AESGP and CHPA response to the
EU-US call for industry input on regulatory issues for possible future EU-US trade agreement

The Association of the European Self-Medication Industry (AESGP) and the Consumer Healthcare Products Association (CHPA) welcome the EU-US call for input on regulatory issues for a possible future EU-US trade agreement.

AESGP and CHPA acknowledge the significant role of the High Level Working Group on Jobs and Growth in the further development of EU-US relations and welcome the group's interim report conclusions. The two associations especially commend the intention to develop in the context of EU-US dialogue "concrete action plans to reduce unnecessary regulatory costs and promote regulatory compatibility".

AESGP and CHPA would like to use the occasion of this consultation to raise for consideration in the future EU-US dialogue the following issues relating to the self-care sector:

a. Market Exclusivity

Currently, the EU offers only a one year exclusivity period for relevant scientific work in the context of the reclassification of an ingredient from prescription to non-prescription status or with regard to a new indication for a known substance. The limited exclusivity period presents a barrier to free trade as it does not provide adequate time to recoup the investment needed to fulfill the relevant EU regulatory obligations.

In comparison, the US practice of granting 3 years data protection promotes innovation and opens up the self-care market to investment. It results in significant public health and economic benefits. Therefore harmonisation with the US provision should be sought for the periods of data protection provided in the EU.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
Directive 2001/83/EC *Article 10* 5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of **one year of data exclusivity** shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. *Article 74a* Where a change of classification of a medicinal	Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.) 21 USC 355(c) and 355(j) (using parallel language for contents of new drug applications, and abbreviated new drug applications, respectively; subsection (b) language shown below) (Waxman-Hatch Act) [I]f an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application

product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for **one year** after the initial change was authorised. **AGENCY:** European Commission	contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application **effective before the expiration of three years from the date of the approval** of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty 1 studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement **effective before the expiration of three years from the date of the approval** of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. **AGENCY:** FDA

b. Manufacturing Audits

Both FDA and European authorities (the European Medicines Agency and member state medicines agencies or other national competent authorities) require audits of pharmaceutical manufacturing facilities.

These audits, which are based on comparable standards and essentially pursue the same goals, are duplicative and thus cause unnecessary cost and redundancy. It is recommended to substantially increase the joint acceptance of audits performed by partner authorities, or acceptance of the documentation gathered by partner authorities during audits.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
The principles and guidelines for GMP are stated in two Directives: • Directive 2003/94/EC for medicines and investigational medicines for human use; • Directive 91/412/EEC for medicines for veterinary use. **AGENCY:** EMA, national competent authorities.	Basic authority for inspections is described in 21 USC 374. **AGENCY:** FDA

c. Foreign Data Acceptance for Marketing Authorisation Applications

FDA frequently does not accept bibliographic data for marketing authorisations, and instead requires new data to be generated on medicinal products in US patients, despite considerable safety and efficacy databases being available from European or other patient groups. However, US patient data is readily accepted as a basis for European Marketing Authorisation applications.

The US practice represents a barrier to free trade by unnecessarily discriminating against companies who have complied data based on clinical trials conducted in the EU. It creates the need for clinically unnecessary and therefore ethically questionable duplication of clinical trials, leading to increases in the costs and time required to gain Marketing Authorisations. As long as data meet FDA's clinical standards, there is no justification for these no to be accepted.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
-	**FDA regulations governing the conduct of clinical trials describe good clinical practices (GCPs) for studies with both human and non-human animal subjects** 21 CFR Part 312 [Docket No. 2004N–0018] Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application **AGENCY:** FDA

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About:

AESGP

The Association of the European Self-Medication Industry (AESGP) is the representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe.

CHPA

The Consumer Healthcare Products Association (CHPA) represents the manufacturers and distributors of non-prescription, over-the-counter (OTC) medicines and dietary supplements in the US.