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Pharmaceutical Advertising

Law and Practice – Pakistan

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PAKISTAN

LAW AND PRACTICE: p.3

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Law and Practice

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CONTENTS

1. Regulatory Framework **p.4**
1.1 Laws and Self-Regulatory Codes p.4
1.2 Application and Legal Value of Regulatory Codes p.4

2. Scope of Advertising and General Principles **p.4**
2.1 Definition of Advertising p.4
2.2 Difference Between Information and Advertising p.5
2.3 Restrictions on Press Releases p.5
2.4 Comparative Advertising p.5

3. Advertising for Unauthorised Medicines or Unauthorised Indications **p.5**
3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications p.5
3.2 Provision of Information During a Scientific Conference p.5
3.3 Provision of Information to Healthcare Professionals p.5
3.4 Provision of Information to Healthcare Institutions p.5

4. Advertising to the General Public **p.6**
4.1 Main Restrictions on Advertising to the General Public p.6
4.2 Information Contained in Advertising to the General Public p.6
4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry p.6
4.4 Restrictions on Endorsements by Healthcare Professionals p.6

5. Advertising to Healthcare Professionals **p.6**
5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals p.6
5.2 Reference to Data Not Included in the Summary of Product Characteristics p.6
5.3 Restrictions on Reprints of Journal Articles p.6

6. Vetting Requirements and Internal Verification Compliance **p.7**
6.1 Requirements for Prior Notification/Authorisation p.7
6.2 Compliance with Rules on Medicinal Advertising p.7

7. Internet **p.7**
7.1 Regulation of Advertising on the Internet for Medicinal Products p.7

8. Inducement/Anti-Bribery General **p.7**
8.1 General Anti-Bribery Rules p.7

9. Gifts, Hospitality, Congresses and Related Payments **p.7**
9.1 Gifts to Healthcare Professionals p.7
9.2 Limitations on Providing Samples to Healthcare Professionals p.7
9.3 Sponsorship of Scientific Meetings p.7
9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events p.7
9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions p.7
9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions p.8
9.7 Payment for Services Provided by Healthcare Professionals p.8
9.8 Prior Authorisations or Notifications p.8

10. Transparency **p.8**
10.1 Requirement to Disclose Details of Transfers of Value p.8

11. Enforcement **p.8**
11.1 Enforcement Bodies p.8
11.2 Initiating Proceedings for Advertising Infringements p.8
11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe p.8
11.4 Relationship Between Regulatory Authorities and Courts p.8
11.5 Recent Enforcement Trends p.8

Contributed by Bharucha & Co ***Authors:*** Mohammad Fazil Bharucha, Samina Naz Siddiqui, Yusra Khalid

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Authors

Mohammad Fazil Bharucha is the Managing Partner of Intellectual Property law firm Bharucha & Co based in Karachi, Pakistan. Over the years he has developed his expertise in other fields of IP such as trade marks and copyright. He is professionally active in various IP forums both locally and internationally and has contributed to awareness of IP in Pakistan not only to the general public but also in educational institutions. He heads the firm and focuses on a range of contentious and non-contentious IP matters, including litigation. With over three decades of experience in areas such as franchising and licensing, together with compliance issues, he often represents clients in the High Court in patent and trade mark disputes. He served as the President of Asian Patent Attorneys Association (APAA), Pakistan Group from 2010 till 2012. He was the Delegate of Independent Members of Pakistan and Kazakhstan of International Association for the Protection of Intellectual Property (AIPPI) from 2011 till 2015. His international professional memberships include AIPPI, IBA, IPBA, INTA, ITMA, CIPA, APAA, Marques, ECTA and LES.

Samina Naz Siddiqui holds a degree of Master of Sciences in Biotechnology. She has been part of the firm since 2008 and is involved in advising clients regarding Patents' Examination Reports, drafting of claims, general correspondence, assignments and searches. She is a registered Patent Agent and a member of APAA.

Yusra Khalid holds a degree of Bachelor of Law, as well as a Master's in Intellectual Property and Information Law. She has been with the firm since 2015, having previously worked as a legal research assistant, as well as holding the position of assistant professor at the University of Houston. She is primarily involved in matters relating to trade mark law, as well as drafting legal documents and conducting research on various legal matters. She is licensed to practise law in Karachi, and is also a member of the Karachi Bar Association.

1. Regulatory Framework

1.1 Laws and Self-Regulatory Codes

In Pakistan, the main legislation governing advertising on medicines is the Drugs Act, 1976 and the Drugs (Licensing, Registering and Advertising) Rules, 1976.

1.2 Application and Legal Value of Regulatory Codes

There are no self-regulatory codes specifically relating to advertising medicines, but the profession of medical and dental practitioners is governed by the Pakistan Medical and Dental Council, which has its own rules and regulations. In addition, the Drug Regulatory Authority was established under the DRAP Act 2012 to provide effective co-ordination and enforcement of the Drugs Act, 1976 (XXXI of 1976), and to bring harmony to the inter-provincial trade and commerce of therapeutic goods.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Generally, an advertisement is defined as "a notice given in a manner designed to attract public attention".

In the context of drugs, advertisement is defined under Section 24 of the Drugs Act, 1976 as "any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of a drug, a substance or a mixture of substances, a remedy or a treatment except the display of sign boards for a clinic, a dispensary or a hospital or such other institution offering treatment".

Furthermore, Rule 30 (11) Schedule G of the Drugs Rules 1976 defines "promotion" as all informational and persuasive activities by manufacturers and distributors that have the effect of inducing the prescription, supply, purchase and/or use of medicinal drugs.

2.2 Difference Between Information and Advertising

Information is defined as awareness created, facts provided or learning about something or someone, whereas "advertisement" means a notice given in a manner designed to attract public attention. In view thereof, a series of communications through disease-awareness campaigns to raise awareness of key issues or to encourage behaviour change and participation may not amount to advertisement but only information, unless drugs to prevent such diseases are also named, etc, during those campaigns.

2.3 Restrictions on Press Releases

Section 31(4) of the Drugs Rules, 1976 states that "a drug or any substance referred to in clause (ii) of Section 24 may be advertised through the Press without reference to the Federal Government if it is merely intended to inform the public of the availability or the price of such drug or any substance referred to in clause (ii) of Section 24, subject to the condition that the Federal Government may prohibit such advertisement if, in its opinion, the public interest so requires."

2.4 Comparative Advertising

Under Section 31(6) of the Drugs Rules, 1976, no advertisement containing any direct or indirect comparison with any other drug or substance or remedy for any disease for the purpose of attracting customers or with a view to discrediting other such products is allowed in any way.

Comparative advertisement in the context of trade marks is permissible so long as it does not cause any confusion or discredit or disparage another trade mark, but compares goods or services meeting the same needs or intended for the same purpose. However, limitations imposed by the Drugs Rules, 1976 would prevail over the provisions of trade mark law.

3. Advertising for Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

According to general practice, trading in unauthorised medicinal products is prohibited, with Section 23 (1)(7) of the Drugs Act, 1976 providing that "no person shall himself or by any other person on his behalf export, import or manufacture for sale or sell any drug which is not registered or is not in accordance with the conditions of registration". There is no specific provision for the advertising of unauthorised medicinal products but, by virtue of the definition of advertisement in the Drugs Act, any such act may be deemed to be promoting the indirect sale of the drug, which may not be permitted.

3.2 Provision of Information During a Scientific Conference

There are no specific provisions regarding making information about a medicine available at scientific meetings before the product is authorised. As scientific meetings are not regulated separately, the issue should be addressed on a case-by-case basis, taking into account whether or not a particular action or the passing on of information constitutes advertising, but generally there should be no restriction on providing information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals.

3.3 Provision of Information to Healthcare Professionals

Information on unauthorised medicines is not allowed to be published if such a publication would constitute advertising. The dispatch of information on an unauthorised medicine to health professionals will normally constitute pre-launch marketing, which may not be permissible.

3.4 Provision of Information to Healthcare Institutions

Providing such information to institutions may be regarded as information designed with the purpose of increasing the sale or use/utilisation of a product, and may be considered as advertising. There appears to be no legal connection between sending such information and healthcare institutions planning their budgets, as healthcare institutions generally plan their budgets in accordance with the legislation and products currently available in the market, irrespective of whether information has been received on medical products yet to be registered.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising to the General Public

Where permissible, advertising to the general public is allowed to help people make rational decisions on the use of drugs determined to be legally available without a prescription, with the following stipulations:

- This shall take account of people's legitimate desire for information regarding their health, and the advertiser shall not take undue advantage of people's concerns about their own health.
- Advertisement shall not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can only be treated by qualified health practitioners.
- Scheduled narcotic and psychotropic drugs shall not be advertised to the general public in connection with the fight against drug addiction and dependency.
- Although health education aimed at children is highly desirable, drug advertisements shall not be directed at children.
- Promotional material shall be factual and claims to cure, prevent or relieve an ailment shall be made only if they can be substantiated.
- Where applicable, advertisements shall also indicate appropriate limitations to the use of the drug.
- When lay language is used, the information shall be consistent with the approved scientific data or other legally determined scientific basis for approval. Language that brings about fear or distress shall not be used.

4.2 Information Contained in Advertising to the General Public

As mentioned in rule 30 (11) Schedule G of the Drugs Rules 1976, and taking into account the media employed, advertisements to the general public may contain the following information:

- the generic name(s) of the active ingredient(s);
- major indication(s) for use;
- major precautions, contraindications and warnings, if any; and
- the name of the manufacturer or distributor.

According to this Schedule, information on price shall be accurately and honestly portrayed to the consumer.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

No direct interaction is allowed between patients or patient organisations and industry; it must be communicated from industry to healthcare professionals or organisations, and then to patients.

4.4 Restrictions on Endorsements by Healthcare Professionals

According to PMDC code of ethics, regulation 54(1), no registered medical or dental practitioner below the rank of a professor may endorse any drug or medical equipment publicly or in print, air or electronic media, and they shall make all possible efforts to ensure that any study conducted on the efficacy or otherwise of any drug or medical equipment is communicated to the public through appropriate scientific bodies or published in the appropriate scientific literature.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

When introduced to a physician for the first time, a new drug should be accompanied by full product information on the basis of the approved scientific data sheet or similar documentation, and shall contain the following:

- the generic name(s) of the active ingredient(s);
- the content of active ingredient(s) per dosage form or regimen;
- the generic name(s) of other ingredient(s) known to cause problem(s);
- the approved therapeutic uses;
- dosage form or regimen;
- side-effects and major adverse drug reactions;
- precautions, contraindications and warnings;
- major interactions;
- the name and address of the manufacturer or distributor;
- reference to appropriate scientific literature; and
- the price of the drug.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

The wording and illustrations in advertisements to physicians and related healthcare professionals shall be fully consistent with the approved scientific data sheet for the drug concerned or another source of information with similar content.

5.3 Restrictions on Reprints of Journal Articles

Reprints of journal articles may be provided to healthcare professionals upon request. According to PMDC code of ethics, regulation 51 (3), registered medical or dental practitioners may accept text or reference books, medical journals, CDs and other educational materials from drug manufacturers or distributors, as the case may be, if they are satisfied that they serve a genuine, demonstrable and direct educational function.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

After seeking advice from the Committee on Advertising, the Federal Government may allow the advertisement of a drug or any substance or remedy as specified in Schedule D of the Drugs Act, or of a treatment or offer of a treatment for any disease. This authority approves the contents of such an advertisement and specifies conditions subject to which such advertisements shall be made.

The Federal Government may withdraw the approval granted to any advertisement, or modify or alter any condition subject to which the advertisement was approved, if it believes it to be in the public interest.

6.2 Compliance with Rules on Medicinal Advertising

There is a mechanism in place to ensure that companies comply with relevant rules/regulations with respect to medicines. A prescribed procedure is followed in the internal company departments set up for this purpose, and specialised personnel are employed before the medicines are transferred to the relevant third parties.

7. Internet

7.1 Regulation of Advertising on the Internet for Medicinal Products

There are currently no specific rules with respect to advertisement on the internet for medicinal products, although Schedule G lists the general information that is required to be disclosed to the public, as provided in **4.2 Information Contained in Advertising to the General Public**.

8. Inducement/Anti-Bribery General

8.1 General Anti-Bribery Rules

The PMDC imposes certain restrictions that prohibit medical practitioners, as opposed to organisations, from receiving gifts, benefits in kind or economic advantages as an inducement to prescribing, supplying, administering, recommending, buying or selling any drug or medical equipment, as the case may be.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

According to PMDC code of ethics, regulation 51, registered medical or dental practitioners may accept promotional aid items (stethoscope, weight machine, hand wash, etc) from drug manufacturers or distributors, provided these items are primarily for the benefit of patients. Text or reference books, medical journals, CDs and other educational materials may also be accepted if they serve a genuine demonstrable and direct educational purpose.

9.2 Limitations on Providing Samples to Healthcare Professionals

According to PMDC code of ethics, regulation 52, registered medical or dental practitioners may accept drug samples for patient use only and not for personal gain or re-sale.

Free samples of prescription drugs may be provided in modest quantities to prescribers, preferably on request. No free sampling of non-prescription drug to the general public is permissible for promotional purposes.

9.3 Sponsorship of Scientific Meetings

Pursuant to Schedule G of the Drugs Act 1976, the intimation regarding scientific symposia, seminars, conferences and such meetings shall be clearly communicated in advance where sponsored by a pharmaceutical manufacturer or distributor. The invitation letter should accurately reflect the presentations and discussions to be held. Any entertainment or other hospitality offered to members of the medical and allied professions shall be secondary to the main purpose of the meeting and shall be kept to a modest level.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

PMDC code of ethics, regulation 53 states that any medical or dental practitioners organising an educational meeting, congress or symposium should ensure that a minimum of 80% of the time allocated for such meeting, congress or symposium is spent on core educational activities, and a maximum of 20% of the total time devoted to recreational activities.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

There are no rules which prevent pharmaceutical companies from giving donations to healthcare professionals or healthcare institutions, or from donating equipment or funding the cost of certain types of services. PMDC include general provisions that impose restrictions on healthcare professionals accepting money as an inducement, in order to protect their professional autonomy or integrity. Please also see **8.1 General Anti-Bribery Rules**.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Healthcare professionals are strictly prohibited under PMDC as set out in regulation 40 from receiving any gift, gratuity, commission or bonus in consideration of or in return for the referring, recommending or procuring of any patient for medical, surgical or other treatment. Healthcare professionals may purchase drugs at a discount directly from the manufacturer, provided that this discount is duly passed on to the patients.

9.7 Payment for Services Provided by Healthcare Professionals

According to PMDC code of ethics, regulation 53 (2), since continuing medical education (CME) or scientific and educational conferences or professional meetings contribute to the improvement of patient care, registered medical or dental practitioners may accept support from manufacturers or distributors of drugs or medical equipment in this regard, provided that any financial support provided is strictly through cheque or bank draft deposited in a duly designated account rather than in their personal bank accounts, and is disclosed to the institution and to the Council upon demand.

9.8 Prior Authorisations or Notifications

According to PMDC code of ethics, regulation 53 (5), registered medical or dental practitioners may accept an invitation and financial support for a domestic or international trip from manufacturers or distributors of drugs or medical equipment subject to the following conditions:

- the trip is primarily for an academic purpose and preferably the selected medical or dental practitioner is presenting a paper in the course of the trip or participating in the proceedings in a similarly meaningful manner;
- the trip is to attend an event of international nature featuring Pakistani as well as non-Pakistani participants;
- the invitation and financial support are for the registered medical or dental practitioner only and not for his or her spouse or children; and
- the medical or dental practitioner shall disclose the purpose and invitation to the institute and to the Council.

Bharucha & Co.
F-7/1, Block 8, KDA Scheme 5
Karachi
Pakistan
75600

Tel: +92 21 3537 9544
Fax: +92 21 3537 9557-58
Email: mail@bharuchaco.com
Web: www.bharuchaco.com

10. Transparency

10.1 Requirement to Disclose Details of Transfers of Value

There are no codes drafted by self-regulatory bodies or the legislative authorities with respect to the disclosure of transfer of value to pharmaceutical companies and healthcare organisations.

11. Enforcement

11.1 Enforcement Bodies

Complaints regarding professional misconduct (inducement), negligence or incompetence among healthcare professionals can be brought to the disciplinary committee of the council in the manner set out in regulation 50 of PMDC code of ethics.

11.2 Initiating Proceedings for Advertising Infringements

A suit can be filed in the court of law for advertisement infringement and/or the other specialised regulatory court, the Drug Court, as set up under section 31 of the Drugs Act, 1976.

11.3 Penalties for Violating Advertising Rules and Rules on Inducements to Prescribe

If a medical professional has violated rules on inducement, the Disciplinary Committee of Council may declare a punishment, which may include the removal of the name of a registered medical or dental practitioner from the register altogether, or for a specified period. The removal of a name is also widely publicised in the local press, and is communicated to different medical associations or societies or bodies internationally or nationally.

11.4 Relationship Between Regulatory Authorities and Courts

The Drug Regulatory Authority of Pakistan deals with the licensing and registration of drugs, but specialised inspectors are appointed by the federal and/or provincial government, and take any necessary action to ensure compliance with local drug laws, such as inspection and/or searches of premises. Such matters are generally brought to the specialised drug courts as set up under the Drugs Act, 1976. While the drug courts have no prescribed procedure under the Act, they follow the procedure as laid down under the relevant codes of procedure.

11.5 Recent Enforcement Trends

There is no public information specific to pharmaceutical advertising, so it is difficult to outline the enforcement trends in this specific field.