EuGMS
European Geriatric Medicine Society
Fostering geriatric medicine across Europe

Genoa, February 4th, 2021

To Mrs. Ursula von der Leyen
President of the European Commission

Pharmaceutical Strategy for Europe: where are older people?

On behalf of the European Geriatric Medicine Society (EuGMS) we write to express our interest in new pharmaceutical strategy for Europe produced by the European Commission.

While its objectives are important for improving health of the European population, we are sincerely concerned that older people receive a very limited consideration in this document.

Indeed, older people are mentioned only twice in the whole document:

"Access to safe, high quality and effective medicines is a key element of social well-being, including for older people" and "the lack of treatments for specific population groups such as pregnant and breastfeeding women and older people".

However, no clear strategy is mentioned to achieve these fundamental aims.

Despite the fact that older people are major users of medicines and experience the highest rate of adverse drug events, they are still generally excluded from clinical trials evaluating new drug therapies. This exclusion –which should be considered as an example of age discrimination in health care -prevents physicians from having the necessary information concerning the efficacy and safety of medicines for their use in older patients and it obliges them to use medicines in patients in whom these medicines have never been tested. This situation has been consistently demonstrated by scientific studies during the last 20 years. It should be mentioned that aFP7 research project, the PREDICT, performed between 2008 and 2010, was completely devoted to this topic (https://cordis.europa.eu/project/id/201917/it). The EuGMS has been pointing out this situation for 10 years. Following EuGMS advocacy, the European Commission stimulated EMA to address this issue.

Consequently, the EMA CHMP adopted the EMA Geriatric Medicines Strategy (Doc. Ref. EMA/CHMP/137793/2011) on 17 February 2011. The Geriatric Expert Group (GEG) has been established by EMA to assist in the implementation of the Strategy. However, it is a "virtual" expert group which communicates by email or teleconference only. The group could only answer to specific requests of CHMP or comment on EMA documents. The role of the GEG was therefore very limited from the beginning, it was clearly written that "the answers (provided by GEG) to queries are of an advisory nature and the final decision on the question submitted will remain under the responsibility of the concerned scientific committee".

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Moreover, due to the Brexit, when the EMA moved to the Netherlands, the activity of the group has de facto ceased, being "geriatrics" classified a lower-medium priority of EMA(EMA Brexit preparedness business continuity plan. 13 October 2017. EMA/196585/2017).It should be noticed that the same problems of lack of scientific studies were observed for children and in this area the EU developed a paediatric regulation in 2007, that has led to a substantial increase of studies in this population, as shown in the report written after 10 years from the implementation

(https://ec.europa.eu/health/sites/health/files/files/paediatrics/docs/2017_childrensmedicines_report_en.pdf).

EuGMS believes that the time has come to develop a specific legislation for drug evaluation in older people, similar to the one produced for paediatrics. Without a mandatory request to evaluate new medicines in older people and related incentives it is very unlikely that the situation will improve, as it did not substantially improve in the last ten years.

Best regards

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