



AMERICAN CHAMBER OF COMMERCE IN INDIA
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Under Secretary, PI-II,

Room No-347, 'A' Wing, Shastri Bhawan,

New Delhi- 110001

Subject: Feedback on Uniform code of Pharmaceutical Marketing Practices

Dear Sir,

As you may be aware, The American Chamber of Commerce in India (AMCHAM- INDIA) is an Association of American Business organizations operating in India. Established in 1992, it has around 500 members. The incumbent US Ambassador to India is the Honorary President of AMCHAM. It has different Sectoral committees including those for Pharmaceuticals and Devices.

We wish to express our sincere thanks for providing this opportunity to offer comments on this draft Code. We welcome this move of the Government aimed at bringing alignment in Pharmaceutical Marketing Practices that would weed out some undesirable practices being adopted in certain quarters.

On behalf of AMCHAM, we are pleased to offer comments on the draft which we hope would be duly considered while finalizing the guidelines.

Please let us know if we could be of any further assistance to you.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sandeep Gupta', is written over a light-colored background.

Sandeep Gupta

Chairman, Pharmaceutical Committee—AMCHAM; CMD, Eli Lilly India

Enclosure : As above

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Uniform Code of Marketing Practice for Indian Pharmaceutical Industry
Comments/Suggestion

Section	Description / Current Text	Suggested Text	AMCHAM Comments
			We feel that a section here should be added (either preceding or within section 1) which should have definitions/applicability /common terms listing for ease of comprehending the overall document
2 (ii)	The name of the product, and a list of the active ingredients, using the <u>common name</u> , placed immediately adjacent to the most prominent display of the name of the product	The term 'Generic name' should replace Common name	---
	The names and photographs of HCPs should not be used in promotional material	The names and photographs of HCP's must not be used in a manner that gives the impression that they are endorsing a particular product/ company	Some material like clinical papers need to have the names and pictures of Healthcare Providers
(ii)	Sample packs shall be limited to prescribed dosages for three patients		Does not specify the methodology to be adopted in case of chronic therapies like diabetes, cancer, hypertension. Also, for chronic therapies, allowance of sampling for 3-4 weeks could be considered.
(iii)	Any supply of such samples must be in response to a signed and dated request from the recipient		There might be practical difficulty in implementing this.
vii)	Each sample shall be accompanied by a copy of the most up-to-date version of the <u>Product</u>	The term 'Product information' should replace Product characteristics	Acceptable regulatory terminology

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	<u>characteristics</u> relating to that product		
5	The companies will maintain a detail record of free samples distributed to Healthcare practitioners		Some clarity would be needed on this point. What constitutes "detail record". While the quantum of free samples distributed product wise would be available, detailed records of samples provided to individual Healthcare practitioners, etc. will be challenging to maintain.
1	No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a pharmaceutical company		<ul style="list-style-type: none"> • Need to clarify definition of a "gift". Promotional aids and items of medical utility should not be considered as gifts. A monetary cap (such as Rs. 500/-) could be considered while allowing those aids/ reminders which are basically meant for improving patient care. Eg: tongue depressors, microfilaments for checking diabetic foot. • Medical education materials like text books and subscription to peer reviewed journals should be allowed to be given to HCP's with an appropriate cap in place.
& 7.2	Companies may legitimately provide assistance that is directly related to the bona fide continuing education of the healthcare professionals and which genuinely facilitates attendance of the healthcare professional for the duration of the educational aspect of		<ul style="list-style-type: none"> • 7.1 and 7.2 are actually in contrast to the MCI notification. Hence this needs to be clarified. The code in this form does not allow genuine sponsorships to international conferences which the MCI guidelines allow in respect to faculties or advisors. As a check, a cap of 6 -7 HCPs per Company per event could be kept to avoid misuse of this provision.

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	the event held in India. Such support and assistance must however, always be such as to leave healthcare professionals' independence of judgment		<ul style="list-style-type: none"> There should also be a CAP on the max no of HCPs that can be invited per company per event even in INDIA
6	Hospitality, sponsorship and meetings: "must be held at an appropriate venue in the country that is conducive to the main purpose of the event"		This statement is contradictory to 7.1 and 7.2 which states that only events in India can be supported. Ambiguity needs to be clarified.