

Federal Agency for Medicines and Health Products

FAMHP

**Active partner in the EU regulatory framework
Supporting innovative drug development**

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famhp



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1. Strategy of the FAMHP (1/2)

- The FAMHP: mid-size agency with full competencies (scientific advice, clinical trials, marketing authorisations, vigilance, inspections of medicines for human and veterinary use)
- Significant investment in the EU regulatory framework at the regulatory, scientific, policy-making level
 - **35** delegates at EMA/the HMA
 - **70** scientific internal experts: multidisciplinary, international
 - expanded database of **800** external experts
- **Special focus on access to innovation**
 - Unmet Medical Need (UMN) and link with Health Technology Assessment (HTA)
 - medical devices, cells and tissues





1. Strategy of the FAMHP (2/2)

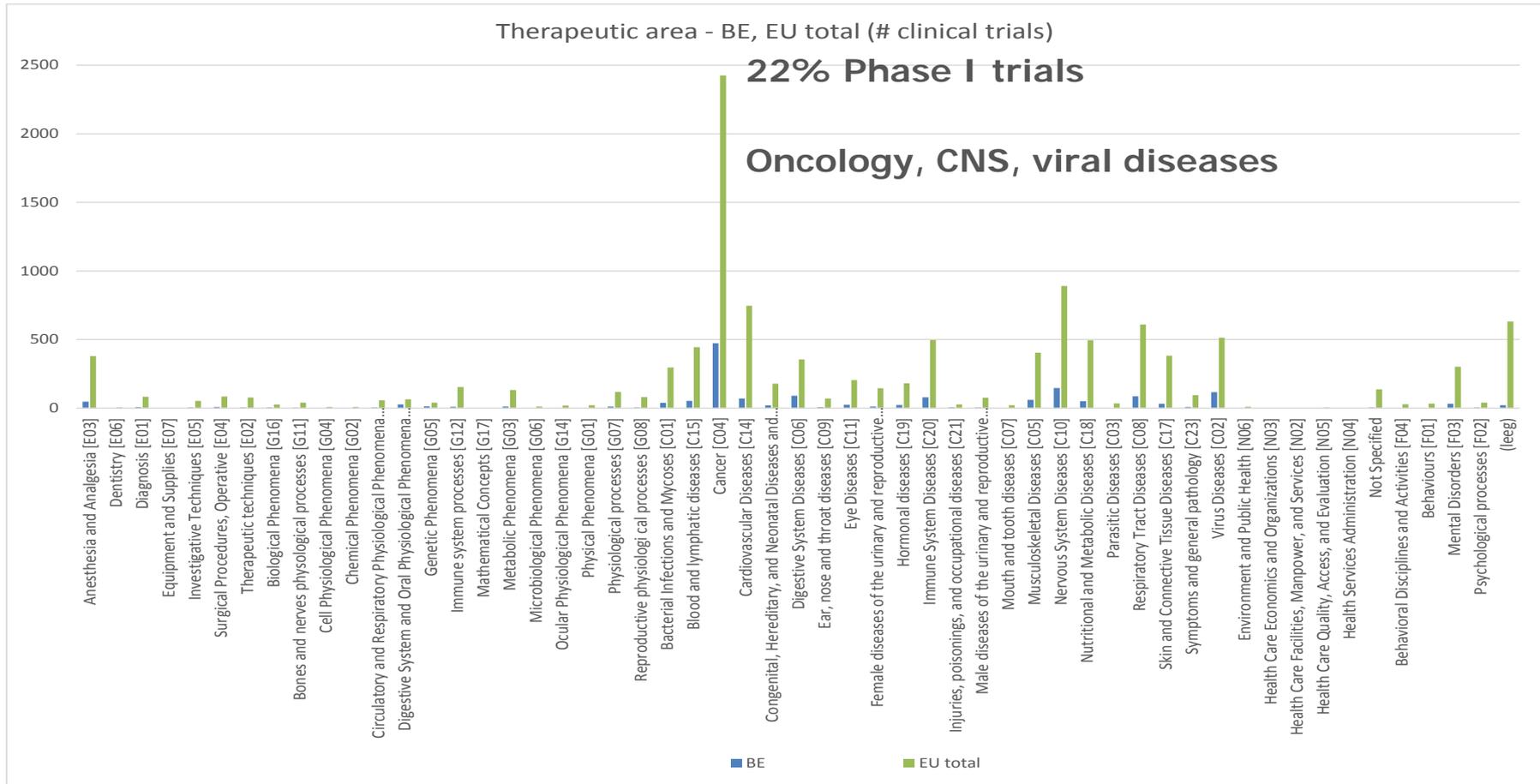
- **UMN (@ EU Commission STAMP; @ HMA working group Access to innovation)**
- **Clinical trials**
 - EU CTR coordination group (EU Commission, EMA, the HMA)
 - the CTFG, Expert group on clinical trials
 - EU Network training Centre
- **National Innovation Office**
- **SAWP (multinational assessment teams)**
- **CHMP (Prime), the PDCO, CAT and PRAC**
- **Spearheads**
 - Vaccines
 - Early Phase Development



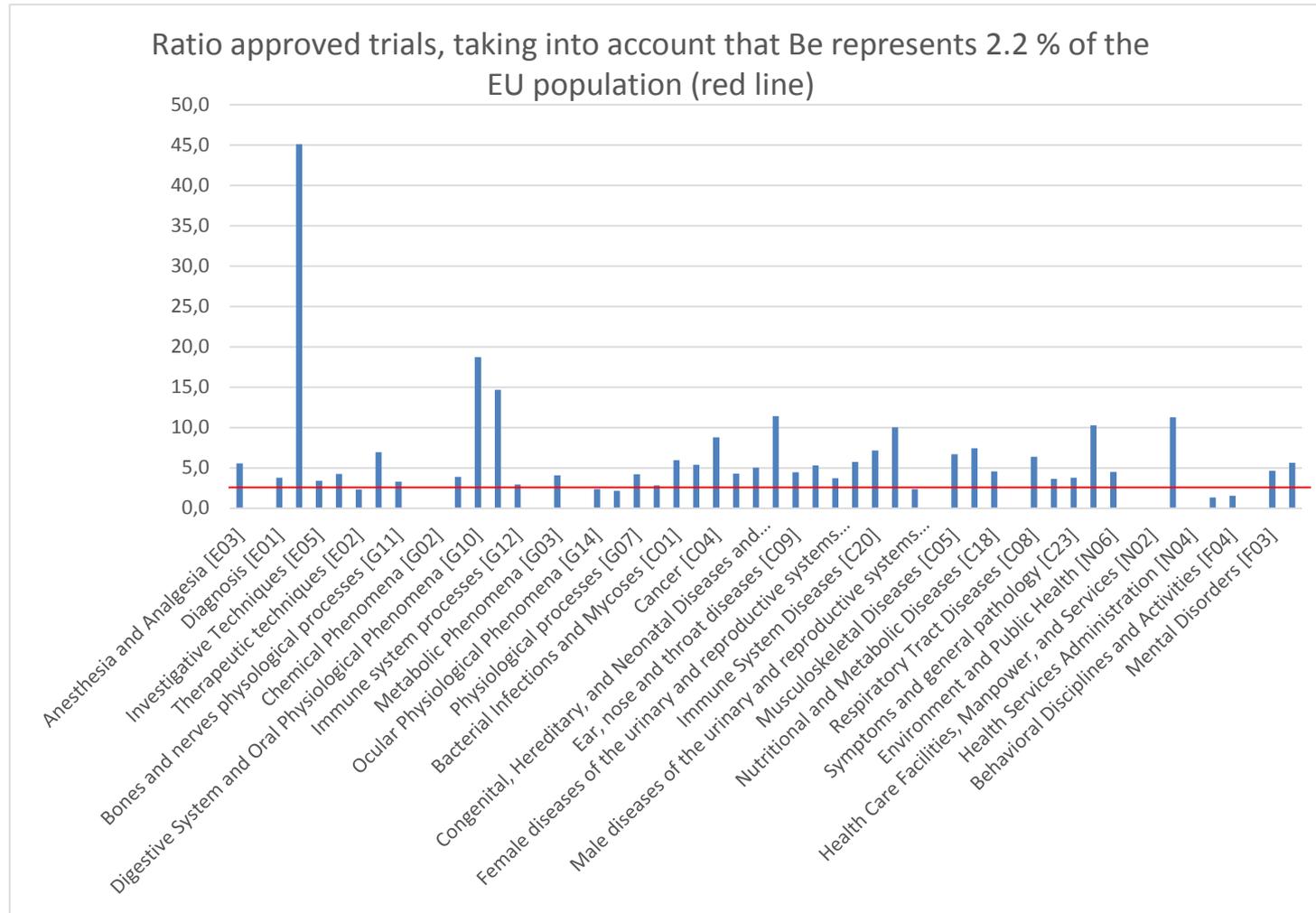
2. Focus on early access to innovation: clinical trials

Approved Trials (2014-2016) per therapeutic area: # trials BE, EU

12% of the trials in EU are performed in BE



Ratio of approved trials (2014 - 2016) per therapeutic area, BE vs. EU and per capita

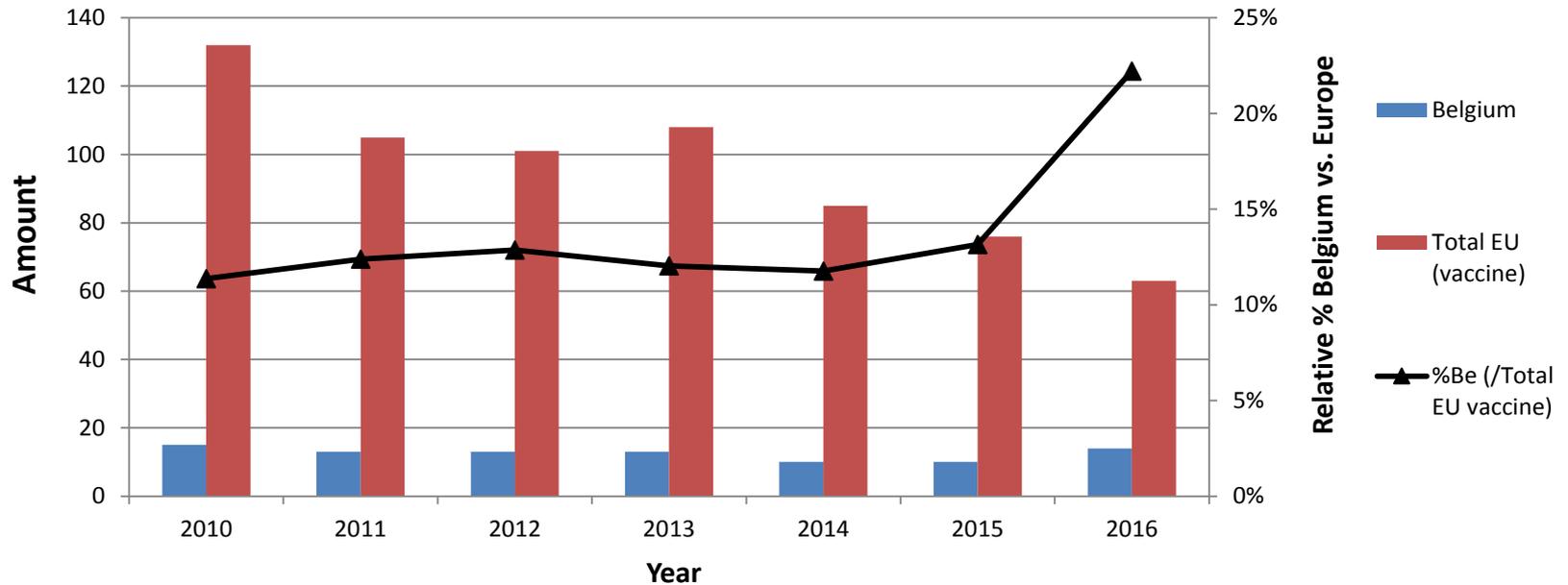


Trials above the red line are better than the EU average

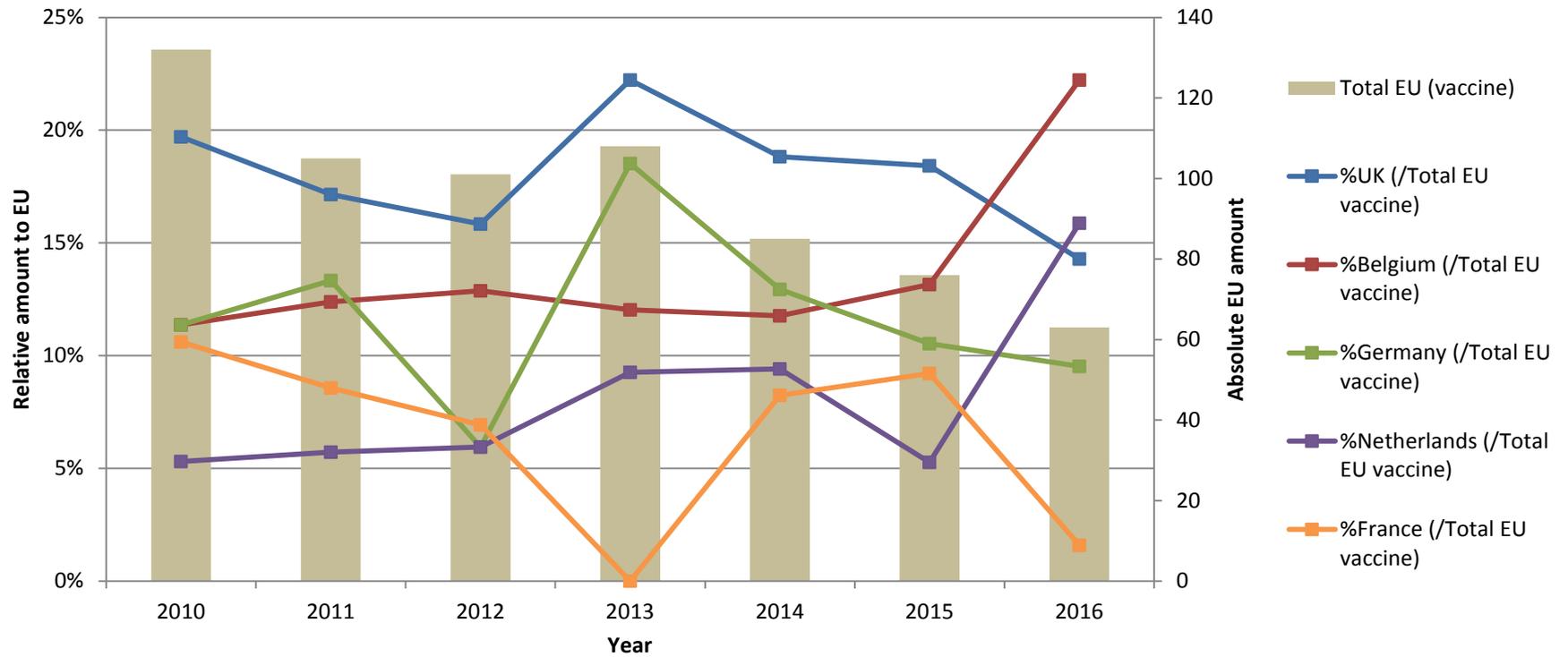


Belgium vs. Europe

Amount of vaccine CT: Belgium vs. Europe



EU landscape



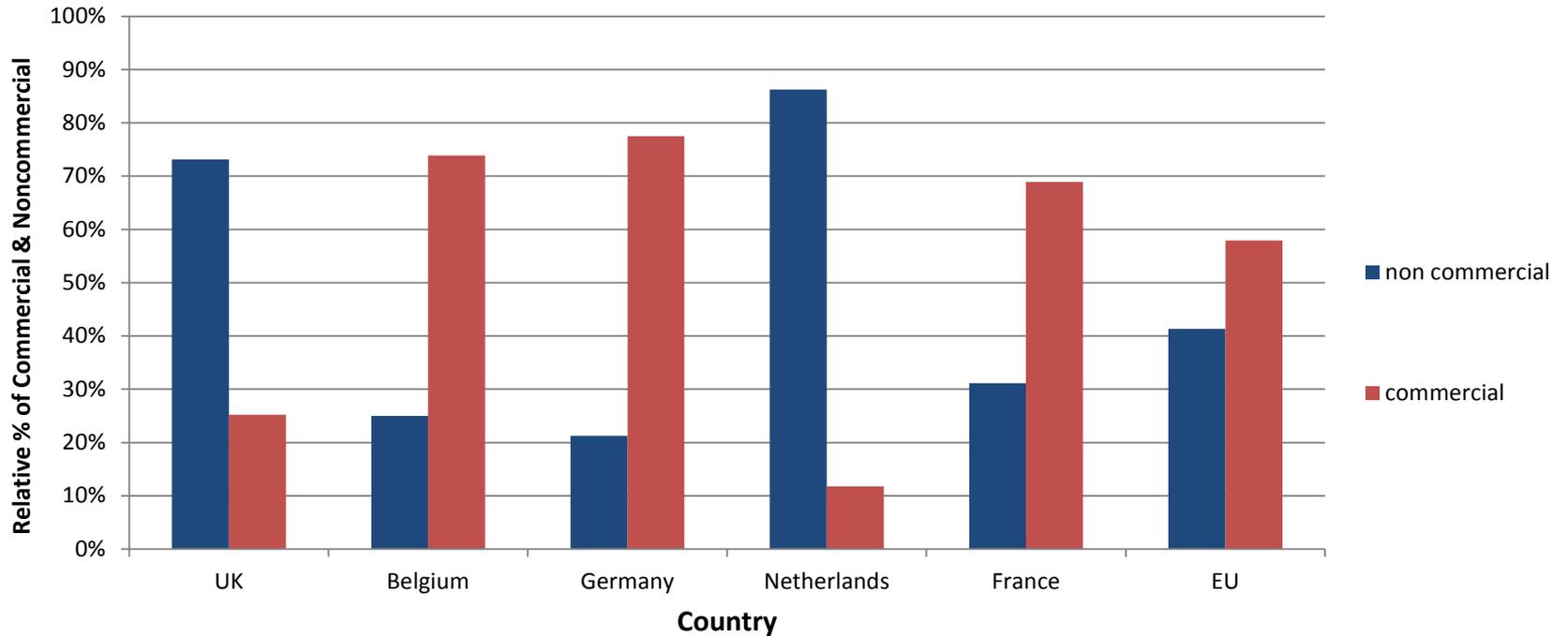
Profile of trials and populations

	Absolute	Relative
Belgium	88	NA
Therapeutic	16	18%
Prophylactic	53	60%
EU	670	NA
Therapeutic	108	16%
Prophylactic	302	45%

Age profile	Amount
In utero	1
Preterm born	0
Newborns	2
Infants	5
Children	5
Adolescents	5
Adults	76
Elderly	36
Individual profile	Amount
Male	76
Female	86
Pregnant	3



Commercial vs. noncommercial





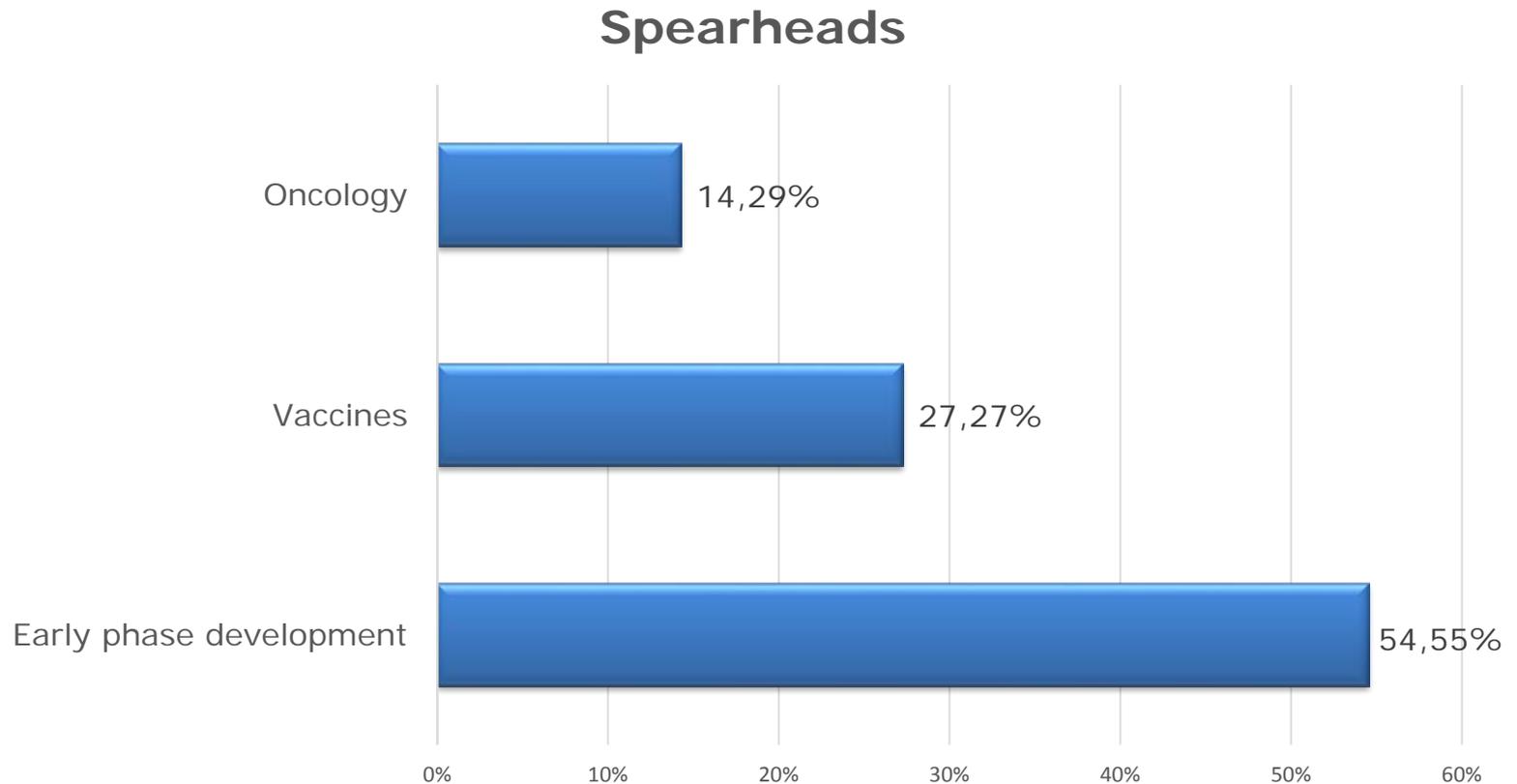
3. Focus on early access to innovation: scientific advice

3 main pillars of future activities

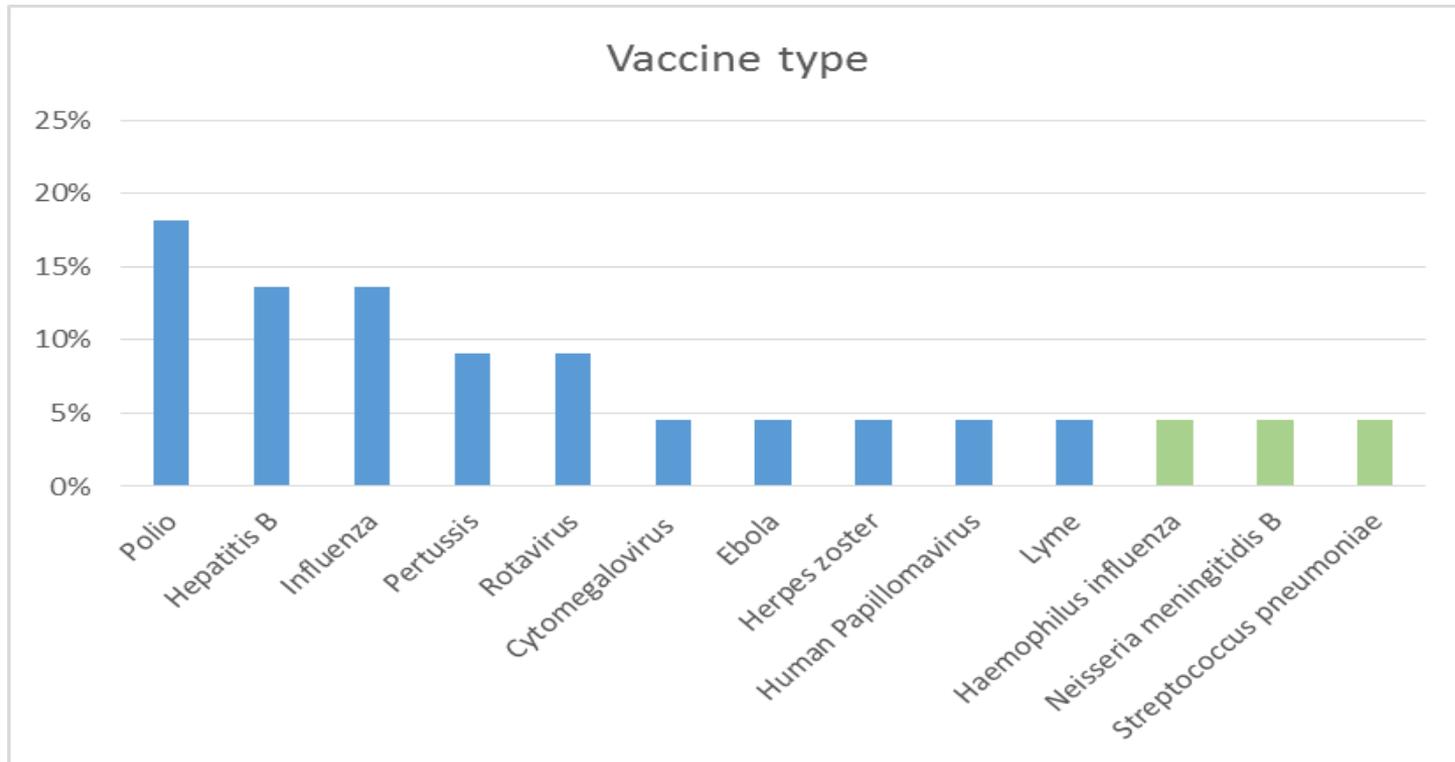
- Scientific & technical/regulatory advice:
 - optimising current services + staggered scope expansion to borderline & DDCPs, IVDs (CoDx), medical devices & Blood, cells & tissues
 - implementing new services (eg. iterative, fast-track advice)
- Specific support to SMEs, start-ups and academic research centers/hospitals
- General innovation support & knowledge management
 - EU-IN activities
 - open to all innovators involved in R&D
 - integrated life-cycle approach



3. Focus on early access to innovation: national scientific advice

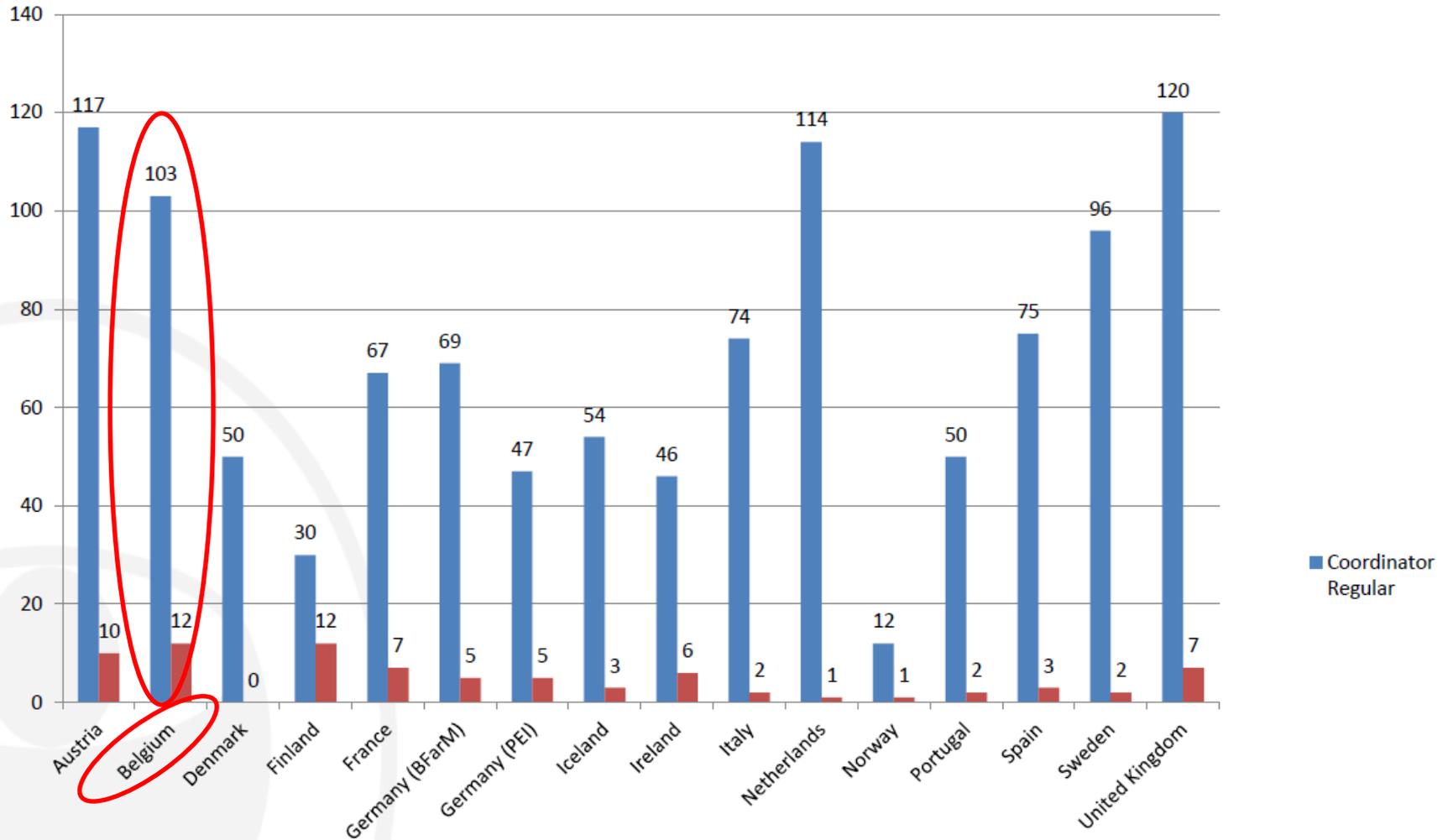


3. Focus on early access to innovation: national scientific advice (applications validated 2015 - 2016)



3. Focus on early access to innovation: scientific advice at SAWP

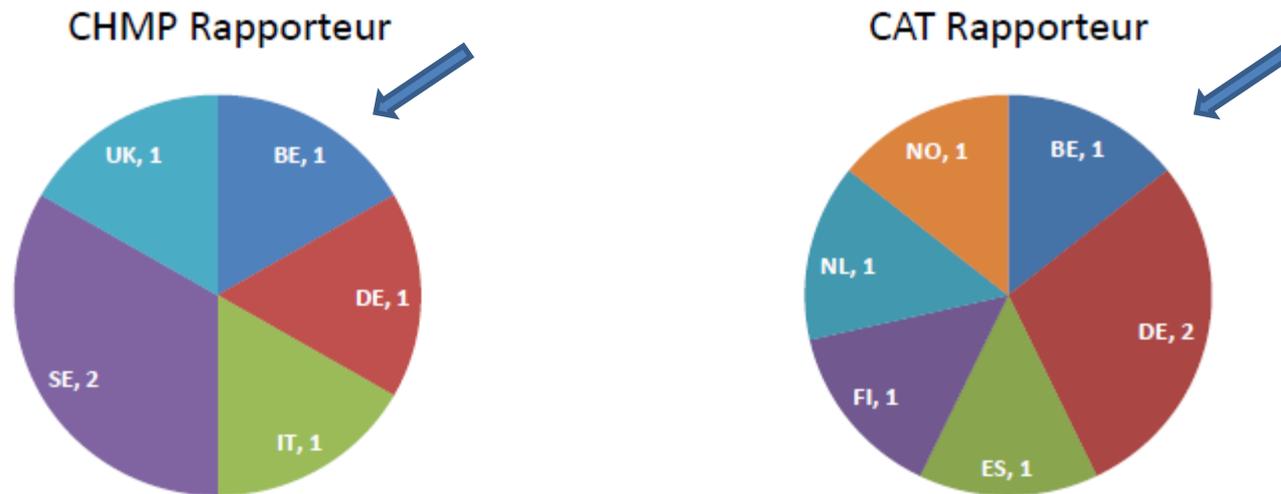
SAWP - Coordinatorships 2016



2012-2017: 45 SAWP advices provided by the BE team (30%)

3. Focus on early access to innovation: PRIME

PRIME – CHMP and CAT Rapporteur appointments in 2016



The FAMHP in the top 5



4. Marketing authorisation: BE rapporteurships



CHMP

- Hexavalent pediatric vaccine
- Pneumococcal vaccine
- Rotavirus vaccine
- Human papilloma virus vaccine
- Influenza vaccines
- Hepatitis B vaccine
- Meningococcal ACWY (RMS)
- Measles Mumps Rubella vaccine (co-rapp)

PRAC

- Hexavalent pediatric vaccine
- Hepatitis B vaccine
- Malaria vaccine
- Meningococcal group B vaccine
- Rotavirus vaccine
- HPV vaccine
- Flu vaccine
- Pneumococcal vaccine (co-rapp)
- Measles Mumps Rubella vaccine (co-rapp)

2012-2017: 17 applications for vaccines via the centralised procedure received @ EMA:

BE @ CHMP: 7 rapporteurships, 3 co-rapporteurships, 5 peer reviews

BE @ PRAC: 7 rapporteurships, 2 co-rapporteurships





5. Spearhead Early Phase Development

- Regulatory and scientific advice concerning early phase trials
- Clinical Trial attractiveness: network of well known phase I centers, recruiting healthy volunteers
- Stable number of phase I and FIH clinical trials
- Phase I centers all inspected for GCP and if producing IMP's also for GMP





5. Spearhead Early Phase Development

- Accreditation of Phase I centers on voluntary basis
- Also recognised clinical centers recruiting patients into early phase clinical trials
- Exploratory clinical trials
- Participation at national and EU level in advices, drafting and training (SAWP, drafting group FIH GL at EMA, the ANSM CSST Rennes, EU NTC)



5. Spearhead Vaccines

A Belgian network of four core expert activities, each embedded within an national and international network





5. Spearhead Vaccines

- Point of reference for regulatory and scientific advice at European and national level
- Clinical Trial attractiveness: network of well known vaccine clinical trial centers, including human challenge unit
- Leading role at EMA CHMP and PRAC for rapporteurship of new marketing authorisation (including first PRIME vaccine evaluation)
- Point of reference for GxP inspections (including third countries inspection)
- Representation in national and internal committees and working groups (EMA Vaccines working party, FDA, WHO Sage, CEPI ...)
- Scientific and regulatory expertise: network of internal and external expertise (universities and research centers, government institutions)





6. Conclusions

- Solid EU regulatory network HMA-EMA is key.
- The FAMHP is fully engaged in this structure and philosophy.
- The FAMHP fully subscribes the necessity to strongly interact with universities and research centers and the pharmaceutical industry (national and global).
- The FAMHP recognises the strengths of the different agencies (i.e. spearheads and multinational teams).
- The FAMHP will consolidate the impact of the Brexit (additional workload/opportunities).





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