HAI EUROPE RESPONSE

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This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI advocates for access to essential treatments that satisfy the priority health care needs of a population.
- HAI Europe promotes better access to medicines by advocating for EU trade policies that are coherent with the EU's commitments on health and development; by campaigning for changes to the EU's internal market laws that hamper access to medicines in Europe; by advancing EU actions on the exploration of new models of medical innovation.
- HAI Europe is committed to ensuring the rational use of medicines through greater controls on medicines promotion, independent medicines information, greater patient involvement in the reporting of adverse drug reactions so that harmful or ineffective medicines are identified more quickly, thereby reducing the threat to public health.
- HAI Europe advocates for the highest levels of transparency, independence and accountability in all aspects of pharmaceutical policy and regulation, as well as the wider participation of patients and consumers in decisions that will affect their health and wellbeing.

Introduction

According to latest estimates[1] people aged 65 years or over will account for 29.5 % of the EU-27's population by 2060 (17.5 % in 2011). The older population is itself progressively ageing, the proportion of those aged 80 years or older will nearly triple between 2011 and 2060. Older people have been identified as the main users of medicines[2].

[1] Eurostat, 2012. *Population structure and ageing available*. [Online] Available at http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Population_structure_and_ageing [Accessed: 24 June 2013].

[2] Cerreta, F., Eichler, HG. and Rasi, G., 2012. 'Drug policy for an aging population – The European Medicines Agency's Geriatric Medicines Strategy'. *NEMJ* [Online] vol. 367 (21), 1972-1974. Available at: http://www.nejm.org/doi/full/10.1056/NEJMp1209034 [Accessed: 24 June 2013].

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In the context of the EMA's reflection process on quality aspects of medicines for older people, HAI Europe welcomes the opportunity to provide input for the development of a reflection paper on this subject and would like to contribute with the following recommendations:

Adequate representation of older people in clinical trials

The Declaration of Helsinki states that those populations that are underrepresented in medical research shall be provided appropriate access to participation[3]. Yet evidence shows that the exclusion of older people from clinical trials remains being a widespread practice[4]. Clinical trials must ensure an adequate representation of older patients in relation to the indication as to obtain accurate safety and efficacy data. The inclusion of specific age-groups within the elderly such as the 'very old' as well as elderly patients with co-morbidities and concomitant therapies needs to be ensured. The specificities of older adults must be considered in both, pre-marketing and post-marketing clinical studies. It is of outmost importance that clinical trial data is publicly accessible in order to allow for independent benefit-risk assessments of medicines and informed decision-making.

Direct patient reporting of adverse drug reactions

Polypharmacy, a common practice within the older population, increases the possibility to suffer from adverse drug reactions (ADR). Direct and spontaneous patient reporting of ADRs is therefore crucial for pharmacovigilance amongst the elderly. Direct patient reports are more explicit than those provided by clinicians since they contain more detailed descriptions of the impact of adverse effects in patients' lives[5]. Patient reporting systems need to be in place as well as mechanisms to encourage direct reporting by the elderly.

Rational use of medicines

Direct to consumer advertising of prescription drugs in whatever form it takes, is a harmful practice that jeopardises public safety and encourages the medicalisation of day to day life. It has been found that drugs that are strongly advertised are for long-term use by large target audiences, often for mild conditions that might not need pharmaceutical therapy[6]. Considering the over medicalisation of the elderly and their use of polypharmacy is crucial to provide prescribers and consumers with independent and comparative information to facilitate informed choices on the use of medicines[7]. Decisions about the most appropriate pharmaceutical therapies shall rely on the most unbiased information and not the most effective promotion.

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[3] World Medical Association, 2008. *World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*. [Online] Available at http://www.wma.net/en/30publications/10policies/b3/ [Accessed: 27 June 2013].

[4] McMurdo, MET.,Witham MD. and Gillespie, ND., 2005. 'Including older people in clinical Research'. *BMJ* vol. 331(7524), 1036-37

[5] Herxheimer, A., Crombag R. and Alves TL., 2010. 'Direct patient reporting of adverse drug reactions. A fifteen-country survey & literature review'. *HAI Europe*. [Online] Available at http://www.haiweb.org/14012010/14Jan2010ReportDirectPatientReportingofADRsFINAL.pdf [Accessed: 26 June 2013].

[6] HAI Europe, 2001. *Direct-to-consumer prescription drug advertising. The European Commission's proposals for legislative change*. [Online] Available at http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf [Accessed on 27 June 2013].

[7] HAI Europe, AIM, ISDB and MIEF, 2012. *Amended proposals on ''information'' to the public: Opening the door to advertising of prescription-only medicines by pharmaceutical companies*. Joint position paper [Online] Available at http://haieurope.org/wp-content/uploads/2012/05/05-Apr-2012-Joint-Analysis-on-Amendment-Info-Proposals-EN.pdf [Accessed: 27 June 2013].

Consider the elderly in drug development processes

Taking multiple medicines at the same time can complicate drug-adherence and lead to medication errors. It is essential that the cognitive and physical impairments of the older population are considered during the drug development process in order to ensure an appropriate design of medicines.

Involvement of the civil society in health decision-making

In line of the objectives of the EMA's Geriatric Medicines Strategy, the Agency shall strengthen and enable the Geriatric Expert Group as to represent at best the interests of Europe's ageing population. Organisations representing patients and consumers must be involved in health decision-making processes. While this seems good practice, it is also important to ensure that civil society organisations base their activities on independent information and do not respond to the interests of the pharmaceutical industry. A study published by HAI Europe[8] found that there is an association between the receipt of corporate sponsorship from the pharmaceutical industry and support given by sponsored civil society groups for an expanded role of the industry as an information provider. This evidences the need to ensure that mechanisms to deal with conflicts of interests are in place when involving civil society organisations. Independent patient, consumer and public health organisations need to be involved in order to make balanced decisions about pharmaceutical regulation.

[8] Perehudoff, KS and Alves, TL., 2011. The patient & consumer voice and pharmaceutical industry sponsorship. *HAI Europe* [Online] Available at http://www.haiweb.org/31012011/31%20Jan%202011%20HAI%20EUROPE%20Research%20Article%20Patient%20&%20consumer%20voice%20and%20pharmaceutical%20industry%20sponsorship.pdf