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GLOBAL LEGAL GROUP, CHAPTER 34

1 GENERAL - MEDICINAL PRODUCTS

1.1 WHAT LAWS AND CODES OF PRACTICE GOVERN THE ADVERTISING OF MEDICINAL PRODUCTS IN MEXICO?

Advertising of medicinal products in Mexico is mainly governed by the General Health Law, and the Regulations of the General Health Law Regarding Advertising.

The authority in charge of enforcing the provisions regarding advertising is the Federal Commission for Protection against Sanitary Risks (COFEPRIS) which is part of the Ministry of Health.

In addition to the Law and Regulations, there are also opinions issued by the Advertising Council, which includes representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media and consumer groups.

Furthermore, the Industrial Property Law and the Federal Law for the Protection of Consumers both have certain provisions regarding advertising, and the National Chamber of the Pharmaceutical Industry has a Code of Ethics that includes provisions regarding advertising. It's important to point out that the provisions of this code of ethics are not mandatory, but failure to comply with it can result in suspension of rights as a member of the Chamber or exclusion from it.

1.2 HOW IS "ADVERTISING" DEFINED?

The Regulations of the Health Law Regarding Advertising define advertising in Article 2, as *"the activity comprehending any process of creation, planning, execution, and circulation of ads in media channels which aims to promote the sales or consumption of products and services"*.

Said regulations also define "ad" as *"the message directed to the public or a section of the same, with the purpose of informing about the existence or characteristics of a product, service or activity for its commercialisation and sale or to motivate a conduct"*.

1.3 WHAT ARRANGEMENTS ARE COMPANIES REQUIRED TO HAVE IN PLACE TO ENSURE COMPLIANCE WITH THE VARIOUS LAWS AND CODES OF PRACTICE ON ADVERTISING, SUCH AS "SIGN OFF" OF PROMOTIONAL COPY REQUIREMENTS?

The Regulations of the Health Law Regarding Advertising do not address this issue specifically.

1.4 MUST ADVERTISING BE APPROVED IN ADVANCE BY A REGULATORY OR INDUSTRY AUTHORITY BEFORE USE? IF SO, WHAT IS THE PROCEDURE FOR APPROVAL? EVEN IF THERE IS NO REQUIREMENT FOR PRIOR APPROVAL IN ALL CASES, CAN THE AUTHORITIES REQUIRE THIS IN SOME CIRCUMSTANCES?

Article 79 of the Regulations of the Health Law Regarding Advertising mentions that publicity related to specific products/services (including drugs) must be previously authorised.

The procedure for approval is through the filing of an authorization request before the COFEPRIS which must include all of the characteristics of the intended advertising.

There is also the possibility of submitting only a notice instead of filing an authorisation request when the advertising is directed to health professionals. Additionally, the regulations allow companies to submit the advertising project before an expert, previously authorised by the Ministry of Health, who will validate that the advertising does not breach any provision of the law. The opinion of this expert can be filed along with the authorisation request to speed

up the authorisation process.

Furthermore, there are also provisions regarding codes of ethics and agreements related to self regulation in advertising that can be entered with the Ministry of Health, which will also speed up the authorisation process.

1.5 IF THE AUTHORITIES CONSIDER THAT AN ADVERTISEMENT WHICH HAS BEEN ISSUED IS IN BREACH OF THE LAW AND/OR CODE OF PRACTICE, DO THEY HAVE POWERS TO STOP THE FURTHER PUBLICATION OF THAT ADVERTISEMENT? CAN THEY INSIST ON THE ISSUE OF A CORRECTIVE STATEMENT? ARE THERE ANY RIGHTS OF APPEAL?

The COFEPRIS has specific authority to order the suspension of an advertising activity in breach of a provision of the Law or Regulations, both to the responsible party and directly to the media channel that is responsible for the advertising, and said media channel must comply within 24 hours.

Even though there are no specific provisions regarding the issuance of corrective statements, COFEPRIS usually gives companies warnings, requesting them to change or modify the publicity that is considered illicit, and has in some cases requested said corrective statements. If the responsible company does not proceed with the modification or statement, a fine can be imposed.

There are two common venues to appeal decisions by COFEPRIS ordering the suspension of an advertising activity or the issuance of a corrective statement: individuals/companies can resort to a review recourse which is decided by the Legal Area of COFEPRIS; or through a nullity trial before the Federal Court for Tax and Administrative Affairs. Our Law Firm usually recommends the nullity trial as a common venue against decisions of the COFEPRIS, as the criteria held by this authority on most cases is to affirm the challenged decision in the review recourse. In addition to this, under some circumstances, a case can be brought before a federal court to request a stay to orders from COFEPRIS.

1.6 WHAT ARE THE PENALTIES FOR FAILING TO COMPLY WITH THE RULES GOVERNING THE ADVERTISING OF MEDICINES? WHO HAS RESPONSIBILITY FOR ENFORCEMENT AND HOW STRICTLY ARE THE RULES ENFORCED? ARE THERE ANY IMPORTANT EXAMPLES WHERE ACTION HAS BEEN TAKEN AGAINST PHARMACEUTICAL COMPANIES? TO WHAT EXTENT MAY COMPETITORS TAKE DIRECT ACTION THROUGH THE COURTS?

The penalties for failing to comply with rules related to advertising are the suspension of advertising activities ordered either to the responsible party or directly to the media and the imposition of a fine, which can range from 1,000 to 10,000 times the official daily minimum wages (around USD \$5.00 per day). The responsibility for imposing these penalties falls directly on the Ministry of Health, through the COFEPRIS.

Regarding the strictness on the imposition of these fines, in our experience, it has been steadily increasing, and the Ministry of Health constantly monitors advertising activities throughout the country. The COFEPRIS has been directing efforts to the entering of coordination agreements related to publicity, and to the enforcement of the same. There has also been a strong coordination effort between the COFEPRIS and the pharmaceutical companies tending to self regulation of advertising, which is still monitored.

Regarding the possibilities for competitors to take direct actions related to advertising activities, the General Health Law and the Regulations of the Health Law regarding Advertising both contemplate the possibility of a so-called “people’s action”, which is a complaint filed before the COFEPRIS regarding a breach in the provisions of the law. Issues related to unfair competition will be directly addressed in question 1.6 below.

Companies belonging to the Self Regulation and Publicity Ethics Council can also file a complaint before this private organism, regarding another member’s advertising. Whereas the Council issues recommendations after hearing both parties, these recommendations are not binding.

1.7 WHAT IS THE RELATIONSHIP BETWEEN ANY SELF REGULATORY PROCESS AND THE SUPERVISORY AND ENFORCEMENT FUNCTION OF THE COMPETENT AUTHORITIES? CAN, AND, IN PRACTICE, DO, THE COMPETENT AUTHORITIES INVESTIGATE MATTERS DRAWN TO THEIR ATTENTION THAT MAY CONSTITUTE A BREACH OF BOTH THE LAW AND ANY RELEVANT CODE AND ARE ALREADY BEING ASSESSED BY ANY SELF- REGULATORY BODY? DO THE AUTHORITIES TAKE UP MATTERS BASED ON AN ADVERSE FINDING OF ANY SELF-REGULATORY BODY?

There are no specific provisions in the law granting capacity to investigate or review self regulation processes, unless these processes refer to legally stated obligations. Authorities can and will review breaches to the Law even if they are being assessed by the Self Regulation and Publicity Ethics Council, and they can take into account the recommendations of this body.

1.8 IN ADDITION TO ANY ACTION BASED SPECIFICALLY UPON THE RULES RELATING TO ADVERTISING, WHAT ACTIONS, IF ANY, CAN BE TAKEN ON THE BASIS OF UNFAIR COMPETITION? WHO MAY BRING SUCH AN ACTION?

Actions based on unfair competition derived from advertising activities can be taken based on the provisions of the Industrial Property Law.

This action can either be brought before the Mexican Institute of Industrial Property by the party directly affected by the advertising activities or it can be started *ex-officio* by this authority and it can lead to a declaration of infringement.

Once this declaration of infringement is firm and beyond the shadow of appeal, the affected party can also claim damages and lost profits before a civil court, deriving from the unfair competition activities.

Additionally, article 32 of the Federal Law for Consumer Protection contemplates the possibility of filing a complaint before the Bureau of Consumer Protection regarding false or tendentious advertising, which can lead to the imposition of a fine and an order to stop the specific advertising activities.

2 PROVIDING INFORMATION PRIOR TO AUTHORISATION OF MEDICINAL PRODUCT

2.1 TO WHAT EXTENT IS IT POSSIBLE TO MAKE INFORMATION AVAILABLE TO HEALTH PROFESSIONALS ABOUT A MEDICINE BEFORE THAT PRODUCT IS AUTHORISED? FOR EXAMPLE, MAY INFORMATION ON SUCH MEDICINES BE DISCUSSED, OR MADE AVAILABLE, AT SCIENTIFIC MEETINGS? DOES IT MAKE A DIFFERENCE IF THE MEETING IS SPONSORED BY THE COMPANY RESPONSIBLE FOR THE PRODUCT?

Article 42 of the Regulations of the Health Law regarding Advertising mentions that advertisement directed to health professionals must include, in every case, information on the Marketing Authorisation number for the product and, thus, advertisements of an unauthorised product are not permitted.

There are no provisions in the Law or Regulations expressly prohibiting a company from making information of an unauthorised product available to health professionals, as long as that information is not considered as advertising, according to the definition of the Law mentioned in question 2.1 above.

The criterion employed by COFEPRIS is that when the information is directly related to the pharmaceutical company, it can be considered as advertising. In view of this, it is common to request an opinion by COFEPRIS before disclosure to seek a confirmation that the corresponding information and the way that it will be presented is not advertising, since it will be otherwise forbidden.

2.2 MAY INFORMATION ON UNAUTHORISED MEDICINES BE PUBLISHED? IF SO, IN WHAT CIRCUMSTANCES?

Published information on unauthorised medicines could be considered as advertising if it falls under the definition provided in question 1.2 above, and thus would be forbidden by the Regulations of the Health Law Regarding Advertising.

Whereas there are no specific provisions regarding general information or information of a strict scientific nature, the COFEPRIS has authority to review said information and determine whether it is of a promotional nature and, thus, it could request the responsible company to modify it or suspend it.

Additionally, since the filing of an application or notice of advertising requires information on the Marketing Authorisation, COFEPRIS will deny any permits for

specific advertisements.

2.3 IS IT POSSIBLE FOR COMPANIES TO ISSUE PRESS RELEASES ABOUT MEDICINAL PRODUCTS WHICH ARE NOT YET AUTHORISED? IF SO, WHAT LIMITATIONS APPLY?

As with the previous question, there are no specific provisions on this issue, but if the press release contains information on both the product and the company, COFEPRIS will most likely consider it as advertisement, and as we mentioned above this activity is forbidden.

Our recommendation for these cases is to consult with the COFEPRIS on whether the press release is considered an advertisement, and act upon the opinion issued by this authority, which is also subject to challenge.

2.4 MAY SUCH INFORMATION BE SENT TO HEALTH PROFESSIONALS BY THE COMPANY? IF SO, MUST THE HEALTH PROFESSIONAL REQUEST THE INFORMATION?

There are no provisions regarding the sending or request of information by health professionals; however, if the information sent falls within the definition of advertising, it would be forbidden by the Regulations of the Health Law regarding Advertising, regardless of the existence of a previous request.

2.5 MAY INFORMATION BE SENT TO INSTITUTIONS TO ENABLE THEM TO PLAN AHEAD IN THEIR BUDGETS FOR PRODUCTS TO BE AUTHORIZED IN THE FUTURE?

As with question 2.2 above, sending information to institutions could be regarded as advertising and, thus, it would be prohibited until a Marketing Authorisation is granted and the advertising is authorised. This is a specific activity that can easily fall within the definition of advertisement, since information for planning budgets, could be interpreted as an intention to promote the product that is under process of authorisation.

2.6 IS IT POSSIBLE FOR COMPANIES TO INVOLVE HEALTH PROFESSIONALS IN MARKET RESEARCH EXERCISES CONCERNING POSSIBLE LAUNCH MATERIALS FOR MEDICINAL PRODUCTS AS YET UNAUTHORISED? IF SO, WHAT LIMITATIONS APPLY? HAS ANY GUIDELINE BEEN ISSUED ON MARKET RESEARCH OF MEDICINAL PRODUCTS?

There is no standard guideline on market research for medicinal products, but the general rules would apply for such a research.

Companies can involve health professionals in market research exercises but the use of the medicinal product that is pending authorisation would be prohibited, unless the study was sanctioned by COFEPRIS as part of clinical trials.

3 ADVERTISEMENTS TO HEALTH PROFESSIONALS

3.1 WHAT INFORMATION MUST APPEAR IN ADVERTISEMENTS DIRECTED TO HEALTH PROFESSIONALS?

According to Article 42 of the Regulations of the Health Law regarding Advertising, advertisement directed to health professionals can only be published in specialised media, and it must be based on the information to prescribe medications, which must contain the following data:

- the distinctive denomination, if this is the case;

- the generic denomination;

- pharmaceutical form and formulation;

- therapeutical indications;
- pharmacokinetics and pharmacodynamics;
- side effects;
- general precautions;
- restrictions of use during pregnancy and breast feeding;
- secondary and adverse reactions;
- medical interactions;
- alterations in results in lab tests;
- precautions related to carcinogenic, mutagenic, theratogenic
- and fertility effects;
- dose and tract of administration;

- manifestations and handling of overdose or accidental

- ingestion;

- presentation or presentations;

- storage recommendations;

- protection notices;

- name and domicile of the laboratory; and

- number of registration of the product before the Ministry of Health (marketing authorisation).

Article 42 also mentions that in case some of the abovementioned data does not exist, this circumstance must be expressly mentioned.

It is also important to notice that these advertisements do not require permission, but only a notice to COFEPRIS, unless it refers to the prescription of the product.

3.2 IS IT A REQUIREMENT THAT THERE BE DATA FROM ANY OR A PARTICULAR NUMBER OF "HEAD TO HEAD" CLINICAL TRIALS BEFORE COMPARATIVE CLAIMS ARE MADE?

Whereas this is not expressly indicated in the Law or Regulations, upon reviewing the truthfulness of the claims contained in the advertisement, the COFEPRIS could require the company to provide information on the specific clinical trials or analysis performed in order to make the corresponding assertions.

3.3 WHAT RULES GOVERN COMPARATOR ADVERTISEMENTS? IS IT POSSIBLE TO USE ANOTHER COMPANY'S BRAND NAME AS PART OF THAT COMPARISON? WOULD IT BE POSSIBLE TO REFER TO A COMPETITOR'S PRODUCT WHICH HAD NOT YET BEEN AUTHORISED IN MEXICO?

Comparative advertisements are contemplated in both the Industrial Property Law and the Federal Law for the Protection of Consumers. Both of these Laws contain provisions related to claims that can be filed against the party responsible for the comparative advertisement.

According to Article 213 of the Industrial Property Law it is possible to use another company's brand name in advertising as long as the comparison is intended to inform the public, and it is not tendentious, false or exaggerated. Article 32 of the Federal Law for the Protection of Consumers also penalises unfair practices in comparative advertisements including unfair use of trademarks, contemplating the possibility of filing a complaint before the Consumer's Bureau for such activities.

As to the referral to a competitor's product that has not been authorised, there are no specific provisions on this regard, and thus our recommendation would also be to submit the ad before COFEPRIS for an opinion or an authorisation, in order for this authority to determine whether the ad implies a risk to public health.

3.4 WHAT RULES GOVERN THE DISTRIBUTION OF SCIENTIFIC PAPERS AND/OR PROCEEDINGS OF CONGRESSES TO DOCTORS?

Article 40 of the Regulations indicates that the circulation of medical or scientific information is regulated if it is made with the purposes of advertisement.

If this distribution is made or could be understood as having advertising purposes, a notice should be sent to COFEPRIS in accordance with article 42 which is addressed in question 3.1 above.

3.5 ARE "TEASER" ADVERTISEMENTS PERMITTED, WHICH ALERT A READER TO THE FACT THAT INFORMATION ON SOMETHING NEW WILL FOLLOW (WITHOUT SPECIFYING THE NATURE OF WHAT WILL FOLLOW)?

There is no specific provision authorising or prohibiting teaser advertisements about medicines, even though the COFEPRIS has been known to make requirements before issuing authorisations on the same when they refer to products that require a medical prescription for their sale and are intended for the general public.

The criterion used by COFEPRIS on these cases is to apply the provisions on general advertising to the teaser ads.

In our opinion, and on a general basis, teaser advertisements can be used, as long as the provisions of the law regarding authorizations or notices are complied with.

4 GIFTS AND FINANCIAL INCENTIVES

4.1 IT IS POSSIBLE TO PROVIDE HEALTH PROFESSIONALS WITH SAMPLES OF PRODUCTS? IF SO, WHAT RESTRICTIONS APPLY?

Providing samples of products is a common practice in Mexico, which is expressly authorised by Article 49 of the Regulations of the Health Law regarding Advertising, mentioning that samples do not require authorisation as advertising as long as they comply with the provisions for the product, and

contain a lesser number of units.

Sampling of products that require a prescription is not allowed when directed to the general public.

The restrictions for samples are the same applicable to the original product, and samples of medications cannot be given out to minors.

We always recommend our clients to have a strict control on product samples since there have been some cases of re-sales of said samples.

4.2 IS IT POSSIBLE TO GIVE GIFTS OR DONATIONS OF MONEY TO MEDICAL PRACTITIONERS? IF SO, WHAT RESTRICTIONS APPLY?

The provisions in Mexican Health Law and its Regulations are silent on this point. Following the principle of law establishing that every activity that is not expressly forbidden is permitted, it is possible to give gifts or donations of money to medical practitioners subject to the general provisions of the Civil Law.

Furthermore Article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids these officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked regulated or supervised by the Government Official.

Doctors working for the Mexican Institute of Social Security (IMSS) or the Institute of Social Security and Services for Government Workers (ISSSTE) are considered as Government Officers, and are not allowed to receive gifts or donations from pharmaceutical companies.

Finally, the Code of Ethics of the National Chamber of the Pharmaceutical Industry indicates, in general terms, that companies must act responsibly regarding sponsorships and donations.

If this practice should be used by pharmaceutical companies in our country, several issues regarding tax provisions would have to be considered in order to justify the donation or gift.

4.3 IS IT POSSIBLE TO GIVE GIFTS OR DONATIONS OF MONEY TO INSTITUTIONS SUCH AS HOSPITALS? IS IT POSSIBLE TO DONATE EQUIPMENT, OR TO FUND THE COST OF MEDICAL OR TECHNICAL SERVICES (SUCH AS THE COST OF A NURSE, OR THE COST OF LABORATORY ANALYSES)? IF SO, WHAT RESTRICTIONS WOULD APPLY?

There are also no specific restrictions in Mexican Law regarding donations or gifts to institutions and the donations of equipment by pharmaceutical companies is common practice. Nevertheless, as mentioned in the previous question, the Code of Ethics points out that these activities must be done responsibly, and there are tax issues that must be considered before making these types of donations or gifts.

4.4 IS IT POSSIBLE TO PROVIDE MEDICAL OR EDUCATIONAL GOODS AND SERVICES TO DOCTORS THAT COULD LEAD TO CHANGES IN PRESCRIBING PATTERNS? FOR EXAMPLE, WOULD THERE BE ANY OBJECTION TO THE PROVISION OF SUCH GOODS OR SERVICES IF THEY COULD LEAD EITHER TO THE EXPANSION OF THE MARKET FOR OR AN INCREASED MARKET SHARE FOR THE PRODUCTS OF THE PROVIDER OF THE GOODS OR SERVICES?

This is another example of a non-regulated specific activity, for which the general provisions have to be taken into consideration, such as the Code of Ethics for the Pharmaceutical Industry. An important issue to take into consideration concerning prescribing patterns are provisions stating that doctors have to indicate the active ingredients of medicines for prescriptions, in order for patients to be able to acquire a generic product when applicable.

4.5 DO THE RULES ON ADVERTISING AND INDUCEMENTS PERMIT THE OFFER OF A VOLUME RELATED DISCOUNT TO INSTITUTIONS PURCHASING MEDICINAL PRODUCTS? IF SO, WHAT TYPES OF ARRANGEMENTS ARE PERMITTED?

There are no specific rules prohibiting this sort of practice and thus the offering of volume related discounts is permitted, and commonly practiced on public tenders and on sales to the public sector.

Even though discounts could have implications derived from our anti-trust Law,

several conditions such as relevant market power, would have to coincide before a violation to the provisions of this law takes place.

4.6 IS IT POSSIBLE TO OFFER TO PROVIDE, OR TO PAY FOR, ADDITIONAL MEDICAL OR TECHNICAL SERVICES OR EQUIPMENT WHERE THIS IS CONTINGENT ON THE PURCHASE OF MEDICINAL PRODUCTS? IF SO, WHAT CONDITIONS WOULD NEED TO BE OBSERVED?

The chapter of the Regulations of the Health Law Regarding Advertising related to advertisement of equipment or medical services is not clear on this point, but there is also a specific provision in said Regulations, which prohibits the promotion of the consumption of a medication offering any other product or service in exchange.

Evidently, this provision is directed to the promotion of consumption by patients, but it could be considered as applicable by COFEPRIS, and thus our recommendation for these cases is to clearly state in the offer that consumption is not being encouraged.

4.7 IS IT POSSIBLE TO OFFER A REFUND SCHEME IF THE PRODUCT DOES NOT WORK? IF SO, WHAT CONDITIONS WOULD NEED TO BE OBSERVED? DOES IT MAKE A DIFFERENCE WHETHER THE PRODUCT IS A PRESCRIPTION-ONLY MEDICINE, OR AN OVER-THE-COUNTER MEDICINE?

This is another situation that is not specifically contemplated by Mexican Law, and thus the possibility to offer a refund would be open, even though this is not a common practice in our country.

There would not be a difference on refund schemes related to prescription-only or over-the-counter medicines.

4.8 MAY PHARMACEUTICAL COMPANIES SPONSOR CONTINUING MEDICAL EDUCATION? IF SO, WHAT RULES APPLY?

As with the previous questions this is an unregulated area in Mexico, but the

Code of Ethics for the Pharmaceutical Industry indicates that these activities must be done responsibly. The response provided in question 4.2 above should be taken into consideration if this activity is to be undertaken.

5 HOSPITALITY AND RELATED PAYMENTS

5.1 WHAT RULES GOVERN THE OFFERING OF HOSPITALITY TO HEALTH PROFESSIONALS? DOES IT MAKE A DIFFERENCE IF THE HOSPITALITY OFFERED TO THOSE HEALTH PROFESSIONALS WILL TAKE PLACE IN ANOTHER COUNTRY?

There are no specific rules applying to this issue, and it is common for pharmaceutical companies to perform these activities for Mexican doctors, both in our country and abroad, but, as we have mentioned the Code of Ethics has some provisions that could be interpreted to apply to this activity. Since agreements are not usually entered regarding the offering of hospitality, our recommendation for pharmaceutical companies is to produce letters of intent in order to justify the expenses before tax authorities.

5.2 IS IT POSSIBLE TO PAY FOR A DOCTOR IN CONNECTION WITH ATTENDING A SCIENTIFIC MEETING? IF SO, WHAT MAY BE PAID FOR? IS IT POSSIBLE TO PAY FOR HIS EXPENSES (TRAVEL, ACCOMMODATION, ENROLMENT FEES)? IS IT POSSIBLE TO PAY HIM FOR HIS TIME?

Paying a doctor for both expenses and for the time invested in scientific meetings is not restricted by Mexican Law and, thus, has been commonly done by pharmaceutical companies in our country. The Code of Ethics of the National Chamber for the Pharmaceutical industry has general provisions regarding the obligation of companies to act responsibly in donations and sponsorships under which these activities could fall.

5.3 TO WHAT EXTENT WILL A PHARMACEUTICAL COMPANY BE HELD RESPONSIBLE BY THE REGULATORY AUTHORITIES FOR THE CONTENTS OF AND THE HOSPITALITY ARRANGEMENTS FOR SCIENTIFIC MEETINGS, EITHER MEETINGS DIRECTLY SPONSORED OR ORGANISED BY THE COMPANY OR INDEPENDENT MEETINGS IN RESPECT OF WHICH A PHARMACEUTICAL COMPANY MAY PROVIDE SPONSORSHIP TO INDIVIDUAL DOCTORS TO ATTEND?

As mentioned in the previous question, since there are no specific restrictions for these activities, a pharmaceutical company would not be liable in principle for the same.

5.4 IS IT POSSIBLE TO PAY DOCTORS TO PROVIDE EXPERT SERVICES (E.G. PARTICIPATING IN FOCUS GROUPS)? IF SO, WHAT RESTRICTIONS APPLY?

As in question 5.2 above, there are no restrictions towards paying doctors for providing expert services and, thus, it has been common practice especially in favour of doctors in charge of conferences at pharmaceutical forums.

5.5 IS IT POSSIBLE TO PAY DOCTORS TO TAKE PART IN POST MARKETING SURVEILLANCE STUDIES? WHAT RULES GOVERN SUCH STUDIES?

There are no specific provisions regulating compensations provided to doctors for their participation in marketing studies, but the general provisions in the Code of Ethics must be taken into consideration.

5.6 IS IT POSSIBLE TO PAY DOCTORS TO TAKE PART IN MARKET RESEARCH INVOLVING PROMOTIONAL MATERIALS?

This is a similar situation as that of the previous question, in which no provision refers to the activity in specific terms.

6 ADVERTISING TO THE GENERAL PUBLIC

6.1 IS IT POSSIBLE TO ADVERTISE NON-PRESCRIPTION MEDICINES TO THE GENERAL PUBLIC? IF SO, WHAT RESTRICTIONS APPLY?

In Mexico, it is possible to advertise non-prescription medicines to the general public, subject to previous authorisation by COFEPRIS. However, according to Article 43 of the Regulation of the Health Law regarding Advertisement, any visual or audio advertisement must bear the following message: *“Consult your physician”*.

Also, said advertisements should mention the correspondent precautions, when the use of the medicine represents any danger in the event of an existing pathology.

Furthermore, Article 44 of the Regulations of the Health Law regarding Advertisement establishes certain restrictions for medicine advertisements.

6.2 IS IT POSSIBLE TO ADVERTISE PRESCRIPTION-ONLY MEDICINES TO THE GENERAL PUBLIC? IF SO, WHAT RESTRICTIONS APPLY?

In accordance to Article 310 of the General Health Law, only nonprescription medicines can be advertised to the general public, and the objective of said advertisements is to inform the public about the characteristics of the products, its therapeutic properties and the form of use.

6.3 IF IT IS NOT POSSIBLE TO ADVERTISE PRESCRIPTION ONLY MEDICINES TO THE GENERAL PUBLIC, ARE DISEASE AWARENESS CAMPAIGNS PERMITTED, ENCOURAGING THOSE WITH A PARTICULAR MEDICAL CONDITION TO CONSULT THEIR DOCTOR, BUT MENTIONING NO MEDICINES? WHAT RESTRICTIONS APPLY?

In Mexico, there are no restrictions prohibiting awareness campaigns, and the Ministry of Health usually coordinates them, sometimes with the participation of a pharmaceutical company.

Since most campaigns are related to specific products, even if those products are not being mentioned, COFEPRIS requires companies to request an authorisation before launching a campaign of this nature.

The restrictions applicable to disease awareness campaigns are the same as the general restrictions on advertising and, therefore, it is important to consult the

Health Authority before launching any kind of awareness campaign.

6.4 IS IT POSSIBLE TO ISSUE PRESS RELEASES CONCERNING PRESCRIPTION ONLY MEDICINES TO NON-SCIENTIFIC JOURNALS? IF

SO, WHAT CONDITIONS APPLY?

The issuance of press releases concerning prescription medicines is possible in Mexico; however, there is a high risk for COFEPRIS to consider them as advertisement, especially when they are contained in non-scientific journals. In view of this, a pharmaceutical company would have only a minor chance of obtaining an authorisation for a press release of this kind, since the same restrictions that apply to general advertising would be applicable.

6.5 WHAT RESTRICTIONS APPLY TO DESCRIBING PRODUCTS AND RESEARCH INITIATIVES AS BACKGROUND INFORMATION IN CORPORATE BROCHURES/ANNUAL REPORTS?

Whereas there are no specific provisions addressing corporate brochures and Annual Reports, the information contained therein could fall in one of the definitions of publicity contained in the Regulations.

Our law firm usually recommends a submission to COFEPRIS advising on the contents of the brochures/reports before their distribution.

6.6 WHAT, IF ANY, RULES APPLY TO MEETINGS WITH AND FUNDING OF PATIENT SUPPORT GROUPS, INCLUDING ANY TRANSPARENCY REQUIREMENT AS REGARDS THE RECORDING OF DONATIONS AND OTHER SUPPORT IN CORPORATE REPORTS?

As we have mentioned, there's a general provision in the Code of Ethics calling for responsibility in donations. There are no specific rules limiting meetings with patient support groups.

7 THE INTERNET

7.1 HOW IS INTERNET ADVERTISING REGULATED? WHAT RULES APPLY? HOW SUCCESSFULLY HAS THIS BEEN CONTROLLED?

In accordance to Article 2 of the Regulations of the Health Law regarding Advertisement, electronic advertisement is considered within the means of advertising regulated by said provisions. However, there are no specific rules for Internet advertisement, since the same rules apply as for other forms of advertising, i.e. television, radio, printed advertisement and other forms of technological media. In this regard, Health Authorities monitor Internet advertisements on a smaller level than the monitoring of television or radio advertisements and, thus, there are not many cases of actions by COFEPRIS related to Internet ads. Nevertheless, in the event any of the provisions of the Health Law or the Regulations are breached through Internet advertising, the responsible company would be subject to the corresponding penalties.

7.2 WHAT, IF ANY, LEVEL OF WEBSITE SECURITY IS REQUIRED TO ENSURE THAT MEMBERS OF THE GENERAL PUBLIC DO NOT HAVE ACCESS TO SITES INTENDED FOR HEALTH PROFESSIONALS?

COFEPRIS requires web pages sponsored by or belonging to pharmaceutical companies to have security means with regards to prescription-only medicines, and even though there are no specific rules describing said levels of security, the common practice has been to include a requirement for a user's name and a password (which can only be granted to credited health professionals) before granting access to information on prescription-only medicines. Other forms of website security would have to be authorised by COFEPRIS before their enactment.

7.3 WHAT RULES APPLY TO THE CONTENT OF INDEPENDENT WEBSITES THAT MAY BE ACCESSED BY LINK FROM A COMPANY SPONSORED SITE? WHAT RULES APPLY TO THE REVERSE LINKING OF INDEPENDENT WEBSITES TO A COMPANY'S WEBSITE? WILL THE COMPANY BE HELD RESPONSIBLE FOR THE CONTENT OF THE INDEPENDENT SITE IN EITHER CASE?

As mentioned in the response to question 7.1 above there are no specific rules for internet advertising. Within its monitoring activities, COFEPRIS could take action in case links to independent websites lead to access, advertisement or information on prescription-only medicines, and could initiate an administrative proceeding against the company providing the links.

7.4 WHAT INFORMATION MAY A PHARMACEUTICAL COMPANY PLACE ON ITS WEBSITE THAT MAY BE ACCESSED BY MEMBERS OF THE PUBLIC?

All company-related information can be placed on a website, but the information that can be provided concerning prescription-only medicines is usually monitored by COFEPRIS.

8 GENERAL - MEDICAL DEVICES

8.1 WHAT LAWS AND CODES OF PRACTICE GOVERN THE ADVERTISING OF MEDICAL DEVICES IN MEXICO?

In Mexico, the same regulations governing general advertisements for the health sector include provisions on the advertisement of medical devices, these being specifically the General Health Law, and Articles 52-56 of the Regulations of the Health Law regarding Advertisement.

COFEPRIS has specific authority to authorise ads related to medical devices, and to determine whether those ads can be directed to the general public or only to health professionals.

8.2 ARE THERE ANY RESTRICTIONS ON PAYMENTS OR HOSPITALITY OFFERED TO DOCTORS IN CONNECTION WITH THE PROMOTION OF A MEDICAL DEVICE?

In Mexico there are no specific restrictions or rules with regards to payments or hospitality offered to doctors in connection with the promotion of a medical device. Therefore, hospitality payments to doctors have no limitations and are subject to the decision of pharmaceutical companies and doctors. This is another common practice in our country and the tax implications of those payments must also be analysed on a case by case basis.

9 DEVELOPMENTS IN PHARMACEUTICAL

ADVERTISING

9.1 WHAT HAVE BEEN THE SIGNIFICANT DEVELOPMENTS IN RELATION TO THE RULES RELATING TO PHARMACEUTICAL ADVERTISING IN THE LAST YEAR?

Whereas there were no modifications to the Health Law regulations for advertising, COFEPRIS has continued its efforts in actions against “miracle” products, sanctioning and removing advertising, and cancelling authorisations for certain products. COFEPRIS has been periodically issuing reports on actions against this type of products.

9.2 ARE ANY SIGNIFICANT DEVELOPMENTS IN THE FIELD OF PHARMACEUTICAL ADVERTISING EXPECTED IN THE NEXT YEAR?

Certain civil actions to claim damages deriving from unfair competition advertising will be attempted.

9.3 ARE THERE ANY GENERAL PRACTICE OR ENFORCEMENT TRENDS THAT HAVE BECOME APPARENT IN THIS JURISDICTION OVER THE LAST YEAR OR SO?

In January '08 there was a reform to the Health Law regulations impacting both R&D and Generics companies on several issues, including renovation of marketing authorisations, the elimination of the distinction between “generic” and “interchangeable generic” medicines, and the shortening of timeframes to obtain marketing authorisations.

This reform also included a modification to requirements for generic medicine applications affecting DPE rights for holders of reference or innovator authorisations, which has been challenged through court actions by R&D companies.

9.4 HAS YOUR NATIONAL CODE BEEN AMENDED IN ORDER TO IMPLEMENT THE CURRENT VERSION OF THE EFPIA CODE OF

OCTOBER 2007?

There has been no reform to implement the EFPIA Code, but we are aware that some R&D companies have been adopting it and that it has been discussed in the AMIIF (Mexican Association of R&D Pharma Companies).