

Medaxes Charter

PREAMBLE

- **Whereas** the Belgian Association for Accessible Medicines ('Medaxes') is the trade association of the Belgian accessible medicines industry.
- **Whereas** Medaxes and its members ('the Members'), have always applied a high ethical standard in their relation with the government authorities, health care professionals and patients.
- **Whereas** Medaxes and the Members consider it worthwhile to translate this high ethical standard into a written ethical code ('the Charter'), to which the current and future Members subscribe.
- **Whereas** Medaxes and the Members consider it important that the Charter is accessible for third parties, and therefore have opted for a concise and understandable text, limiting the procedural aspects to a strict minimum.
- **Whereas** the Charter also reflects the most recent version of the Code of Conduct of the European association 'Medicines for Europe'.

- Article 1.** Medaxes and the Members shall strive to increase patient access to health care by offering affordable and high standard qualitative medicinal products.
- Article 2.** The Members always respect industrial property rights (patents, trademarks, copyrights, know-how, ...) that seem or can reasonably be considered valid and relevant, and acknowledge the importance of such rights as an incentive for research & development.
- Article 3.** The Members acknowledge the importance of providing accurate, fair, objective and non-misleading information concerning medicinal products to health care professionals and – whenever applicable – to patients. Any information or advertising on medicinal products towards third parties shall be checked and approved in advance by the relevant Members' responsible person for information. The Members will foresee the necessary safeguards to ensure internal compliance.
- Article 4.** The Members shall in particular not offer or grant advantages or benefits, whether pecuniary or in kind, nor directly nor indirectly, to wholesalers, healthcare professionals or institutions where the prescription, the dispensation or the administration of medicinal products takes place, unless (i) such or advantages are inexpensive, (ii) concern the health care professional practice and (iii) are not offered in large quantities or on a continuous basis as a support for the concerned practice.
- Article 5.** The Members ensure that scientific events which they directly or indirectly support are held within the framework foreseen by national regulations, as laid down in article 10 of the Belgian Medicines Act of 25 March 1964. Such scientific events shall always be exclusively scientific in nature. The event must take place at a suitable location that is appropriate to the scientific purpose of the event. Any hospitality offered at the time of scientific events shall be reasonable and secondary to the scientific purpose of the meeting, and shall exclusively be offered to the health care professionals with exclusion of the accompanying persons which are not health care professionals themselves. The Members will foresee the necessary safeguards to ensure internal compliance. Whenever applicable, a prior visa from the legally accredited ethical platform shall be obtained.

- Article 6.** The Members acknowledge that European Competition law and national competition rules apply to the exchange of sensitive commercial information in the context of a trade association such as Medaxes. Therefore, the Members shall avoid discussing non-public prices, company market shares, customers, or commercially sensitive information, or if such discussion is nevertheless required for whatever reason, carefully check compliance with competition rules on a case-by-case approach.
- Article 7.** The Members acknowledge that their medical representatives should be acquainted with and respect the applicable legal provisions and regulations, and shall foresee appropriate training in this respect. Any training of medical representatives shall also emphasize the cost efficiency of each treatment and the quality, safety and efficacy of medicines.
- Article 8.** The Members may give subsidies, grants, scientific prizes, sponsoring, or provide services to third parties, or make means available to institutions, organisations or associations that are made up of healthcare professionals and/or that provide healthcare or conduct research. Such offer of financial and operational means (i) must be compatible with all legal provisions (ii) may not harm the reputation of the accessible medicines sector, (iii) have a value added for healthcare and/or general interest, and (iv) shall be confirmed in writing.
- Article 9.** The Members shall in granting samples strictly comply with the provisions of the Royal Decree of 11 January 1993 establishing the conditions under which medicinal products for human use can be provided in the form of samples.
- Article 10.** The Members may ask healthcare professionals or organisations as consultants or advisors, whether in groups or individually, for services such as speaking at or chairing scientific meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, post-marketing and non-interventional studies or participation in market research, etc., where the concerned health care professionals receive a remuneration and/or are expected to travel, as long as such remuneration is in proportion to the services rendered. Any such services shall be confirmed in writing.

Article 11. Any direct or indirect, financial or non-financial support by the Members of patient organisations shall be the subject of a prior internal approval process and subsequently laid down in a written non-exclusive agreement mentioning at least the purpose and amount of such support. The Members shall transparently document and publish any such support to patient organisations in accordance with the Belgian law dated December 18th, 2016 ('Sunshine Act'). The Members acknowledge that any editorial input towards patient organisations shall be purely objective and scientific of nature and may not be provided as a means of own commercial gain. Members shall ensure that their support to patient organisations is always clearly acknowledged and apparent from the outset.

Article 12. The Members acknowledge that promoting transparency of relations and interactions between companies and healthcare professionals or organisations strengthens trust in health industry, facilitates objective and independent decision-making and stimulates integrity and ethical conduct. The Members shall therefore document and disclose any transfer of value which they make, directly or indirectly, for the benefit of a healthcare professional or organisation, in accordance with the requirements foreseen by the Sunshine Act and through means of the legally accredited platform 'BeTransparent.be' for such publication. Any disclosure shall be in accordance with the Belgian and European data privacy legislation.

Article 13. Any legal entity or natural person is entitled to file a complaint for non-compliance by one or more of the Members with the present Charter. Under penalty of inadmissibility, such complaint shall be (i) in writing, (ii) sufficiently detailed in fact and in reason, (iii) accompanied with credible elements of proof or at the very least a beginning of proof, (iv) not anonymous, (v) addressed to 'Medaxes, Sint-Amandsstraat 2, 1853 Strombeek-Bever' and (vi) accompanied by the commitment of the complainant that he will not use, neither directly or indirectly, the decision resulting from the Medaxes ethical complaint procedure, for filing a judiciary complaint or similar complaint, whether legal or non-legal. In case the complaint is already part of judicial proceedings or government investigation, the complaint shall also be inadmissible. The complaint will be processed by an external and independent legal counsel (including legal professionals registered at the bar). The decision will be accompanied, if needed, with the sanction Medaxes deems appropriate, such as a reprimand or corrective measures.

Article 14. Any of the Members that consider filing a complaint or similar procedure, whether legal or non-legal, against another Member, will first try to resolve their dispute amicably before filing any such a complaint or procedure. The managing director of Medaxes may fulfil an informative role in such prior amicable discussions or appoint a Member to such end, without expressing an opinion on the merits of the case.

Article 15. The applicable legal provisions shall always be considered a minimum standard under the present Charter. In case of conflict between any of the provisions of the present Charter and the applicable legal provisions, the more stringent provision shall apply. In case of silence or obscurity of any provision of the present Charter, the Medicines for Europe Code of Conduct shall apply.

20 September 2018