ANNEX 1 – Proposed Amendment to Article 86.2

TITLE VIII **ADVERTISING** *Article 86*	TITLE VIII **ADVERTISING** *Article 86*
1. For the purposes of this Title, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular: — the advertising of medicinal products to the general public, — advertising of medicinal products to persons qualified to prescribe or supply them, — visits by medical sales representatives to persons qualified to prescribe medicinal products, — the supply of samples, — the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal, — sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products, — sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.	1. For the purposes of this Title, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular: — the advertising of medicinal products to the general public, — advertising of medicinal products to persons qualified to prescribe or supply them, — visits by medical sales representatives to persons qualified to prescribe medicinal products, — the supply of samples, — the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal, — sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products, — sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.
2. The following are not covered by this Title: — the labelling and the accompanying package leaflets, which are subject to the provisions of Title V, — correspondence, possibly accompanied by	2. The following are not covered by this Title: — the labelling***, which shall always at least specify the International Non-Proprietary Name,*** and the accompanying package leaflets, which are subject to the provisions of Title V, - ***the summary of product characteristics,*** - ***the publicly accessible version of the assessment report,*** — correspondence, possibly accompanied by

material of a non-promotional nature, needed to answer a specific question about a particular medicinal product, — factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims, — information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.	material of a non-promotional nature, needed to answer a specific question about a particular medicinal product, — factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims, — information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. —
	1. The marketing authorisation holder may, in respect of **authorised medicinal products subject to medical prescription*****, make available*** **to the general public or members thereof the*** ***following information*** **:** **(a)*** ***the most recent*** **summary of product characteristics*** ***as approved by the competent authorities during the course of marketing authorisation and authorisation renewal*** **;** **(b)*** ***the most recent*** **labelling and package leaflet as approved by the competent authorities*** ***during the course of marketing authorisation or authorisation variation;*** **and** ***c)*** **the*** ***most recent,*** **publicly accessible version of the assessment report*** ***as*** **drawn up by the competent authorities*** ***during the course of marketing authorisation and authorisation updates*** ***The information referred to in points (a), (b) and (c) shall be presented in a format that faithfully represents the officially approved information drawn up by the competent authorities. The information shall be made available both in electronic and printed form and in formats appropriate for the blind and partially-sighted.***