

Uniform Code for Pharmaceutical Marketing Practices (UCPMP) Decoded

November 2017

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1. Promotion of Drugs and Medical Devices in India

I. Background

India does not have a specific law at present that regulates promotion and marketing of drugs and medical devices by companies before health care practitioners (“HCPs”). Advertisement of drugs and medical devices to end consumers, on the other hand, is heavily regulated (see Annexure-A). The Central Government had published a set of guidelines in December 2014 called “Uniform Code of Pharmaceutical Marketing Practices” (“UCPMP”) as guidance to the industry for promotion and marketing of drugs and medical devices. However, these guidelines are voluntary and do not have the force of law, at present.

The government is contemplating a separate code for promotion of medical devices called Uniform Code for Medical Device Marketing Practices (“UCMDMP”). However, the code has not yet been finalized. Until UCMDMP is officially published, the UCPMP should be treated as the official guidance for promotion of medical devices by medical devices companies. Accordingly, in the paragraphs below, the reference to the word “drug” should be considered as a reference to “medical device” as well.

II. Salient Features for UCPMP

A. Claims

- Claims for usefulness of a drug must be based on an up-to-date evaluation of all the evidence.
- The word “new” must not be used for any drug which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.

- The word “safe” must not be used without any qualification and it must not be state categorically that a medicine has no side effects, toxic hazards or risk of addiction.

B. Comparison of drugs

- Comparison of drugs must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or any other way
- Brand name of other companies must not be used on comparison unless the prior consent of the companies concerned has been taken.
- Other companies, their products, services or promotions must not be disparaged either directly or by implication.

C. Information on promotional materials

- Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:
 - » The relevant drug, the name and address of the holder of the authorization of the drug or the business name and address of the part of the business responsible for placing the drug on the market
 - » The name of the drug and a list of the active ingredients using the generic name, placed immediately adjacent to the most prominent display of the name of the drug;
 - » Recommended dosage, method of use and where not obvious, method of administration;

- » Adverse reactions, warnings and precautions for use and relevant contraindications of the product;
- » A statement that additional information is available on request;
- » The date on which the above particulars were generated or last updated.
- Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.
- All promotional materials appearing in journals, the publication of which is paid for or secured or arranged by a company and referring by brand name to any product of that company, must comply with (the requirements immediately above) as appropriate, irrespective of the editorial control of the material published.
- Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.
- The names or photographs of healthcare professionals must not be used in promotional material.
- Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.
- Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

- Audio-visual material must be supported by all relevant printed material so that all relevant requirements of the Code are complied with.

D. Free Samples

- Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.
- Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.
- The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:
 - » Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product
 - » Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment ;
 - » Any supply of such samples must be in response to a signed and dated request from the recipient;
 - » An adequate system of control and accountability must be maintained in respect of the supply of such samples;
 - » Each sample pack shall not be larger than the smallest pack present in the market.
 - » Each sample shall be marked “free medical sample - not for sale” or bear another legend of analogous meaning;
 - » Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act, 1940) relating to that product
- A pharmaceutical company shall not supply a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquillizer.

- The companies will maintain details, such as product name, doctor name, quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.

E. Gifts and other benefits

- No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers etc.
- Gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) (such as tickets to entertainment events) also are not be offered or provided.
- Travel facilities: Companies or their associations/representatives or any person acting on their behalf shall not extend any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to Health Care Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc. as a delegate. It is hereby clarified that in any seminar, conference or meeting organized by a pharmaceutical company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate, it will be at his/her own cost.
- Hospitality: Companies or their associations/representatives shall not extend any hospitality like hotel accommodation to Healthcare Practitioners and their family members under any pretext.

- Cash or monetary grants: Companies or their associations/representatives shall not pay any cash or monetary grants to any healthcare professional for individual purpose in individual capacity under any pretext
- Funding for medical research, study etc., can only be extended through approved institutions by modalities laid down by law/ rules/guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.

III. Way forward

It has been two years since the UCPMP was published. However, due to its non-binding nature, the adaption of UCPMP has been slow. Companies who are part of a multi-national group were able to become compliant with UCPMP in a very short span of time because they were already complying with their respective internal global ethics policies. Many domestic companies, too, have successfully transformed their marketing practices to comply with UCPMP. However, some domestic companies are yet to undertake the transformation. The Central Government had, at the time of publication of the UCPMP, informally communicated to the industry that a failure to comply with the UCPMP by the industry as a whole will force it to make UCPMP mandatory. Given the patchy adoption of the UCPMP by the industry as a whole, it seems that the Government may be left with no option but to enforce UCPMP as a law. How and when will that happen, is yet to be seen. But there have been some very interesting developments on this front in this year, most notable of which is discussed over-leaf.

2. New Development - Essential Commodities (Control of Unethical Practices in the Marketing of Drugs) Order, 2017

I. Background

Various news reports have confirmed that the Central Government is contemplating introduction of Essential Commodities (Control of Unethical Practices in the Marketing of Drugs) Order, 2017 ("**Draft Order**") that would regulate promotion and marketing of pharmaceutical drugs by pharmaceutical companies before the HCPs.

In the paragraphs below, we have summarized the key features of this Draft Order. We have also analyzed the order for its impact on the industry.

One interesting feature to note, at the outset, is that the Draft Order will be a law unlike UCPMP which is a guidance document. It is proposed to be issued under the Essential Commodities Act, 1955 ("**EC Act**"). The EC Act regulates production, supply, distribution, trade and commerce of essential commodities. All drugs and regulated medical devices are considered as essential commodities in India. Since EC Act is public welfare legislation, it is implemented in a very strict manner. The Courts have also shown reluctance in interfering in the implementation of orders issued under the EC where orders had the potential of affecting businesses in an adverse manner but were achieving a larger public interest.

Another interesting feature to note, at the outset, is that unlike UCPMP, the Draft Order will not apply to promotion of medical devices. However, it is expected that the any future order applicable to medical devices would be modeled on the Draft Order. Therefore, it could be helpful for the medical device companies to be aware of this development.

II. Salient features

- The Draft Order seeks to regulate -
 - A. claims that pharmaceutical companies make in course of promotion, including manner of making such claims.
 - a. The list includes claims that are:
 - i. Misleading and likely to induce unjustifiable drug use or give risk to undue risk
 - ii. Not capable of substantiation
 - iii. Not in good taste
 - iv. Comparative vis-à-vis another drug unless capable of substantiation
 - b. Any use of the word "safe" unless it is not properly qualified
 - c. Promotional material that is designed in a matter that disguises its real nature
 - B. interaction of pharmaceutical companies with HCPs in terms of:
 - a. offer of free samples except for full course of therapy of maximum three patients for purpose of acquiring experience of therapy
 - b. offer of gift, cash card, hampers etc. or anything which generate "monetary benefit" or allow "gains in kind" to the HCP or its family members
 - c. provision of registration fee, travel facility, stay or food in India or outside India including a vacation for attending seminar, continuing medical education programmes ("**CME**") or scientific meeting;

- d. extend grants or funds for medical research or clinical trials except through approved institutions
- A proven offence -
 - A. Under paragraph (A) above, will invite criminal prosecution for the pharmaceutical company and persons in-charge to the extent described in Annexure-B.
 - B. Under paragraph (B) above, will invite suspension of marketing activity of the “highest selling” drug of the pharmaceutical company in India based on the moving annual turn-over of preceding twelve months and confiscation of the entire stock of such drug available in the market. The period of suspension will be proportional to the “monetary consideration” involved in the offence. The sentence may be “commuted” against payment of an amount direction proportional to the sentence. A table describing the different tiers of suspension and amount payable for commutation of offence is can be found in Annexure – B.
- The Draft Order envisages the establishment of a new authority called Ethics Compliance Officer who will be responsible to inquire into any allegation of violation of the Draft Order and to award or commute penalty as is prescribed by the Draft Order.
- The pharmaceutical company will be given an opportunity to be heard before an order for suspension of marketing is passed.

III. Positives (silver lining)

The Draft Order brings some welcome changes -

- The Draft Order applies to domestic companies and MNCs alike. It is common knowledge that the MNCs abide by strong ethical codes for promotion. The Draft Order should level the playing field for both MNCs and domestic companies.

- The Draft Order does not prescribe any punishment for supply of gifts and freebies, travel, hospitality etc. up to INR 1,000 (approximately USD 15) to HCPs. This should allay concerns with respect to provision of inexpensive brand reminders and leave behind material to the HCPs by sales representatives of pharmaceutical companies. This should also allay concerns with respect to sponsoring moderate food and local travel for HCPs.
- The Draft Order identifies and expressly prohibits misleading claims that are meant to induce “medically unjustifiable drug use”. This is significant and in public interest because the regulators are struggling to control “off-label” use of drugs in India in absence of any law governing “off-label” use.
- The Draft Order gives legal validity to the ability of pharmaceutical companies to organize awareness campaigns in public institutions such as hospitals and to remunerate HCPs for participation in such awareness campaigns by paying them an amount equivalent to their average daily pay. This should allay concerns of pharmaceutical companies as well as the HCPs who hesitate to participate in awareness campaigns organized by pharmaceutical companies due to uncertainty about its legality and loss of a day’s income on account of fear of violating law by accepting remuneration.

IV. Negatives

The Draft Order could impact the industry negatively due to the following reasons -

- It is arguable that the Draft Order indirectly stops a pharmaceutical company from sponsoring HCPs to attend a seminar, conference, meeting etc. organized by the company itself to promote a drug and to disseminate information. The basis of this argument is as follows: The Draft Order prescribes that a pharmaceutical company shall not make available any travel facility, stay or food cost within India or outside India to HCP. In the same clause, however, it provides that a pharmaceutical company may sponsor

a seminar, CME or scientific meeting, provided such an event is organized by an association and such association maintains records of sponsorship, expenditure agenda and minutes for a period of three years. Reading the clause as a whole, it appears that the Draft Order intends to stop pharmaceutical companies from sponsoring HCPs with respect to travel, stay or food except in cases where the sponsorship is done by way of a contribution to an association who organizes the event.

- The scope of prohibition on giving of gifts appears to have been increased to include “anything that generates monetary benefit”. It is common practice for pharmaceutical companies to provide educational material such as standees, posters, biological models etc. that aid the HCP to explain the disease as well as benefit of a therapy to the patient. It is not clear whether this practice would fall foul of the new scope.

V. Grey areas

The Draft Order is not without its share of grey areas that may pose a challenge for both – the government to administer and the industry to comply.

- *Absence of clarity about methodology used for calculation of expenses:* It is unclear how the amount of money spent by pharmaceutical companies in the promotion and marketing of drugs in violation of Draft Order will be calculated. For example, if a pharmaceutical company offers a one-time gift worth INR 250 on the occasion of a HCPs birthday, it is not punishable as per the tiered punishment framework since the price of the gift is less than INR 1,000 (see Annexure-B). However, the pharmaceutical company may offer separate gifts of INR 250 on different occasions over a long period, such that the aggregate price of gifts may exceed INR 1,000. In such a case, will the pharmaceutical company be liable or not liable? Similarly, if a company sponsors travel of a HCP for an amount less than INR 10,000 (USD 150) and also sponsors hospitality of the same HCP for

an amount less than INR 10,000 (USD 150), both these offences on a standalone basis may invite a sentence of suspension of marketing for a period of 6 months (see Annexure-B). In such a case, would the company be liable for two sentences of suspension of marketing for a period of 6 months (amount to 12 months in total) or be liable for one sentence of suspension of marketing for a period of 9 months (on account of having sponsored the same HCP with expense more than INR 10,000 in total).

- *Liability on account of non-compliance by third party associations:* The pharmaceutical companies are permitted to sponsor seminars, CME or scientific meetings organized by third party association as long as the associations keep and maintain complete record of the expense, contribution, detailed agenda and minutes for a period of three years. It is not clear whether there will be any liability on a pharmaceutical company if an association defaults in its obligation and is unable to satisfy the government with respect to record of expenditure made on HCPs.
- *Scope of “suspension of marketing:* It is unclear whether the punishment of suspension of marketing implies suspension of direct or indirect interaction with HCPs or suspension of sales activity by the pharmaceutical company. The latter is an extreme and counter-intuitive interpretation because all drugs are essential commodities in India and suspension of sale of an essential commodity may go against public interest. Therefore a reasonable interpretation would be that the company would have to cease all promotion of its highest selling drug. At the same time it may could possibly continue to receive orders on the same.
- *Absence on clarity on punishment for violating provisions with respect to claims:* The Draft Order prescribes that where a pharmaceutical company violates its provisions with respect to claims made for promotional purposes, it shall be liable to such penalty as are specified under “*Drugs and Cosmetics Act, 1940, the Drugs and Magic Remedies (Objectionable Advertisement) Act,*

1954 or the Essential Commodities Act, 1955 and the rules and regulations made thereunder”.

It is not clear what the objective of the government behind this linkage is, especially since the Drugs and Cosmetics Act, 1940 and the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 do not deal with “promotion” directly. These legislations regulate advertisement of drugs. Therefore, it could be hypothesized that the government intends to treat promotion as advertisement and apply the provisions for punishment in case of an advertisement related offence to a promotion related offence. Further, all the legislations linked by the Draft Order prescribe different punishments. For example, the first violation of Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 invites six months in imprisonment while first violation of Essential Commodities Act, 1955 may invite one year of imprisonment. So, it is unclear what will the exact punishment for an offence related to promotion under the Draft Order.

VI. When will Draft Order become law?

The Draft Order is presently a ministerial level draft. Once finalized, the Central Government has the power to give it legal effect immediately.

i. Whether the government is obligated to publish draft for public comments:

The EC Act, under which the Draft Order in its final form is sought to be issued, does not make it obligatory on the government to publish the order in advance whether for intimation or for comments from public.

ii. Whether the order can be challenged:

As per our preliminary analysis, the government seems to be lacking in its powers to issue the Draft Order under the EC Act. As mentioned earlier, the EC Act gives the government the power to regulate production, supply, distribution, trade and commerce of essential commodities by way of an order. Through the Draft Order, the government is, in

effect, attempting to regulate the claims made by pharmaceutical companies in their promotional material and the interaction of pharmaceutical companies with HCPs. These activities (i.e. making of claims and interaction) may not necessarily fall squarely within the scope of “production, supply, distribution, trade and commerce” of drugs. Therefore, the Central Government may be short on legal competence to give Draft Order the effect of law under EC Act.

VII. Gearing-up for the Draft Order

It is likely that the Draft Order may take shape of the law without advance intimation. Therefore, it is pragmatic to strategize and prepare for such an event.

- The current Standard Operating Procedure for Promotion before HCPs (“**Promotion SOP**”) should be revised to reflect that:
 - » The definition of HCPs includes medical practitioners, dentists, chemists and pharmacists.
 - » All claims in promotional material are complete, capable of substantiation and in good taste;
 - » Any claim made in a promotional material will not lead to medically unjustifiable use of the drug or give rise to undue risk;
 - » The design of promotional material will not disguise its real nature (e.g. paid editorials, paid articles etc. that do not disclose its nature and source of funding).
 - » The term “same” will not be used without proper qualification
- The current Standard Operating Procedure for Interaction with HCPs (“**Interaction SOP**”) should be revised to reflect that:
 - » The definition of HCPs includes medical practitioners, dentists, chemists and pharmacists.

- » The sales representative will prepare and maintain a record of samples supplied to each HCP and ensure that the number of samples should not exceed requirement of three patients for full course of therapy;
- » No payment will be made directly to an HCP for travel, stay or food except when such HCP is providing a service as professional service provider. The Draft Order does not affect the ability of the pharmaceutical companies to contract with HCPs in their professional capacity to provide services.
- » All payments with respect to travel, stay or food of HCP with respect to their attendance in a seminar, CME or scientific meeting will be made by way of contribution to the organizer who should be a third party association.
- » The remuneration paid to HCPs for participation in screening camps and awareness campaigns on a daily basis will not exceed their average daily income.
- » No gifts, cash card, hamper or anything which generate monetary benefit or allow gains in kind will be offered to HCPs
- » No grants or funds for medical research or clinical trials shall be extended to HCPs except as per the legal process.

VIII. Our view on Draft Order

It is undeniable that the current guidance on promotional and marketing practices (i.e. UCPMP) has not found many takers due to its voluntary nature. Therefore, a law that sensibly regulates promotional and marketing would be

welcome especially since the industry seems to be operating by different standards of self-governance. However, the Draft Order does not feel to be that law. Due to its grey areas, it comes across as “quick-fix” to fill the void left open by UCPMP rather than a thought-out and measured response to prevailing situation.

The Draft Order seems to be largely modeled on the UCPMP with very interesting omissions (see Annexure-C for detailed comparison). Therefore, those pharmaceutical companies who are already in compliance with the UCPMP should find it relatively easier to comply with the Draft Order in case it takes form of the law. However, all companies alike should take serious cognizance of the Draft Order because of the quantum of punishment it prescribes. Any violation of the Draft Code may result in the confiscation of stock of the highest selling brand of the company and suspension of marketing activity for the same brand for at least a quarter of a year. It is possible to commute the suspension, but the amount to be deposited for it may be as high as INR 10,00,00,000 (USD 1.5 Million). Therefore, it will not hurt to be prepared. We have already suggested preparatory steps to be taken in this note so that the Draft Order does not find any one unprepared when it becomes a law.

The medical devices industry should note that the Draft Order is not applicable to promotion of medical devices. However, as indicated in earlier paragraphs, it is expected that the any future order applicable to promotion of medical devices would be modeled on the Draft Order. Therefore, it may be useful for the medical device companies to remain updated about the fate of the Draft Order.

Annexure – A

In India, the following laws, regulations and guidelines apply to advertisement of drugs and medical devices:

1. Drugs & Cosmetics Act, 1940;
2. Drugs & Cosmetics Rules, 1945;
3. Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954;
4. Consumer Protection Act, 1986
5. Advertising Standards Council of India's Code for Self-Regulation in Advertising;

I. Legal and Regulatory Framework

For the purpose of this note, we have segregated the laws / regulations under Section I and Section II. Section I covers those instruments that have the force of law. Section II herein contains guidelines which have been promulgated by industry bodies in India for self-regulation and are non-binding since they do not carry the force of law.

A. Pharmaceutical / Medical Devices Laws and Regulations

i. Drugs & Cosmetics Act, 1940 (“DC Act”)

The DC Act, *inter alia*, prohibits the sale of misbranded, adulterated and spurious drugs and select notified medical devices. The DC Act does not specifically deal with the promotion of drugs and notified medical devices. However, it provides the framework for the issuance of rules that regulate advertisement of drugs and notified medical devices, as below.

ii. Drugs & Cosmetics Rules 1945 (“DC Rules”)

The DC Rules are framed under the DC Act and, *inter-alia*, contain provisions relating to

restrictions on advertisement of drugs and notified medical devices that may purport or claim to prevent or cure specified diseases or ailments. It prohibits advertisement of drugs that require prescription (i.e. drugs identified in Schedule H, H1 and X of DC Rules). It further prohibits drugs and notified medical devices to claim to prevent or cure or to convey to the intending user thereof any idea that it may prevent or cure one or more of the diseases or ailments specified in Schedule J of DC Rules.

iii. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (“DMR Act”) and Rules, 1955 (“DMR Rules”)

The primary objective of the DMR Act and DMR Rules is to, *inter-alia*, control the advertisement of drugs and all medical devices in terms which suggest or are calculated to lead to the use of that drug or medical device for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule of DMR Act and DMR Rules. Unlike DC Rules that apply to select notified medical devices, DMR Act and DMR Rules apply to all medical devices.

iv. The Consumer Protection Act, 1986 (“CPA”)

The CPA does not regulate advertisement as an activity. However, it places a bar on any false or misleading representation made to a consumer regarding the need or usefulness of a product. If it is found that a company has misled consumers by, *inter alia*, making a false or misleading representation, it may be required to pay damages to the consumer to compensate for / remedy the loss or injury caused under the provisions of CPA. It may also be required to issue corrective advertisements to neutralize the effect of the misleading advertisements under the provisions of CPA.

B. General Advertising Laws / Regulations and National or Regional Trade Associations' Codes of Conduct

i. Advertising Standards Council of India's Code for Self-Regulation in Advertising ("ASCI Code")

The ASCI Code is framed by the Advertising Standards Council of India (ASCI), which is a voluntary self-regulatory body and not a Government body. The ASCI Code aims to regulate the content of promotions or advertisements. This Code applies to advertisers, advertising agencies, media and others such as market research companies who are members of ASCI. This Code has also been accepted by individuals, corporate bodies and associations engaged in or otherwise concerned with the practice of advertising with the ASCI Code serving as the basic guidelines.

Under the ASCI Code, the responsibility for its observance lies with all those who commission, create, place or publish any advertisement or assist in the creation or publishing of any advertisement. Under the provisions therein, all advertisers, advertising agencies and media are expected not to commission, create, place or publish any advertisement which is in contravention of the ASCI Code. The ASCI Code applies to advertisements read, heard or viewed in India even if they originate or are published abroad so long as they are directed to consumers in India or are exposed to significant number of consumers in India. It may be noted, though, that the orders of ASCI are not enforceable through the court enforcement mechanism.

Annexure – B

A. Penalty for proven offence related to claims

Imprisonment or fine or both

B. Penalty for proven offence related to interaction with HCPs

Confiscation of stock and suspension of marketing of highest selling drug in the manner specified in the table below.

Sr.no	Pecuniary value of violation (In Rupees)	Penalty by suspension of marketing of highest selling drug for:	Amount equivalent, for commutation of offense. (In Rupees)
1.	More than 1,000 up to 5,000	Three months	5,00,000
2.	More than 5,000 up to 10,000	Six months	10,00,000
3.	More than 10,000 up to 50,000	Nine months	50,00,000
4.	More than 50,000 up to 1,00,000	One year	1,00,00,000
5.	More than 1,00,000	More than one year	10,00,00,000

Annexure – C

Comparison 1

UCPMP and Draft Order

Sr. No	Text In UCPMP	Text in Draft Order	Difference
1.	<p>Claims for usefulness of a drug must be based on an up-to-date evaluation of all the evidence.</p> <p>The word “new” must not be used for any drug which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.</p>	<p>(A pharmaceutical company engaged in production manufacture or selling or distribution of drugs or its agent may not:)</p> <p>Make any claim in respect of promotion of any drugs which are:</p> <p>f. Not reliable, verifiable, accurate, truthful, informative, balanced, up-to-date or capable of substantiation and is in good taste; or</p> <p>g. Misleading or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.</p>	<p>The Draft Code places stricter restriction on claims related to use of drug</p> <p>The Draft code does not regulate the use of the word “new” in claims</p>
2.	<p>The word “safe” must not be used without any qualification and it must not be state categorically that a medicine has no side effects, toxic hazards or risk of addiction.</p>	<p>Use the word “safe” unless it’s properly qualified</p>	<p>Draft Code does not specifically stop companies from claiming “no side effects, toxic hazards or risk of addiction”.</p>

<p>3.</p>	<p>Comparison of drugs must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or any other way</p> <p>Brand name of other companies must not be used on comparison unless the prior consent of the companies concerned has been taken.</p> <p>Other companies, their products, services or promotions must not be disparaged either directly or by implication.</p>	<p>Make comparison of drugs unless it is based on factual and fair statements capable of substantiation</p>	<p>Draft Code does not mandate that prior consent of third party brand owner be taken in case of claims related to comparison of brands;</p>
<p>4.</p>	<p>Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:</p> <ul style="list-style-type: none"> i. The relevant drug, the name and address of the holder of the authorization of the drug or the business name and address of the part of the business responsible for placing the drug on the market ii. The name of the drug and a list of the active ingredients using the generic name, placed immediately adjacent to the most prominent display of the name of the drug; iii. Recommended dosage, method of use and where not obvious, method of administration; iv. Adverse reactions, warnings and precautions for use and relevant contraindications of the product; v. A statement that additional information is available on request; vi. The date on which the above particulars were generated or last updated. 	<p>Design promotional material in respect of the drugs so as to disguise its real nature.</p>	<p>Draft Code does not prohibit use of names or photographs of HCPs in promotional material.</p> <p>Draft Code does not prescribe mandatory particulars and declarations to be inserted in each promotional material such as “additional information available on request”, “date of last update” etc.</p> <p>Draft Code does not of regulate the design of paid promotional content, except to the extent of requiring pharmaceutical companies to disclose real nature of such content</p>

Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.

All promotional materials appearing in journals, the publication of which is paid for or secured or arranged by a company and referring by brand name to any product of that company, must comply with (the requirements immediately above) as appropriate, irrespective of the editorial control of the material published.

Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.

The names or photographs of healthcare professionals must not be used in promotional material.

Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.

Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

Audio-visual material must be supported by all relevant printed material so that all relevant requirements of the Code are complied with.

<p>5.</p>	<p>Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.</p> <p>Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.</p> <p>The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:</p> <ol style="list-style-type: none"> i. Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product ii. Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment; iii. Any supply of such samples must be in response to a signed and dated request from the recipient; iv. An adequate system of control and accountability must be maintained in respect of the supply of such samples; v. Each sample pack shall not be larger than the smallest pack present in the market. vi. Each sample shall be marked “free medical sample - not for sale” or bear another legend of analogous meaning; vii. Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act, 1940) relating to that product <p>A pharmaceutical company shall not supply a sample of a drug which is an anti- depressant, hypnotic, sedative or tranquillizer.</p> <p>The companies will maintain details, such as product name, doctor name, quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.</p>	<p>Offer free samples to any medical practitioner:</p> <ol style="list-style-type: none"> a. Except for a full course of therapy of maximum three patients for the purpose of acquiring experience of therap. b. unless such samples are of the same dosage and printed in the label with the expression “free medical sample- not for sale” c. a register for the distribution of the samples are maintained...* inspection from time to time to such officer of the Central Government or State Government duly authorized in writing <p>*Text unavailable at time of writing</p>	<p>The Draft Order does not prohibit supply of anti-depressant, hypnotic, tranquilizers or sedatives to HCPs and does not feature the same “smallest available pack” restriction</p>
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6.	<p>No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers etc.</p> <p>Gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) (such as tickets to entertainment events) also are not be offered or provided.</p>	<p>Offer gift, cash card, hampers or anything which generates monetary benefit or allows gains in kind to the medical practitioner or any retail chemists or their family member</p>	<p>The Draft Order prohibits giving of anything that “generate monetary benefits” or “allows gain in kind”. This has increased scope of items that may be looked at as “gifts”.</p>
7	<p>Travel facilities: Companies or their associations/representatives or any person acting on their behalf shall not extend any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to Health Care Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc. as a delegate. It is hereby clarified that in any seminar, conference or meeting organized by a pharmaceutical company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate, it will be at his/her own cost.</p> <p>Hospitality: Companies or their associations/representatives shall not extend any hospitality like hotel accommodation to Healthcare Practitioners and their family members under any pretext.</p> <p>Cash or monetary grants: Companies or their associations/representatives shall not pay any cash or monetary grants to any healthcare professional for individual purpose in individual capacity under any pretext... (contd. below)</p>	<p>Make available any travel facility, stay or food cost within India or outside, including rail, air, ship, cruise ticket, any registration fee or offer paid vacation to any medical practitioner or his relatives for attending any seminar, continuing medical education or scientific meeting.</p> <p>Provided that a pharmaceutical company may sponsor any seminar, continuing medical education or scientific meeting organized by the Medical Association, subject to the condition that the Association maintains a register of such seminar, continuing medical education or scientific meeting as the case may be, with complete information about expenditure and the source of the</p>	<p>The Draft Order increases scope of restriction on sponsorship of travel of HCPs for participation in events to all HCPs, irrespective of whether they participate as delegates or not.</p> <p>The Draft Order envisages sponsorship of travel, stay and food of HCPs by making a contribution to the event organizer, which must be a third party association.</p> <p>The Draft Order permits pharmaceutical companies to organize screening and awareness campaigns in public institutions and remunerate HCPs on a daily basis in accordance with their average daily income.</p>

		<p>contribution, detailed agenda and minutes thereof and kept for a period of three years and made available to such officer of the Central Government or State Government duly authorized in writing</p> <p>Provided further that the pharmaceutical company or its agents may organize screening camps or awareness campaigns in the public institutions like hospitals, health centres approved by the Central or the State Government, as the case may be without using the screening camps or awareness campaigns for surrogate advertisement of its products.</p> <p>Provided also that the pharmaceutical company may compensate the medical practitioner attending the screening camps or awareness campaigns for the day in commensuration with their average daily income</p>	
8.	<p>(from above) ...Funding for medical research, study etc., can only be extended through approved institutions by modalities laid down by law/rules/guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.</p>	<p>Extend grants or funds for medical research or clinical trials, except through approved institutions subject to any law in force for the time being or any protocol relating to the project.</p>	<p>The Draft Order does not obligate pharmaceutical companies to disclose grants or funds for medical research or clinical trials as long as they are given as per law.</p>

Comparison 2

MCI Code of Ethics (Ethical Guidelines Applicable to Medical Practitioners in their Interaction with Industry) and Draft Order

Sr. No	MCI Code of Ethics	In Draft Order	Analysis
		(A pharmaceutical company engaged in production manufacture or selling or distribution of drugs or its agent may not:)	
1.	<p>Gifts: A medical practitioner shall not receive any gift from any pharmaceutical or allied healthcare industry and their sales people or representatives.</p>	Offer gift, cash card, hampers or anything which generates monetary benefit or allows gains in kind to the medical practitioner or any retail chemists or their family member	The Draft Code places stricter restriction on giving of gifts etc. by including “anything which generates monetary benefit or allows gains in kind” in its scope.
2.	<p>Travel facilities: A medical practitioner shall not accept any travel facility inside the country or outside, including rail, road, air, ship, cruise tickets, paid vacations etc. from any pharmaceutical or allied healthcare industry or their representatives for self and family members for vacation or for attending conferences, seminars, workshops, CME programme etc. as a delegate.</p> <p>Hospitality: A medical practitioner shall not accept individually any hospitality like hotel accommodation for self and family members under any pretext.</p>	Make available any travel facility, stay or food cost within India or outside, including rail, air, ship, cruise ticket, any registration fee or offer paid vacation to any medical practitioner or his relatives for attending any seminar, continuing medical education or scientific meeting.	The Draft Code places stricter restriction on sponsorship of travel and hospitality since it applies to all HCPs, whether delegate or not.

3,	A medical practitioner shall not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose in individual capacity under any pretext...(contd. below)	Extend grants or funds for medical research or clinical trials, except through approved institutions subject to any law in force for the time being or any protocol relating to the project.	The Draft Code clarifies that all grants or funds for medical research or clinical trials will be provided to approved institutions (not to HCPs directly).
4.	(from above)...Funding for medical research, study etc. can only be received through approved institutions by modalities laid down by law / rules /guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.	Extend grants or funds for medical research or clinical trials, except through approved institutions subject to any law in force for the time being or any protocol relating to the project.	The Draft Code covers both grants and all other types of funding.

About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. We provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner.

As a firm of specialists, we work with select clients in select verticals on very complex and innovative transactions and disputes.

Our forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and Medical Devices and Nanotechnology.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automobile, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprise marquee Fortune 500 corporations.

Our ability to innovate is endorsed through the numerous accolades gained over the years and we are also commended by industry peers for our inventive excellence that inspires others.

NDA was ranked the ‘Most Innovative Asia Pacific Law Firm in 2016’ by the *Financial Times - RSG Consulting Group* in its prestigious FT Innovative Lawyers Asia-Pacific 2016 Awards. While this recognition marks NDA’s ingress as an innovator among the globe’s best law firms, NDA has previously won the award for the ‘Most Innovative Indian Law Firm’ for two consecutive years in 2014 and 2015.

As a research-centric firm, we strongly believe in constant knowledge expansion enabled through our dynamic Knowledge Management (‘KM’) and Continuing Education (‘CE’) programs. Our constant output through Webinars, Nishith.TV and ‘Hotlines’ also serves as effective platforms for cross pollination of ideas and latest trends.

Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has been developed into a global case study and published by John Wiley & Sons, USA in a feature titled ‘Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage’ in the September 2009 issue of *Global Business and Organizational Excellence (GBOE)*.

A brief below chronicles our firm’s global acclaim for its achievements and prowess through the years.

- IDEX Legal Awards: In 2015, NDA won the “M&A Deal of the year”, “Best Dispute Management lawyer”, “Best Use of Innovation and Technology in a law firm” and “Best Dispute Management Firm” <<http://idexlegalawards.in/ArticlePage.aspx?aid=6>>. Nishith Desai was also recognized as the ‘Managing Partner of the Year’ in 2014.
- Merger Market: has recognized NDA as the fastest growing M&A law firm in India for the year 2015.
- Legal 500 has ranked us in tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014, 2017)

- International Financial Law Review (a Euromoney publication) in its IFLR1000 has placed Nishith Desai Associates in Tier 1 for Private Equity (2014, 2017). For three consecutive years, IFLR recognized us as the Indian “Firm of the Year” (2010-2013) for our Technology - Media - Telecom (TMT) practice.
- Chambers and Partners has ranked us # 1 for Tax and Technology-Media-Telecom (2014, 2015, 2017); #1 in Employment Law (2015 & 2017); # 1 in Tax, TMT and Private Equity (2013, 2017); and # 1 for Tax, TMT and Real Estate – FDI (2011).
- India Business Law Journal (IBLJ) has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015
- Legal Era recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013).

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Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "*Hotlines*". These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *NDA Insights* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction.

We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports.

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