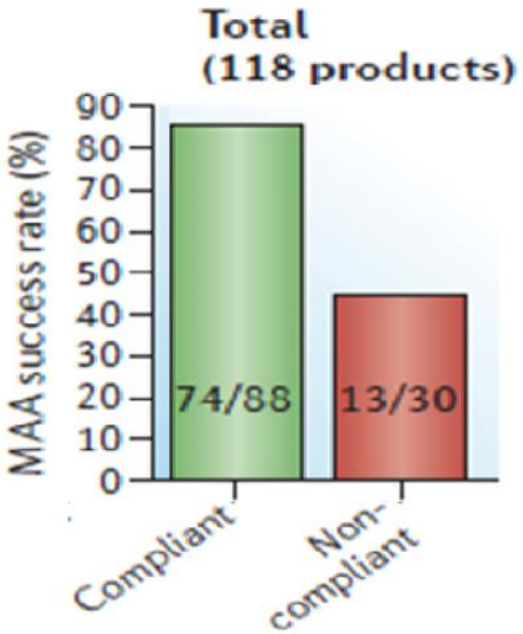


26 % of SA by SMEs

46 % of PA by SMEs

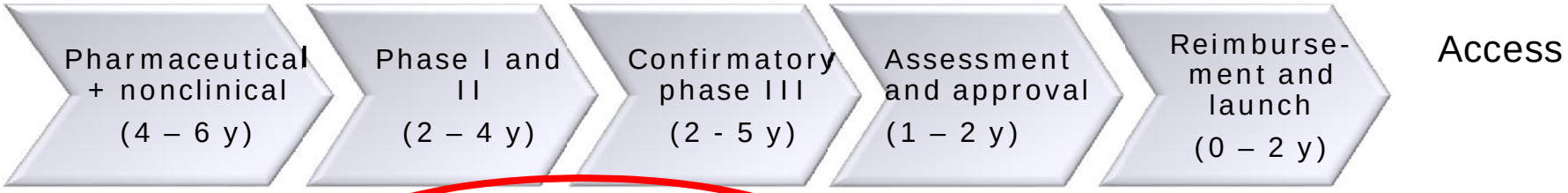
Positive impact of SA adherence on MAA outcome

MAA success for MAAs with SA/PA submitted in 2008–2012



The typical long route of medicines to patients

Development phase



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

0.01-0.1% 5-10% 50-60% 75-90%

Joint HMA-EMA EU Innovation Network

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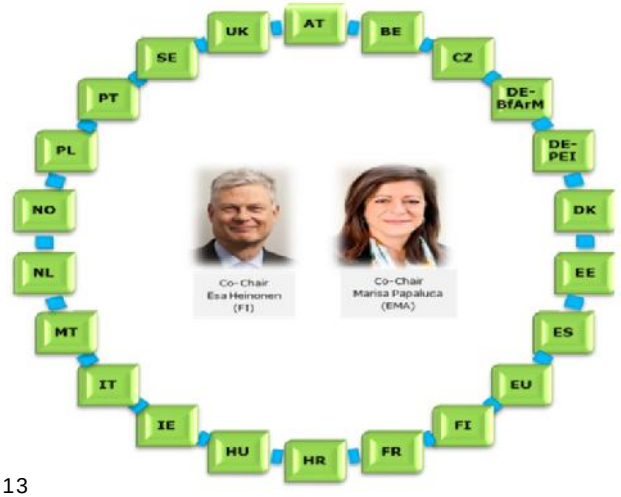
In 2015, EMA and the EU national competent authorities strengthened their collaboration to support medicine innovation and early development of new medicines in the EU by establishing the EU innovation network.



EMA and the HMA adopted the mandate of the EU Innovation Network in October 2016

PRIME – Priority Medicines

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PRIME: in brief

Medicines eligible for PRIME must address an unmet medical need.

Preliminary data must be available showing the potential to address this need and bring a major therapeutic advantage to patients.

EMA will provide early and enhanced support to optimise the development of eligible medicines, speed up their evaluation and contribute to timely patients' access.

Benefits of PRIME

FOR PATIENTS

- PRIME is driven by patients' needs.
- It focuses on medicines that address an unmet medical need, i.e. offer a major therapeutic advantage over existing treatments, or benefit patients with no current treatment options for their disease.
- It helps to translate research into the development of medicines while meeting regulatory requirements.
- It aims to bring promising treatments to patients earlier, without compromising high evaluation standards and patient safety.

FOR MEDICINE DEVELOPERS

- PRIME helps developers of promising new medicines to optimise development plans.
- It fosters early dialogue with EMA to facilitate robust data collection and high quality marketing authorisation applications.
- It speeds up evaluation so that medicines can reach patients earlier.
- It encourages developers to focus resources on medicines likely to make a real difference to patients' lives.

PRIME – Priority Medicines

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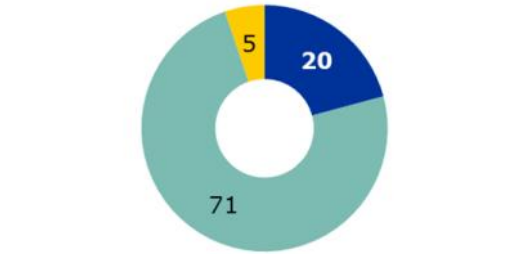
Which medicines are NOT eligible for PRIME?

Medicines that do not address an unmet medical need.

Medicines that do not bring a major therapeutic advantage to patients.

Medicines that are already on the market.

PRIME eligibility recommendations adopted by 21 April 2017

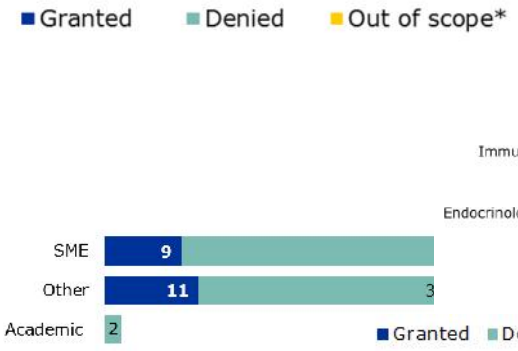


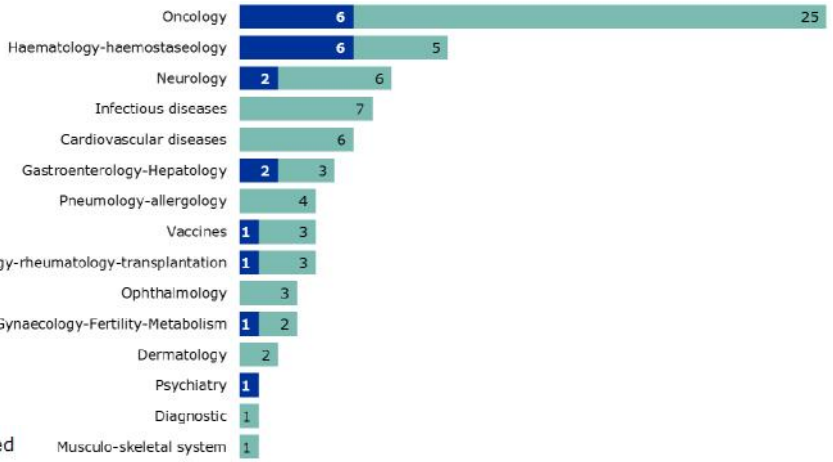
> 90 eligibility requests

20 granted*

~ 50% SMEs

> 50% Advanced therapies





Adaptive Pathways – harnessing existing tools

Conditional marketing authorisation (in EU legislation)

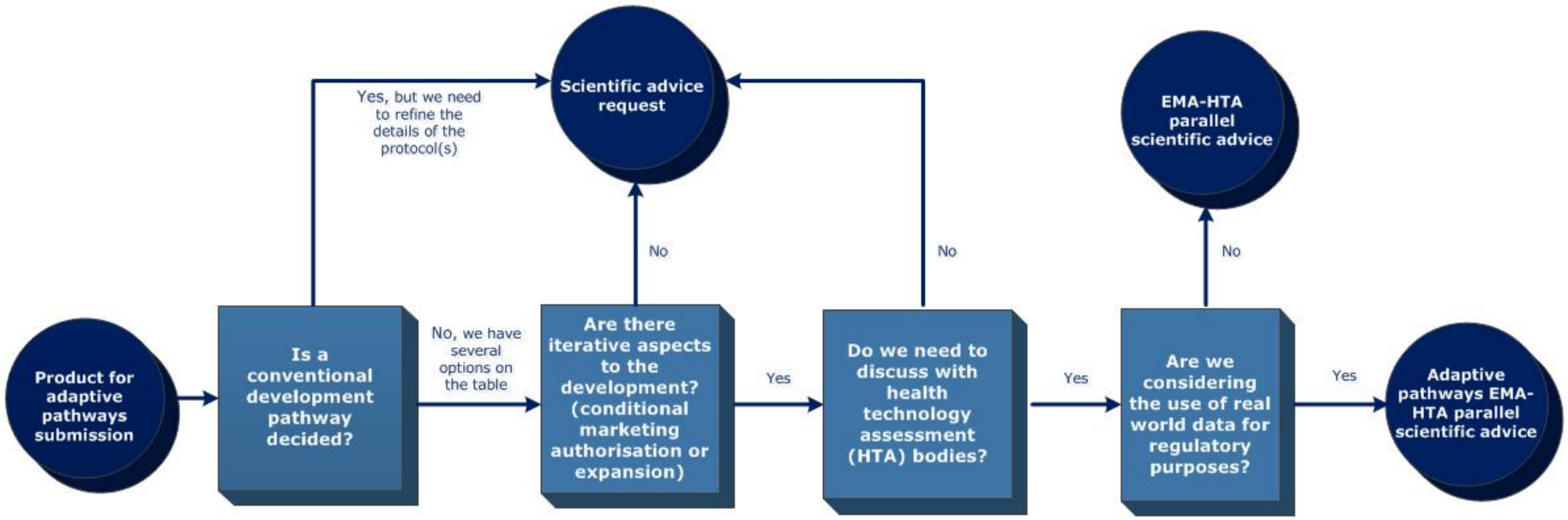
Post-marketing commitments; Risk Management Plans (in PharmacoVigilance Regulation)

Multi-stakeholder scientific advice

Registries, other data sources

Adaptive pricing/reimbursement (managed entry agreements)

Product eligibility for adaptive pathways



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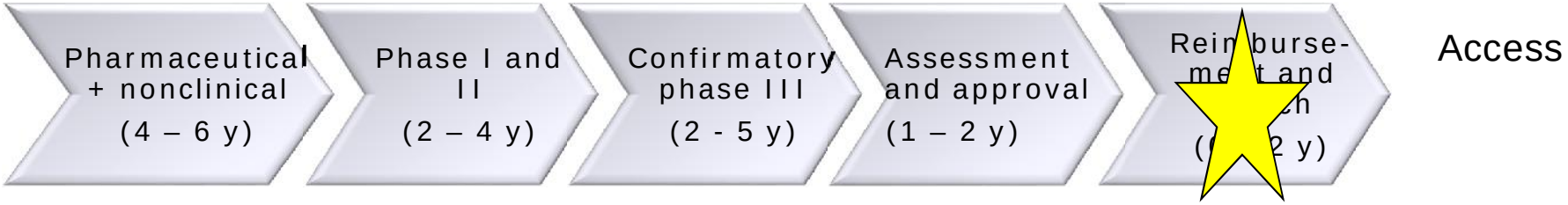


Chance of reaching access for a product entering the development phase:

0.01-0.1% 5-10% 50-60% 75-90%

Collaboration with HTA

Joint Scientific Advice with Health Technology Assessment bodies

- Possibility for Applicants to discuss together with Regulators and Health Technology Assement bodies (HTAs) early in development what is needed to do, not only for the benefit/risk asessment (Regulators), but also decide on the added value (HTAs) so that HTAs recommend reimbursement and the product gets to the patients.

Domains of (untapped) synergies between regulators and HTAs

Collaboration in the PRIME scheme

Linking existing initiatives on horizon scanning

Exchange on the regulatory assessment / label to ensure better understanding

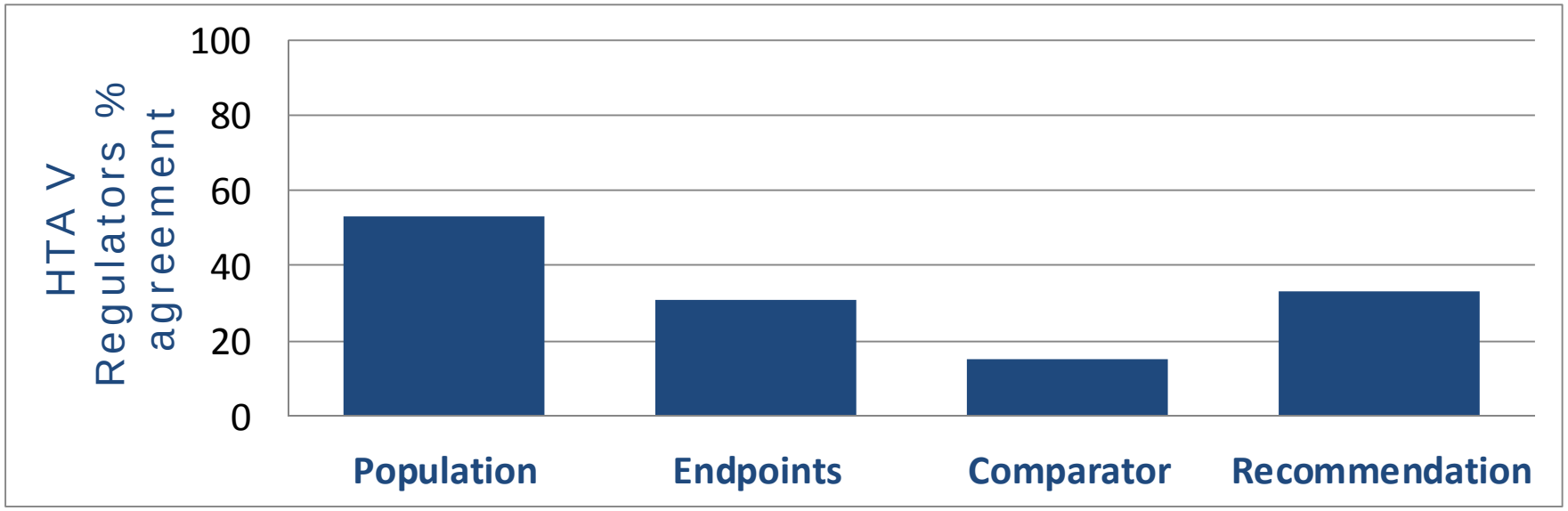
Most developed: early dialogue / parallel scientific advice

Potential collaboration on “Late dialogues”

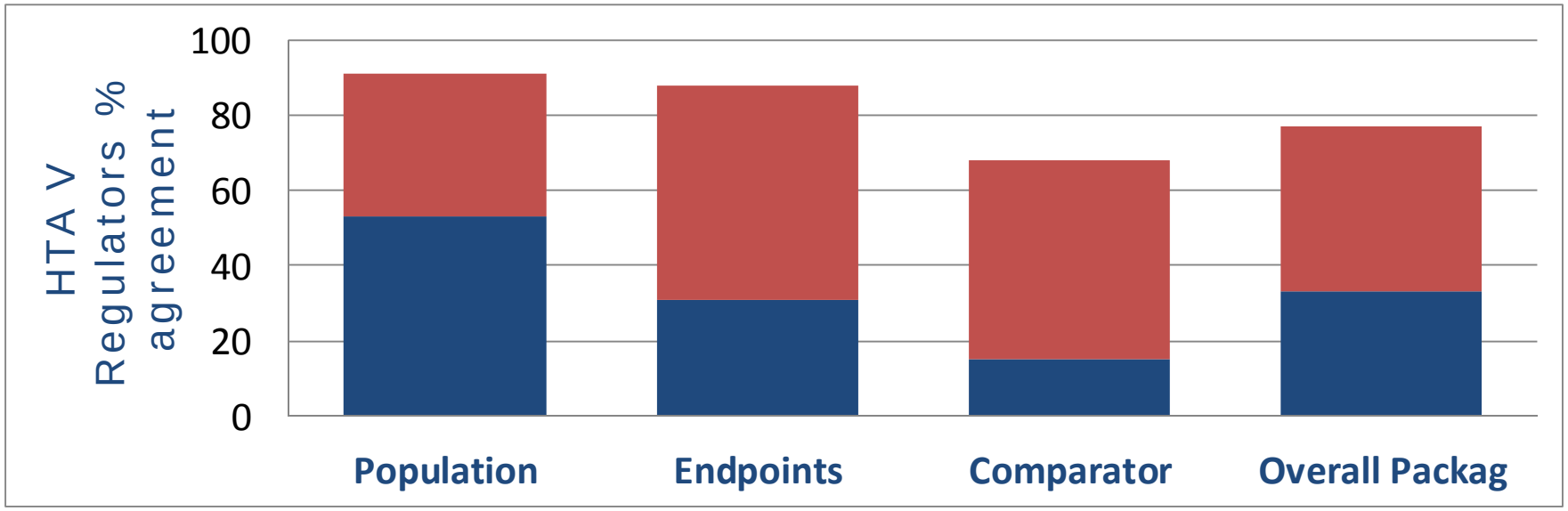
Patient registries to address different uncertainties (clinical, economic, health system utility)

HTA-regulatory collaborations need to reflect appropriate balance between the enabler and the gatekeeper roles to ensure effective, well-aligned and sustainable healthcare systems in EU.

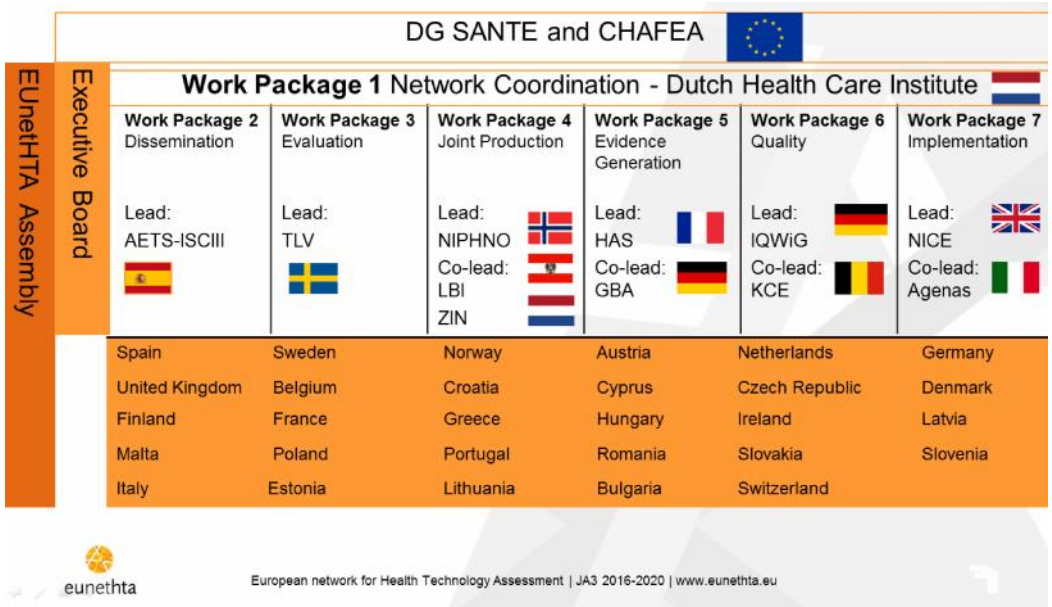
Can Parallel Advice help?



Can Parallel Advice help?



EMA contribution to Joint Action 3



- WP 4 – joint production (contribution is here with regard to exchange after CHMP Opinion)

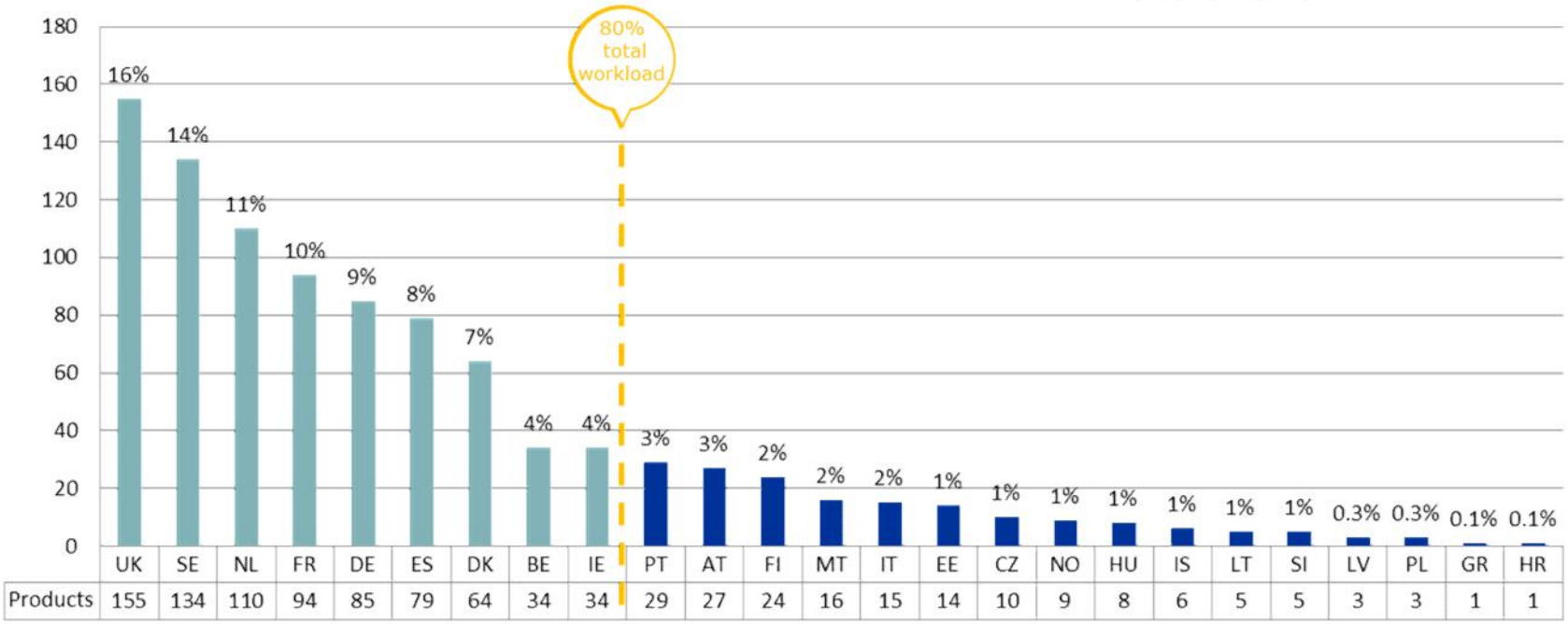
- WP5 – life-cycle approach to improve evidence generation:
  part a = early dialogues
  part b = post-licensing evidence generation

Efficacy - Workload (re)-distribution within the EU Network

Human Medicines

CHMP – Post-Authorisation Rapporteur – product distribution*

MS with no Rapporteurship appointment:
BG, CY, LU, RO, SK, SL



	UK	SE	NL	FR	DE	ES	DK	BE	IE	PT	AT	FI	MT	IT	EE	CZ	NO	HU	IS	LT	SI	LV	PL	GR	HR
Products	155	134	110	94	85	79	64	34	34	29	27	24	16	15	14	10	9	8	6	5	5	3	3	1	1

*as of 29 March 2017

CHMP – Post-Authorisation Co-Rapporteur – product distribution*

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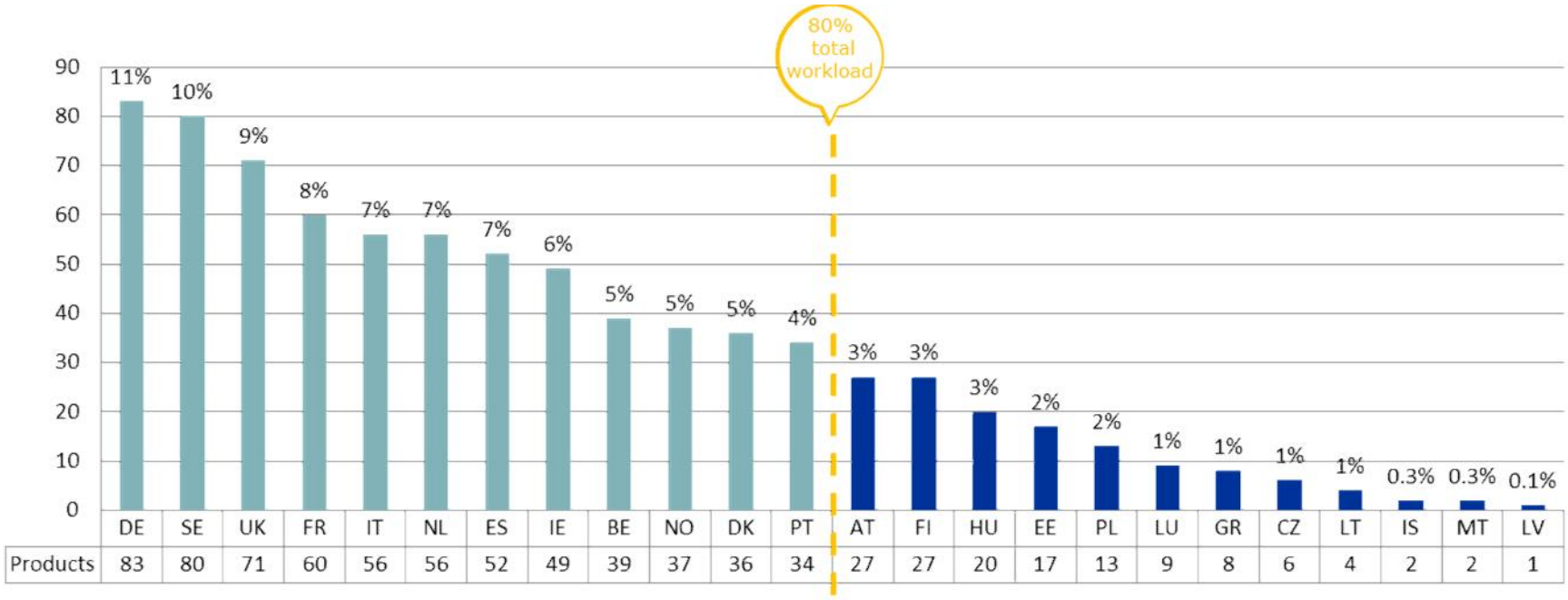
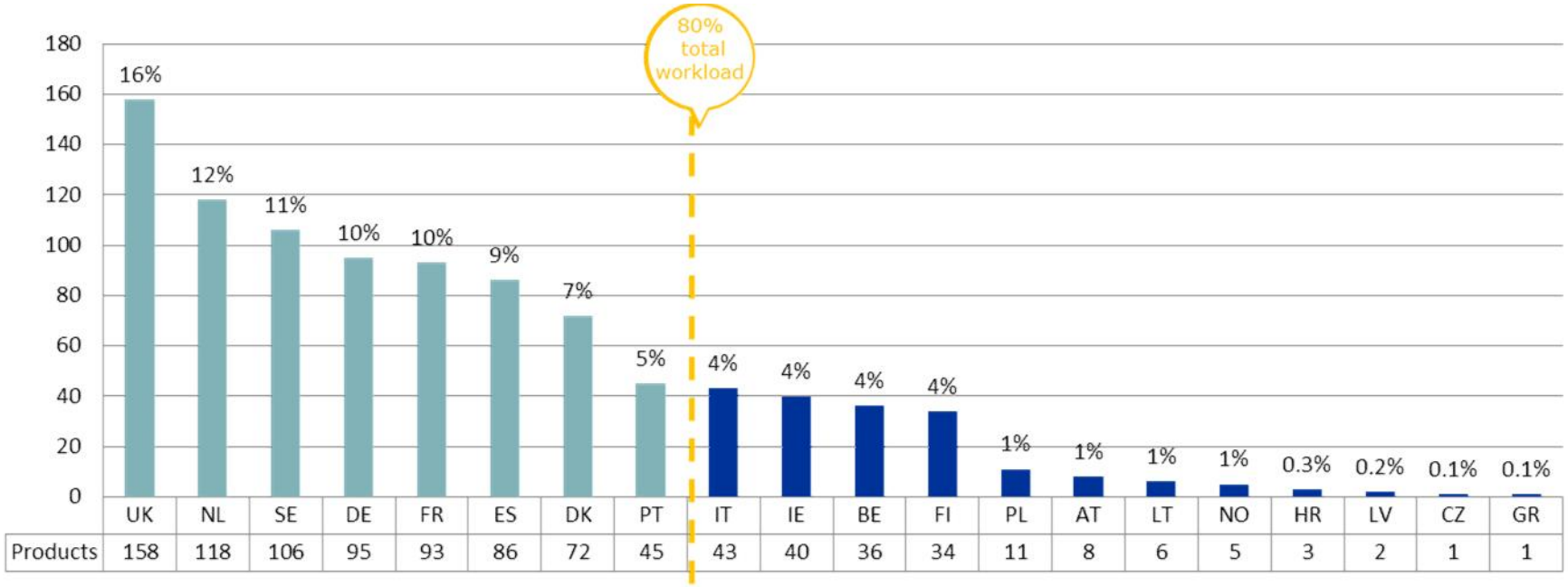


	DE	SE	UK	FR	IT	NL	ES	IE	BE	NO	DK	PT	AT	FI	HU	EE	PL	LU	GR	CZ	LT	IS	MT	LV
Products	83	80	71	60	56	56	52	49	39	37	36	34	27	27	20	17	13	9	8	6	4	2	2	1

*as of 29 March 2017

PRAC – Post-Authorisation PRAC Rapporteur – product distribution*

MS with no Rapporteurship appointment:
BG, CY, EE, HU, IS, LU, MT, RO, SK, SL



	UK	NL	SE	DE	FR	ES	DK	PT	IT	IE	BE	FI	PL	AT	LT	NO	HR	LV	CZ	GR
Products	158	118	106	95	93	86	72	45	43	40	36	34	11	8	6	5	3	2	1	1

*as of 29 March 2017

PRAC – Post-Authorisation PRAC Co-Rapporteur – product distribution*

MS with no Rapporteurship appointment:
~~BG, CY, HR, LV, RO, SK, SL~~

*as of 29 March 2017

Initiatives to support the network

- MNAT
- EU NTC

Multinational Assessment Team - Purpose

- MNATs aim to maximise use of resources and expertise and facilitate NCAs participation in assessments maintaining the high quality of scientific work.
- The Multinational assessment team (MNAT) concept allows:
  - the option of an assessment team to be formed from different National Competent Authorities (NCAs)
  - payment by EMA to the individual NCAs according to the share of the remuneration agreed by the involved NCAs.

Multinational Assessment Team – Current status

- The MNAT was introduced in 2013 (for initial MAAs for human medicines) and gradually extended (for veterinary medicines, for scientific advice and MRL applications).
- So far only 5 NCAs have not yet participated in MNAT (neither as (Co)-Rapporteur/Coordinator, nor as assessor).
- Over past months EMA has developed the MNAT post-authorisation.

EU Network Training Centre (EU NTC)

Towards a European Central Platform

- for exchange of **information** and
- supply of **regulatory and scientific trainings**
- across the EU regulatory Network

with mission

- to assure the **quality**
- to promote **harmonisation** of standards for assessment

HMA
Heads of Medicines Agencies

Joint EMA-HMA initiative
Co-Chairs:Christa Wirthumer-Hoche and Fergus Sweeney

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Conclusion

....we need strong NCAs for EU sustainability, quality and competitiveness

- Hub of expertise for the centralised & national assessment
- Hub for local academia & industry
- Hub for pharmacovigilance
- Link to HC systems, Health Care Professionals and patients
- Hub for post marketing data generation, RWE and HTA/payers support

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Thank you for your attention

Further information

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