Dear Mr. Athanase Benetos,

Many thanks for your enquiry regarding considerations given to older people in the Pharmaceutical Strategy and drug evaluation in older people.

The pharmaceutical strategy for Europe aims at making the EU pharmaceuticals system better in terms of bringing safe effective and high quality medicines to patients of all groups including older people.

Indeed, the strategy covers extensively the issue of unmet medical need and recognises the burden on specific population groups such as older people. The needs of these population groups are the driver for key flagship actions. These cover the revision of the general pharmaceutical legislation to better incentivise innovation for unmet needs but also the provision of solutions to long standing problems such as antimicrobial resistance.

The strategy does not stop there. It is a key consideration of future EU pharmaceutical policy to ameliorate the situation as regards access to affordable medicines and security of robust supply chains so as to mitigate the issue of shortages. These considerations are essential for all patient population groups and can be expected to have a horizontal positive effect. Finally, the flagship objective of future proofing of legislation to take into account digitalisation and new possibilities driven by high performance computing and use of real work evidence recognises the need to avoid biases based on gender, race or other biases which would most certainly include age.

As a significant contribution to the Pharmaceutical Strategy, the Commission regards its priority to timely and adequate implementation of the Clinical Trials Regulation (EU) 536/2014. The Regulation will become applicable as of early 2022. As a driving principle, the CTR describes that unless it is justified in the protocol, trial participants should represent the population, including age groups, that are likely to use the investigated medicinal product (recital 14). Accordingly, Member States Concerned has to assess in the context of the relevance of the trial, whether trial participants represent the population to be treated, and if not, the justification provided by the sponsor in the protocol (Art 6, Annex I.17.y).

The EMA is paying specific attention, in the provision of Scientific Advice, to monitor and actively reject age-based exclusion criteria. This is in line with ICH E7, E8 and E6: these guidelines mark a drive to move away from an approach of protection by exclusion to one of protection through research. The aim is to enrol, in trials for medicines authorisation, a population representative of the real-world use population.

To enhance knowledge on representativeness, the EMA has also recognised that age alone is not a reliable predictor of outcomes: we have been the first regulatory agency to encourage the use of frailty status characterisation of patients enrolled in clinical trials.

Finally, the CHMP specifically reports, in their assessment on efficacy and safety data acquired in old and older-old patients, with the aim to inform physicians on the level of knowledge available on newly applied medicines.

Kindest regards,

Secretariat B4

Nancy Saba

European Commission
Directorate-General for Health and Food Safety – DG SANTE

Unit B4 – Medical products: quality, safety, innovation

101 rue Froissart / B-1049 Brussels/Belgium