Geriatric Regulation; can we do without?

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To properly address the differences with potential impact on the medication's safety and efficacy profile for the geriatric population, medicine developers should specifically design the clinical programs to support adequate testing in older patients.
To this end, EMA introduced its Geriatric Medication Strategy in 2011 (GMS).

Aims

This study aimed:

- to assess the effectiveness of EMA's GMS in the first 7 years of its introduction;
- to evaluate whether medication for older patients will continue to be developed under the current GMS, without the need for a "Geriatric Regulation" in the future.

Methods

We assessed the SmPCs and EPARs for the therapeutic areas presented in the Table, and analysed:

- elderly representation in Clinical Trials (CTs);
- adequacy of safety information in the product information; and
- existence of special pharmaceutical development to address the difficulties in medicine administration for the older patients

Therapeutic area	#med <2011	#med >2013
COPD	1	1
CHF	2	1
Glaucoma	2	2
Hypertension	2	2
RA	3	3
Osteoporosis / Menopause-associated	1	2
Breast cancer	1	2
Colorectal cancer	1	1
Lung cancer	2	2
Prostate cancer	1	1
Parkinson's	2	3
TOTAL	**20**	**22**

Results

Our analysis identified similar trends in geriatric medicine development in the two periods studied.
Older patients were under-represented in CTs, including studies to evaluate the safe use of medication by this patient population (see Figure 1).

Results for the analysis of section 4.4 show that the adequacy of information for the geriatric population is not improved after 2013 (see Figure 2). Adequacy is not improved after 2013. This is also the case for Sections 4.2 4.5 and 4.8 (not shown).

We further identified a lack of extra provisions or development processes for pharmaceutical forms to ease medicine administration for the elderly (see Figure 3).

Figure 1: Elderly representation in CTs/Disease area

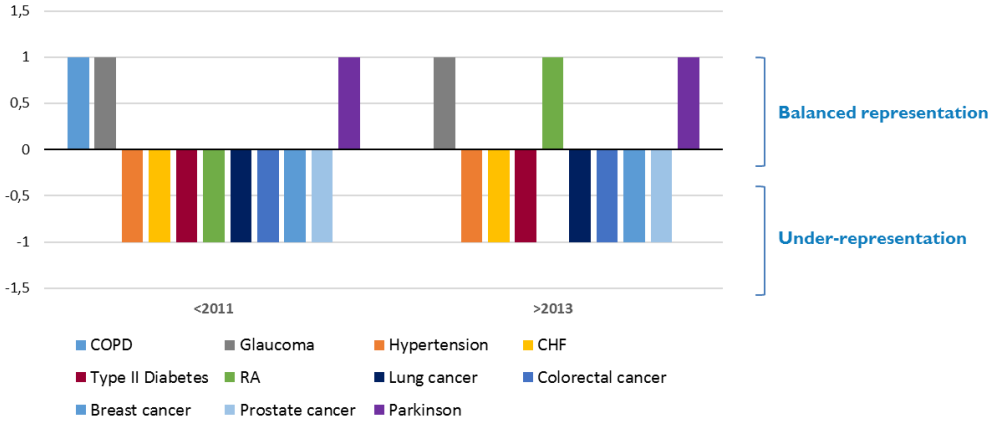


Figure 2: Number of products with info on elderly in Section 4.4

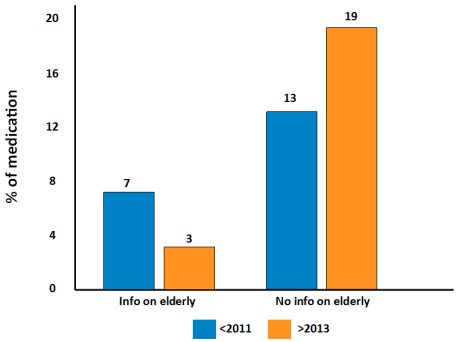
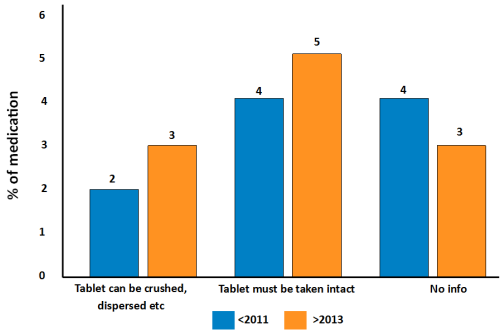


Figure 3: Provision if tablet cannot be swallowed



Conclusion

The results suggest that, in the first 7 years after the introduction of EMA's GMS, medicine developers have failed to abide by the standards set in it.
Lack of improvement could revive the call for a "Geriatric Regulation".