



MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD



agencia española de
medicamentos y
productos sanitarios



Regulatory initiatives for measuring the impact of risk minimisation measures

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- Evaluation on the effectiveness of risk minimisation measures is also a responsibility of national agencies and EMA (as per legislation)
- Priorisation criteria being developed
- Collaboration, so that national initiatives are shared, and work under a common protocol is promoted whenever feasible



- **Awareness of risk minimisation measures?**

- **Effectiveness of risk minimisation measures?**



- **Awareness of risk minimisation measures**

Results from a survey of healthcare professionals under SCOPE Joint Action (Strengthening collaboration for operation of pharmacovigilance in European Union)

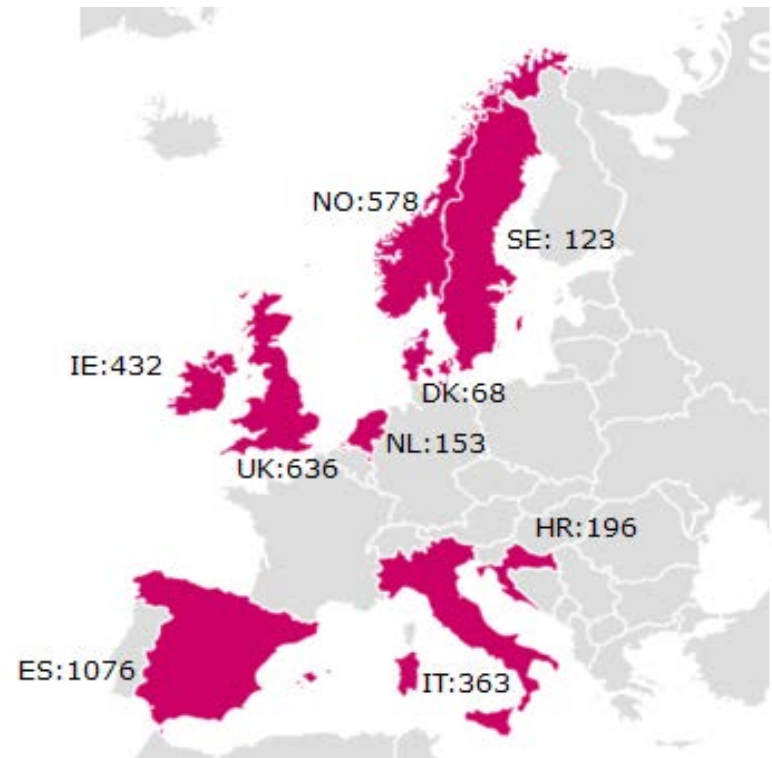
DK, ES, IE, IT, HR, NL, NO, SE, UK



Some Results

- 3625 respondents
 - 1766 GPs
 - 222 cardiologists
 - 1300 pharmacists
 - 337 other

	N (%)
Female	2215 (61)
Primary employment setting	
Community-based	2570 (70)
Hospital-based	857 (24)
Other	244 (6)
Age	
<35 year	625 (17)
35 – 45 year	964 (27)
46 – 55 year	1071 (30)
>55 year	964 (27)
Accreditation	
<5 years	370 (10)
5 – 20 years	1394 (38)
>20 years	1859 (51)

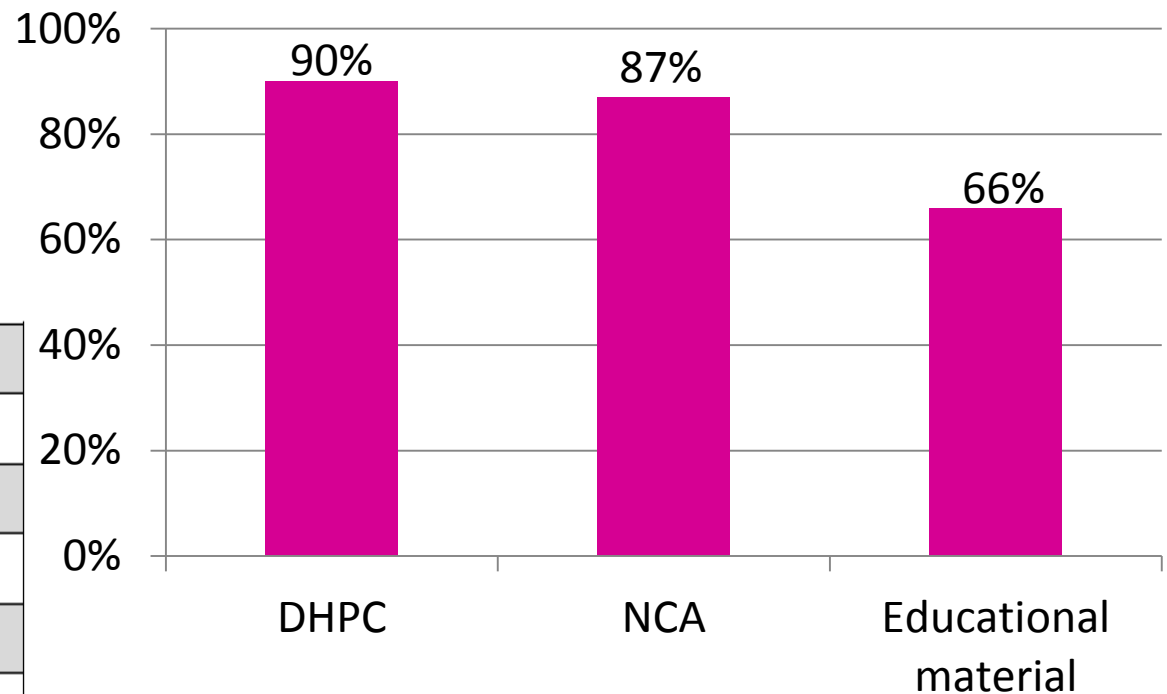




Familiarity

Yes, I have received
this type of
information and I
sometimes read it

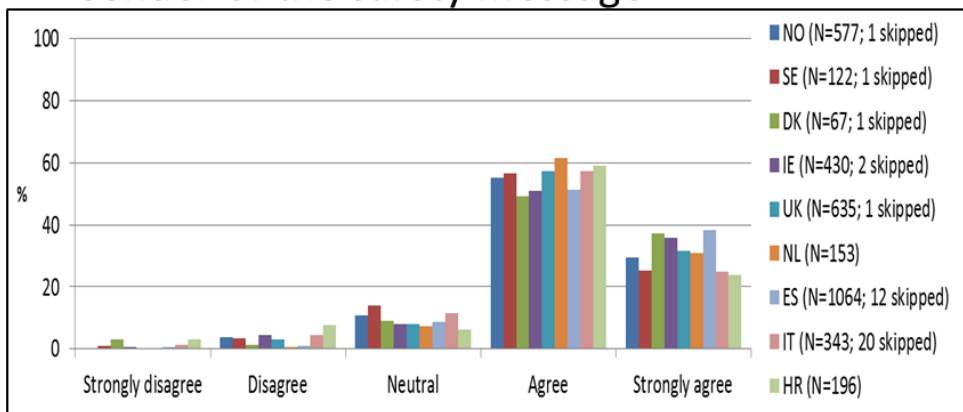
Range DHPCs	
Country	77% NO – 97% IE
Profession	85% other – 94% GPs
Range NCA	
Country	28% NL – 96% ES
Profession	74% cardiologists – 91% other
Range Educational material	
Country	60% ES – 79% IE
Profession	45% other – 74% pharmacists



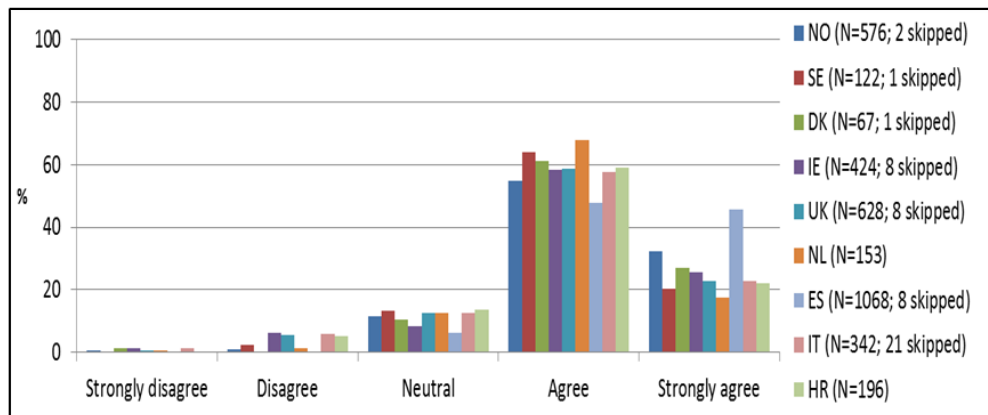


Sender

- I only read the safety information if, I trust the sender of the safety message



- I only take action in response to a safety warning if, I trust the sender of the safety message



MOST POSITELY EVALUATED SENDERS

NCA

Professional bodies

MOST NEGATIVELY EVALUATED SENDERS

Lay press

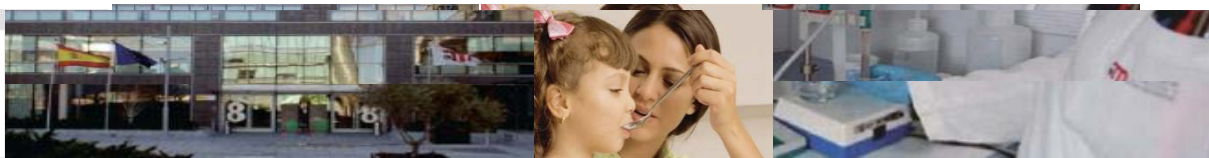
Pharmaceutical companies



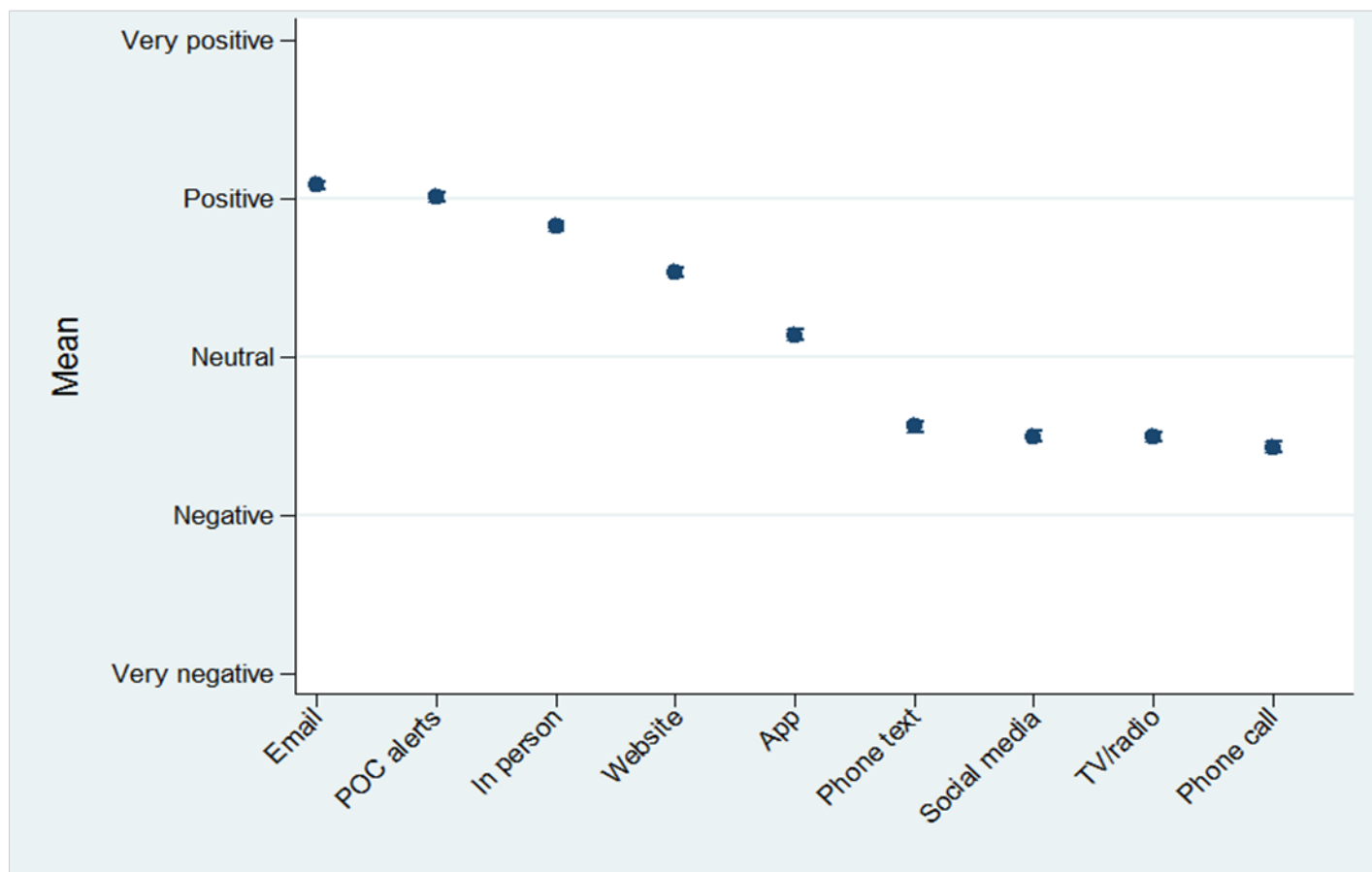
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Alternative channels





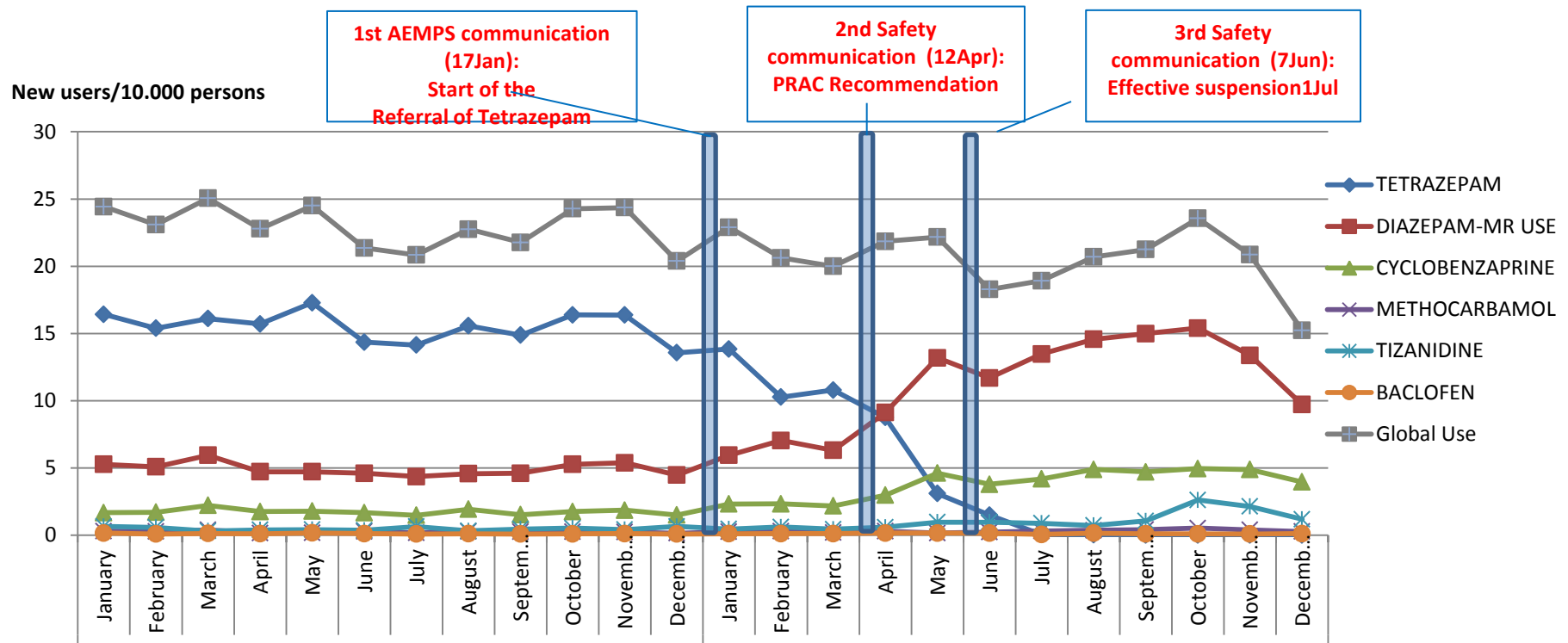
● **Evaluation of risk minimisation measures**

Some examples from Spain on recent referrals

- Tetrazepam
- Cyproterone/ethinylstradiol
- Ibuprofen/dexibuprofen



Consequences of tetraxepam withdrawal in Spain

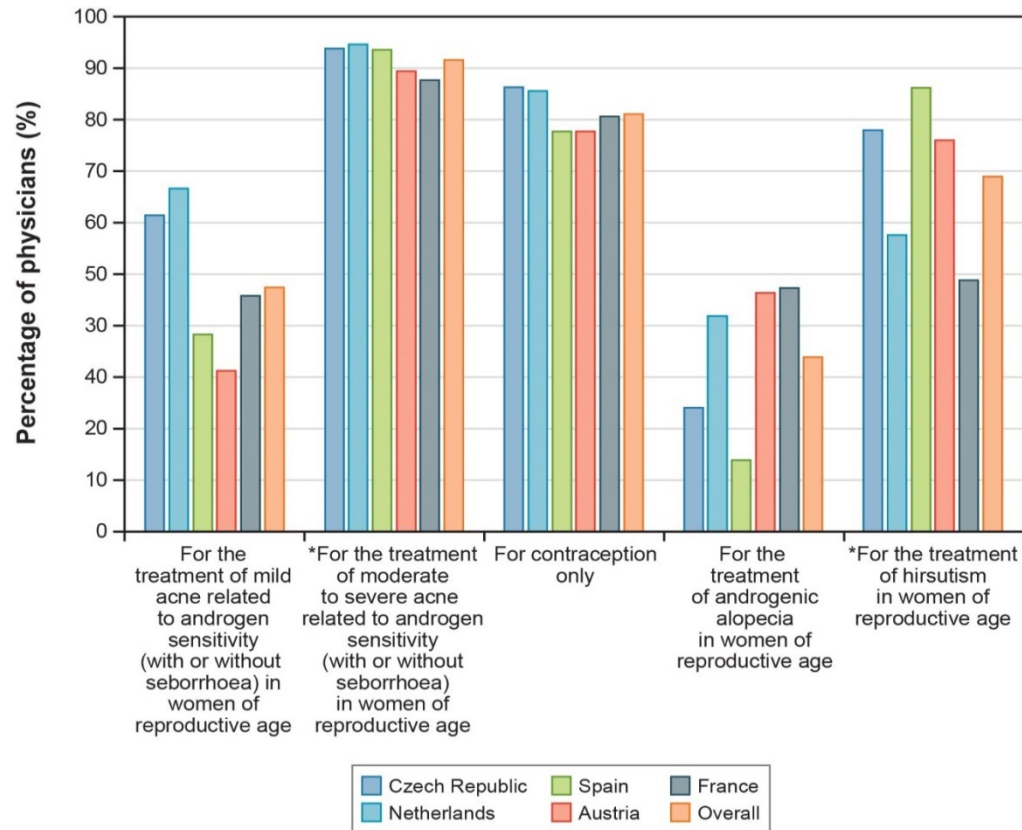




Cyproterone/ethinylestradiol.- Knowledge of approved indications after post-referral RMM (survey by MAH)

- Moderate to severe acne - 92.0%
 - Hirsutism - 69.2%
- Mild acne* is **not** an approved indication - 47.6%
- Contraception is **not** an approved indication - 81%
- Androgenic alopecia is **not** an approved indication - 34.0%

Physicians' knowledge of the contraindications was high overall (92.2%-98.8%)



* A higher percentage of physicians who reported receipt of any of the CPA/EE materials correctly indicated that this was not an approved indication compared with physicians who received no educational materials

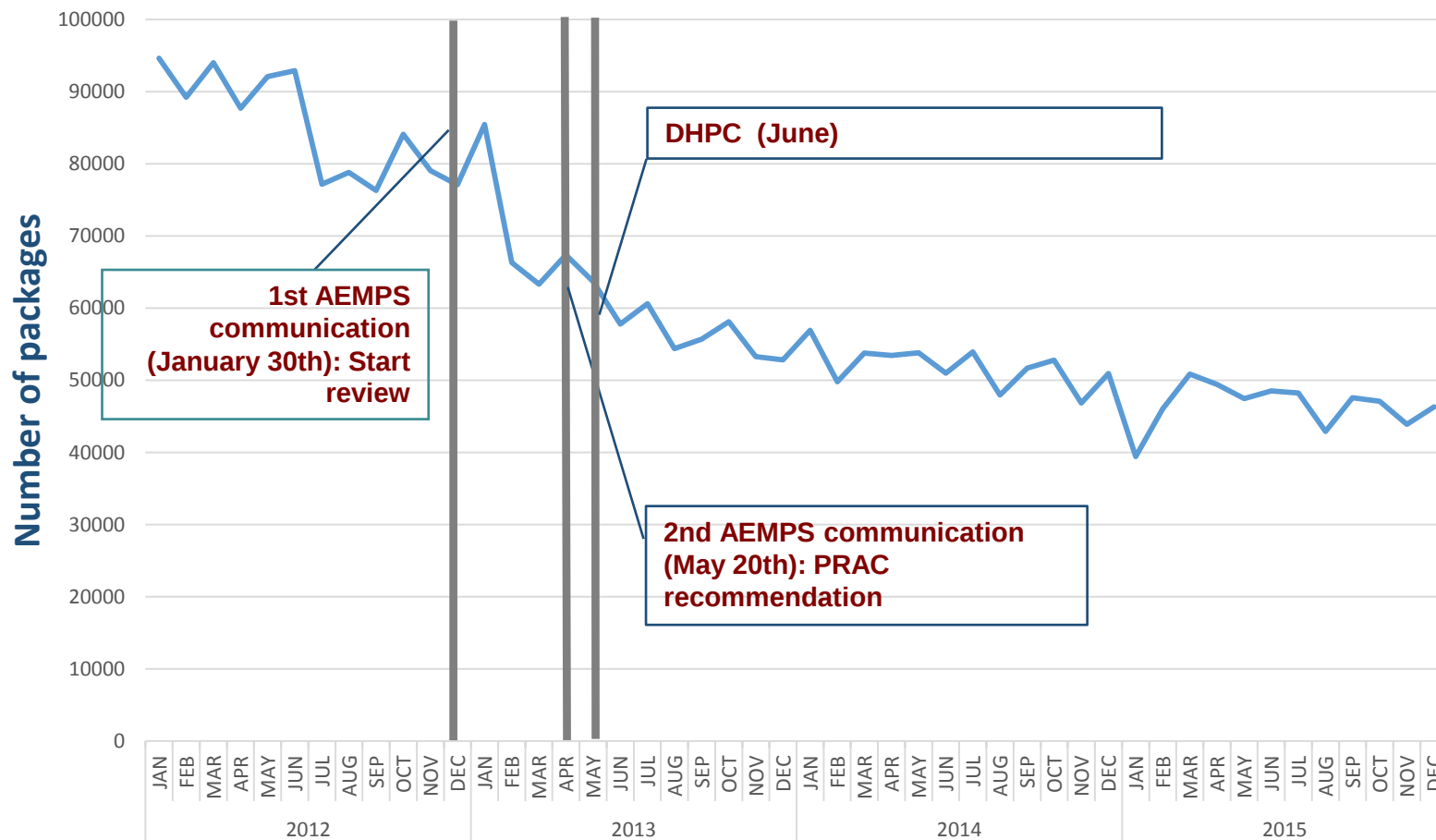


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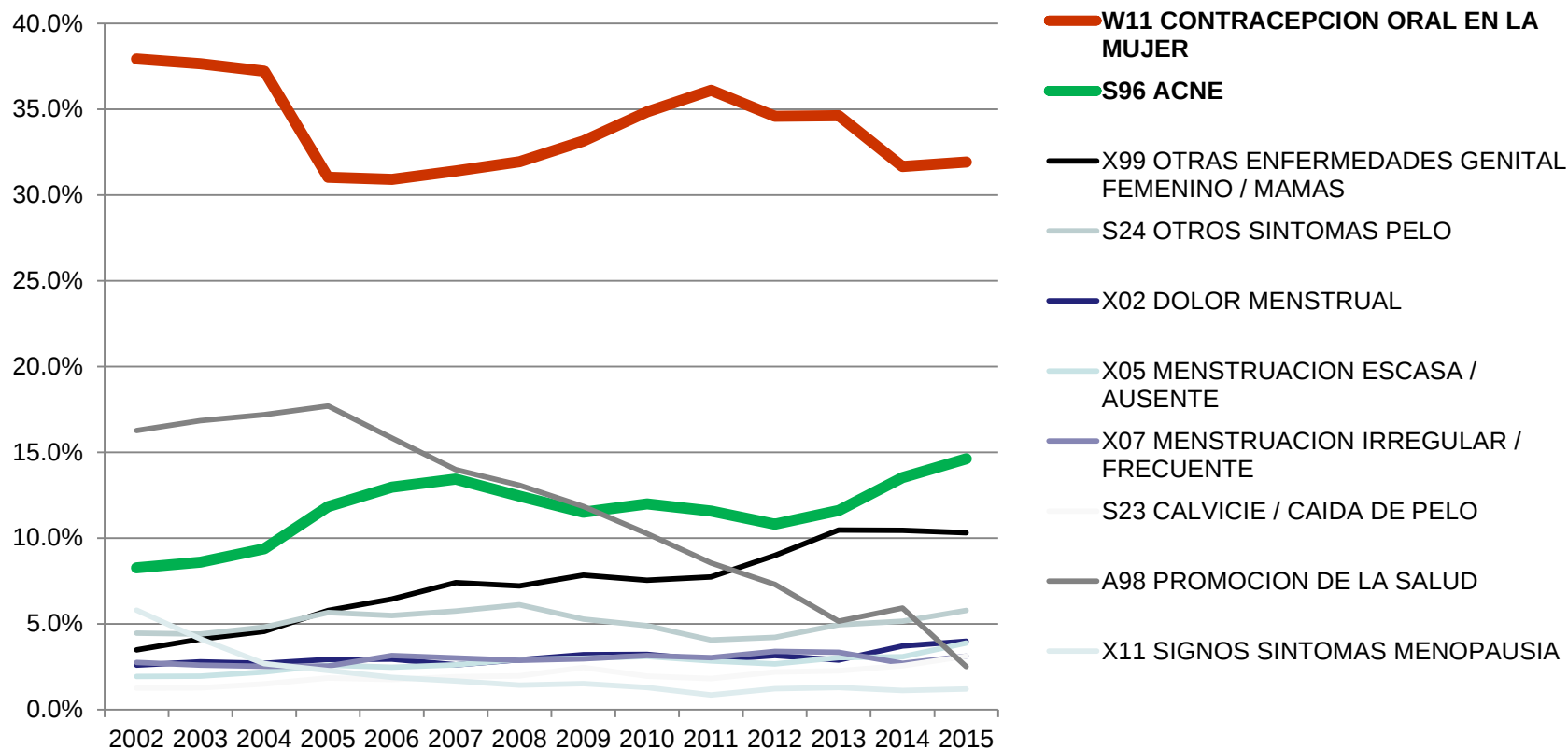


CYPROTERONE / ETHINYL ESTRADIOL CONSUMPTION in Spain





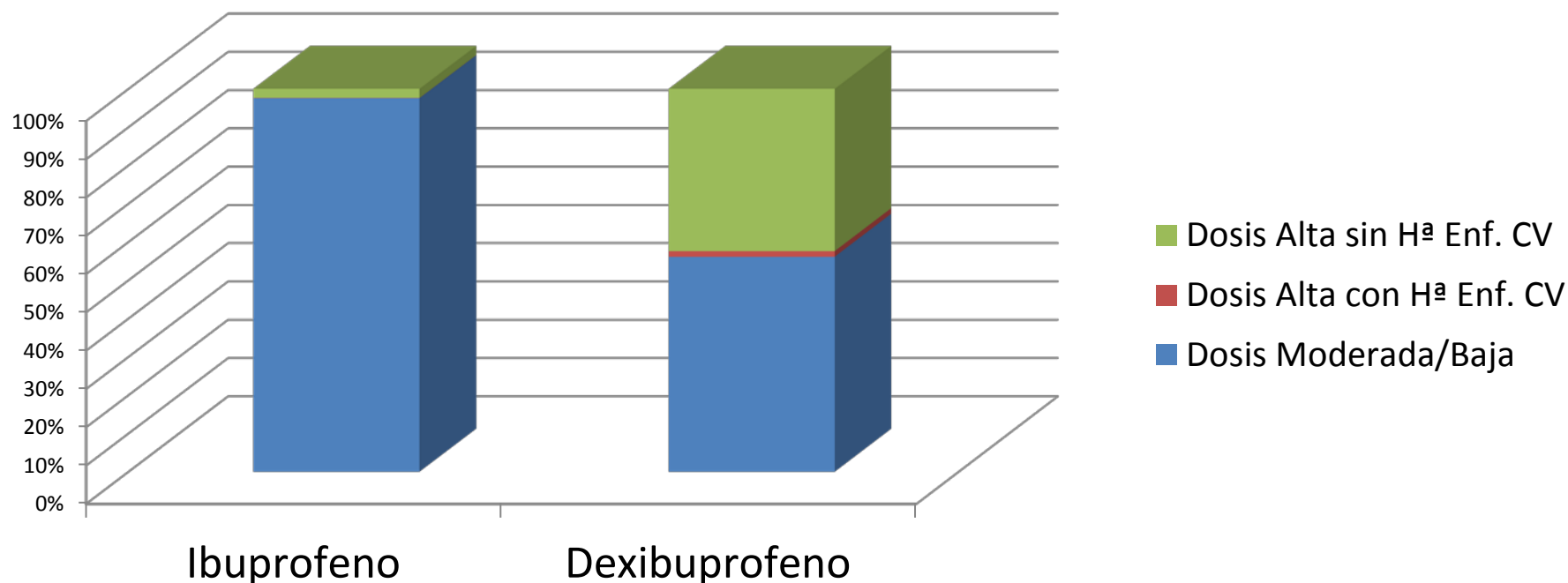
Cyproterone/ethinylestradiol- Prescription-related diagnosis in BIFAP database (primary healthcare electronic records)





Knowledge about use (important for RMMSs)

Use of high doses of ibuprofen and dexibuprofen in patients with history of CV risk





Lessons learnt

- Work in tailoring communications to receiver preferences (SCOPE results)
- Take into account therapeutic context within evaluation (not just product-oriented) (tetrazepam)
- Different approaches needed for a complete picture (cyproterone/ethinylestradiol)
- National context important when issuing communications (dexibuprofen)
- Besides... many factors influencing uptake of measures



So much work still to do!!!!

Thank you for the attention!!!