LIBERALIZATION OF FORMER RESTRICTIONS ON FOREIGN DRUG MANUFACTURERS TO HOLD TITLE OVER SANITARY REGISTRATIONS REQUIRED TO MARKET DRUGS IN MEXICO

Little has been said in regard to the regulatory reforms that were made to the Health Supplies Regulations (*Reglamento de Insumos para la Salud)* (HSR) that were published on August 5, 2008, notwithstanding the significance which said reform had as regards the manner in which access to the Mexican market of drugs manufactured abroad was controlled, as well as the manner in which business in the drug market is done in Mexico.

More than 17 months after the amendments were published, these become relevant if one takes into consideration that as of August 2010 and onwards foreign manufacturers of any type of drugs may directly obtain the sanitary registration required to market them in Mexico.

ANTECEDENTS OF THE REGULATORY REFORM

First it is necessary to say that the prior requirements required any foreign drug company wishing to market its drugs in Mexico to register the drug with the Mexican health authorities. However, in order to obtain this registration, the company had to obtain a "sanitary license for an establishment engaging in the processing and manufacture of drugs", and to do so, it had to have a manufacturing plant or laboratory in Mexico that made the drugs or biological products for human use or consumption. In other words, foreign drug companies were required to have a production plant in Mexico in order to be able to register a drug manufactured abroad. This plant could be either directly established by the foreign drug company or be a Mexican company associated with the foreign drug company by means of joint venture or distribution agreements.

The situation described above lasted for many years, despite the various international treaties signed by Mexico during the time it opened up its economy to the global markets, since all matters pertaining to health issues were left out of these treaties, as these were considered to be a fundamental issue of Mexican public order dealing as they do with the protection of the general population from any kind of sanitary risk or harm, including the risks associated with the use of pharmaceutical drugs. Moreover, article XX of the GATT[1], to which Mexico and most of all other countries adhered, established that all international or regional actions intended to prevent the impairment of measures to protect human life and health were not to be considered as non-tariff restrictions.

With this same precautionary orientation, the World Health Organization (WHO) underscored in a study published at the meetings held in Geneva in 2003, that the use of ineffective, unsafe, poor quality, harmful medicines could lead to therapeutic failure, exacerbation of disease, drug resistance and sometimes to the patient's death**,** and could also have the effect of undermining confidence in health systems, health professionals and the pharmaceutical product manufacturers and distributors, and therefore, governments had to have

[1] The General Agreement on Tariffs and Trade, which was later replaced by the World Trade Organization, founded in 1995.

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strong and efficient regulatory authorities charged with overseeing the manufacture, marketing and use of medicinal drugs, in order to protect and promote public health**.**

Notwithstanding the foregoing, some countries questioned Mexico's conditioning the marketing in the country of drugs of foreign manufacture to having a production plant in Mexico, by arguing that the principles of national treatment and the elimination of non-tariff barriers to which Mexico had adhered under various international treaties demanded the elimination of this requirement.

The truth of the matter is that the requirement of having a plant in Mexico was applied equally to both Mexican and foreign nationals, therefore invalidating the argument of unequal treatment, while the requirement was fully justified under the terms of article XX of the GATT and was consistent with WHO's position in regard to the control of sanitary risks relating to the manufacture, trade and massive use of medicinal drugs.

In fact the Mexican plant requirement was intended to be used by the Mexican health authorities as a pharmacovigilance tool, since when a foreign drug manufacturer opened a subsidiary in Mexico, Mexican health authorities could have access to a specific site in the country where they could supervise whether the drug manufacturing practices for a given product were homologous to Mexican manufacturing practices, whether the drugs of foreign origin where properly stored and, when the plant was owned by a Mexican manufacturer, this manufacturer had to have experience in the production of drugs similar to those intended to be imported, who would then ensure that the production process of the imported drug was similar to the one used in the country, and that the drugs produced abroad were stored under conditions that assured their quality, safety and efficacy.

Nevertheless, these requirements were also subject to criticism because in practice they resulted in foreign manufacturers contacting local ones who many times engaged in the production of drugs different from those to be imported, and were used only for the latter to apply for sanitary registration of the drugs and to act as the foreign manufacturer's first instance distributor in Mexico, thus circumventing the purposes of the requirement. In other words, this led to just a "formal compliance" with legal provisions and not to the achievement of sanitary control as intended by the regulatory law on the matter.

It would seem that all of this is only history and that as a result of the reform, the discussion becomes one of purely academic interest, but in truth it is necessary to examine this issue in detail in order to understand how the amendment of just two provisions of the HSR (articles 168 and 170) in August of 2008, altered a regulatory body of law whose mainstay was the requirement of having a production plant in Mexico.

The fact is that the HSR had already suffered a series of amendments, such as those published on January 2, 2008, and only if we analyze these as a whole can we understand what was achieved, what was given up, and how can the new regulatory framework work in controlling the sanitary risks involved in the entry of foreign drugs without having to comply with the Mexican production plant requirement.

When a new set of regulations are enacted or existing ones are amended, there is no requirement for them to be preceded by a statement of purpose providing a rationale for the objectives, scope and consequences of such regulatory reforms, and in this regard the following are the author's own considerations as regards the matter under discussion.

We are not certain as to which were the reasons for this reform. Was it meant to counter drug shortages in the country? Were there, in fact, shortages? or else – Did the Mexican government seek to establish a procurement system of lower-priced drugs intended to compete with those already sold in Mexico? Given the laws of supply and demand, it would seem that with a wider range of products being offered, the prices of comparable drugs already sold in the country would tend to fall.

We therefore think that this reform requires a more in-depth analysis in order to assess whether the HSR, as now amended, are internally consistent and if they can be applied with efficacy, or else whether they lend themselves to various interpretations and as a result a foreign manufacturer may become trapped in protracted processing in order to obtain a sanitary registration or worse, that drugs of dubious quality will be imported into the country.

ELIMINATION OF THE MANUFACTURING PLANT REQUIREMENT

We again would like to mention that this issue has not been discussed at any length, and those who have addressed it seem to be of the opinion that it is no longer required to have a manufacturing plant in order to obtain the sanitary registration of a drug. However, it seems that there are no solid grounds to make this affirmation, because the new provisions clearly establish that registration may only be obtained by such Mexican or foreign legal entities or individuals who have a drug manufacturing plant or laboratory in Mexico or else by **"**foreign manufacturers that have a license, certificate or document evidencing that they have an authorization issued by their country of origin to manufacture drugs. In other words, and in either case, the requirement subsists of having a production plant, either in Mexico or abroad.[2]

Furthermore, some of the reasons for the reform that were given to the public by Mexican public officials at international forums were the following:

- That it was passed in order to allow laboratories of other countries to more efficiently produce and market antiretroviral and other kinds of drugs in Mexico, mainly to combat diseases that have become serious public health problems, as in the case of AIDS.

- That it was intended as a mechanism to guarantee more competitive prices, that is to say, lower drug prices. Particularly for those consumers who do not have access to public health services. That is to say, to make drugs available for this segment of the population.

[2] Article 168 of the Health Suppliers Regulations. In order to become the holder of a sanitary registration of a drug it is necessary to be in the possession of a sanitary license for a manufacturing plant or laboratory of drugs or biological products for human consumption. In the case of foreign manufacturers, they must have a license, certificate or document evidencing that the company has a permit to manufacture drugs, issued by the proper authority of the country of origin.

They also stated that the measures would be applied gradually in order to avoid negative effects on the Mexican drug industry, but that some of them would be taken immediately, as in the case of antiretroviral drugs, for the reasons mentioned above. They also argued that an increase in the supply of drugs would foster their diversification.

SCOPE OF THE REFORM

Under the regulations as now amended, foreign drug manufacturers will no longer be required to enter into joint venture or distribution agreements with Mexican manufacturers to apply for and obtain the sanitary registration of their drugs, provided they have a legal representative that is domiciled in Mexico.[3] Therefore, the reform has the following implications:

a) Foreign drug manufacturers that had not entered into the Mexican market for fear of having a Mexican company apply for and obtain the sanitary registration of their drugs on their behalf and later refuse to transfer it to them, will have the opportunity of directly doing so. Some of them had refused to participate altogether in the market under the former scheme because they argued that they were placed in a vulnerable position by such intermediation, for example as regards contract prices.

b) Many foreign manufacturers who are already active in the Mexican pharmaceutical sector will have the opportunity of requiring that their business partners or distributors that have a production plant in Mexico deliver the sanitary registrations obtained under the former scheme by means of an assignment agreement approved by the Federal Commission for the Protection of Sanitary Risks (Spanish acronym: COFEPRIS).

c) For the Mexican companies who are already partners of foreign drug manufacturers, the reform provides them with an opportunity to guide and convince their foreign partners to implement actions to ensure greater control and oversight over the drugs manufactured abroad that have to comply with a multiplicity of requirements to ensure proper monitoring of their quality, safety and efficacy.

Although several groups of drugs are already being introduced and marketed in the country under this new scheme and the manner in which operations in this market are being conducted is already being restructured, the business opportunities for drugs of all kinds became a concrete possibility in August of 2010.[4]

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[3] Nevertheless, in order to market in Mexico drugs that are manufactured abroad, they will have to: (1) have a subsidiary who has been granted a sanitary license to store, distribute and/or sell and market them, (ii) enter into an agreement for the storage and distribution of the drugs with a Mexican company that does not belong to the corporate group to which the foreign manufacturer belongs, who has the required sanitary license, or else (iii) sell the drugs directly to the business concerns that make them available to the final consumers.

[4] The dates on which the reforms were to become effective by type of drugs as published in the Official Gazette of the Federation on August 5, 2008 are the ones listed below:

a) On the day following publication as regards compliance therewith, for retroviral drugs;
b) Six months after publication for vitamins, vaccines, serums, blood derivatives, antitoxins, hormonal drugs of biological origin, homeopathic medicines and herbal medicines.
c) Twelve months after publication for biotechnological and biological medicines not specified in the preceding paragraph.

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CHALLENGES FOR MANUFACTURERS, OTHER AGENTS AND THE AUTHORITIES

For manufacturers and other agents participating in this sector, the challenge is to acquire a precise understanding of the legal framework applicable to all the stages implicit in the manufacturing and/or marketing of drugs, taking into account the multidisciplinary knowledge required to do so. Should potential foreign market participants fail in acquiring this understanding, they could have a mistaken conception of the manner in which the pharmaceutical drug business in Mexico should be conducted.

For example, the processing for the granting and renewal of sanitary authorizations and registrations usually takes a long time, and if the integration of the relevant file is not properly done from the very beginning, that is to say, if both the general and specific requirements are not met, the relevant applications may be subject by the authorities to the fulfillment of specific conditions or refusals, resulting in costly delays that will place the company at a disadvantage with respect to its competitors.

Moreover, with the amendments made to article 376 of the General Health Law (GHL) published on February 24, 2005: (i) the sanitary registrations granted for pharmaceutical drugs are now only effective for 5 years, although the term may be extended for like terms upon request by the interested party; (ii) the registrations that had been granted for an open term before the above mentioned date, were by reason of such amendments, required to be submitted for review by the sanitary authorities in order to obtain a five-year renewal, and the term to do so expired on February 24, 2010, and (iii) registration or renewal will only be granted if the Ministry of Health is able to verify the safety and therapeutic efficacy of the drugs by checking that they comply with all requirements, tests and all conditions that are set forth in legal provisions of general applicability. Currently the authorities have a list of more than 15,000 drugs pending registration renewal. This state of affairs, together with the elimination of the Mexican plant requirement, has imposed upon the authorities a significantly greater workload which has become an obstacle in complying with the terms provided by law to resolve on all applications that have been and are being submitted.

Although one of the intended outcomes of the reform is to increase competition between patented and generic drugs, the renewal of the drugs whose sanitary registrations were granted before the reform became effective and are about to expire will be a significant challenge for Mexican sanitary authorities, since in some cases the title over the trademark is held by a foreign person even though the person who holds formal title to its sanitary registration is a Mexican entity who entered into joint venture or distribution agreements with the drug's manufacturer and who could refuse to assign title over the sanitary rights registration to the drug's foreign manufacturer under an agreement approved by COFEPRIS.

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d) Eighteen months after publication for medicines containing narcotics or psychotropic drugs and non-prescription drugs in accordance with the provisions of sections I, II, III, V and VI of article 226 of the General Health Law, and

e) Twenty four months after publication for all remaining medicines as specified in section IV of the General Health Law.

It should be kept in mind that in order to renew a sanitary registration the authorities require information on the products that is only available to, or can only be supplied by, the manufacturer, such as providing evidence that the manufacturer holds title over the patent or has been licensed to use it. Now, should there be any conflict between the foreign drug manufacturer that also owns title over the trademark used to market a drug, and the Mexican laboratory or manufacturing plant that is the formal title holder of the sanitary registration which is about to expire, but who does not have all the information required to renew the registration, the possibility arises for the foreign manufacturer to refuse to provide such information thus causing the sanitary registration to expire, finally allowing the foreign manufacturer to apply for a new registration over which it will hold direct title and market the drug under its trademark, which had already been positioned in the market by its former Mexican business partner.

There is one more risk that can be faced by both of the parties in a conflict such as the one we have been discussing, and that is that all parties applying for new sanitary registrations and those just wishing to renew them may be asked to comply with new requirements heretofore not contemplated by them, since the abrogation of the supplement to the 8th edition of the Mexican pharmacopoeia, which contained the provisions governing specific requirements that had to be met by those applying for sanitary registration, has left a regulatory vacuum.

Finally, compliance with new general requirements could give rise to the worst-case scenario for both manufacturers and authorities, leading up in the best of circumstances to a series of never-ending discussions on the manner in which they must be complied.

LOGISTICS TO BE FOLLOWED BY A FOREIGN DRUG MANUFACTURER IN APPLYING FOR AND OBTAINING A SANITARY REGISTRATION

I. Submission of Sanitary Registration Application

In interpreting the provisions of the HSR as a whole, it can be seen that the **applicant must be the "manufacturer of the product",** and this must be evidenced by submitting the license, certificate or document that provides proof that the applicant company has the **permit to manufacture the relevant drugs, issued by the proper authority of the country of origin.**

Nevertheless, in the event the drug to be registered is an allopathic drug, the manufacturer must also provide proof that it holds title to the patent still in effect over the active ingredient or substance or else provide proof that it has the relevant license, and both the title over the patent and the license need to have been registered with the Mexican Institute of Industrial Property.

Regardless of the foregoing, application may also be filed for sanitary registration for a generic of an allopathic drug that is still protected by a patent, either by the title holder itself or by another person; this in order to conduct the studies, tests and production trials required, within

3 years before the patent expires**.** In this event, the sanitary registration for the generic will granted only after the relevant patent has expired.[5]

With respect to the difficulty of determining who is the actual manufacturer of a foreign drug and as a consequence to whom must the sanitary registration be granted, it is pertinent to comment that both of the title-holding schemes described below are common in the pharmaceutical industry**:**

- Scheme 1: Title over the sanitary registrations and patents over all drugs marketed by the companies belonging to an international pharmaceutical group is usually held by the holding company of the group. The holding company has facilities in countries around the world which manufacture the same drug at its different stages.

- Scheme 2: The party that applied for sanitary registration of a foreign drug makes use of a company (not part of its group) that manufactures the drug under a contract manufacturing agreement (maquila) that is located in a country different from that of applicant.

If we take into consideration the documentary requirements to evidence that a party is the manufacturer of a foreign drug, and despite the fact that the authorities will have difficulty in supervising the various stages in the manufacture of the relevant health product, it is our belief that Mexican sanitary authorities may tend to recognize the party who holds title over the rights to market the drug as the manufacturer, and therefore, as the person legally entitled to apply for its sanitary registration.

Nevertheless, providing proof that the applicant is the manufacturer is not the only requirement that has to be met in applying for sanitary registration of a foreign drug, also a series of documents have to be submitted depending on the drug involved.[6,6]

Consequently, we believe that an applicant will have not only to provide proof that GMP are followed in applicant's country of origin, but also that all its affiliates or else, all contract manufacturers that are involved in the manufacturing process of the health product in question have all official certifications and operating facilities required to manufacture the drug under conditions that ensure its quality, safety and efficacy in accordance with the sanitary regulations of all the countries where any of its manufacturing stages take place.

[5] Art. 167-Bis of the HSR. In this regard it should be pointed out that this procedure may result in a series of legal or administrative disputes relating to the use of information that is protected, taking into consideration the Mexican Industrial Property Law (IPL) and without doubt because a regulatory provision is being afforded greater scope than that of the law that is to be enabled by it, even if the IPL is not taken into account.

[6] In the case of allopathic drugs: certificate releasing the drug for sale and marketing issued by the sanitary authority of the country of origin; (ii) the GMP (good manufacturing practice) certificate issued by the proper authority of the country of origin; (iii) document designating a legal representative domiciled in the United Mexican States, and (iv) the identification of the drug's origin. We should mention that GMP certificates are only effective for 30 months, and therefore these documents will have to be submitted to the authorities repeatedly in order to avoid receiving precautionary notices.

It is worth mentioning here that that GMP certificates are usually issued for effective terms of 30 months, thus implying the need to submit these documents to the authority from time to time as required to avoid cautionary compliance notices from being issued.

It is also believed that the Mexican sanitary authorities will reserve to themselves the right to inspect not only the applicant's manufacturing facilities or laboratories, but also those of all the affiliates or contract manufacturers involved in the manufacturing process, in order to have effective control over the sanitary risks involved at all stages of the manufacturing process.

II. Submission of the scientific and technical information that provides proof of the quality, safety and efficacy of the foreign drug

Applicants will also have to submit, in addition to all the documents that evidence manufacturing quality, all the scientific and technical information that provides proof of the drug's quality, safety and efficacy, meeting all of the same requirements imposed on a drug manufacturer that has a plant in Mexico. This information is classified in accordance with the type of drug involved.[7] Complying, with the foregoing will not preclude the obligation of having to meet the specific requirements that may be established for compliance with Mexican official standards by means of the new editions of the Mexican pharmacopoeia and its supplements.

III. Submission of a document certifying that the foreign manufacturer has a legal representative domiciled in Mexico

The party interested in obtaining sanitary registration for an allopathic drug must submit a copy of the power of attorney vested in its legal representative and evidence of the latter's domicile in Mexico together with the application for registration. In regard to this requirement, the HSR are silent on the role this representative will have, they do not clarify whether this person will only act in the name and on behalf of the foreign entity in obtaining the sanitary registration or else, whether the representative will play a more significant role. Therefore, this persons or entity could not be considered to be the person who will assume the sanitary liability for the drug, and therefore we believe that this situation is detrimental to the functions of pharmacovigilance which were exercised by the authorities through the person who assumed sanitary liability at a production plant located in Mexico before the reform being discussed was enacted.

Now, as regards this legal representative, the lack of clear provisions with respect to the obligations that are assumed is a matter of significant concern and should be a determinant factor in making the decision of accepting or not to act as such.

IV. Performing all required tests on the drugs

[7] For homeopathic remedies and herbal drugs: (i) certificate releasing the product for sale and marketing issued by the proper authority of the country of origin; (ii) the certificate of analysis issued by the manufacturer of the drug and on the manufacturer's stationary, endorsed by the sanitary authorities of the foreign and Mexican companies, and (iii) the letter of designation as manufacturer's representative, only when the laboratory that manufactures the product abroad is not an affiliate or parent company of the laboratory that is applying for registration.

In accordance with article 376 of the GHL, all tests specified in the rules of general applicability issued by the Ministry of Health must be conducted on a drug in order to be able to obtain its sanitary registration.

V. Submission of proof that the foreign drug complies with the applicable particular requirements

It is worth mentioning that the general nature of the obligations that have to met under the HSR may lead some applicants to argue that they have complied will all the requirements to obtain the sanitary registration for the type of drug involved, without actually guaranteeing that the drug complies with the quality, safety and efficacy characteristics required, since for this to be the case, the drug would need to comply also with the particular or specific requirements that were in the past contemplated in the 8th edition of the Mexican pharmacopoeia supplement that was abrogated, which used to list in detail all the information that had to be submitted to obtain the relevant registration. Since this document is no longer in force, applicants may take undue advantage of this situation and limit themselves to comply only with the formal requirements to obtain registration, a situation which may place the final consumers of the drug at risk. On the other hand, this situation could become a discretionary tool in the hands of the authority to deny registration.

We therefore consider that the issuance of a Mexican official standard providing for all the general and specific requirements that must be met to obtain sanitary registration of drugs is necessary, thus affording legal certainty, security and equal treatment to all applicants while at the same time fostering the application of uniform standards with respect to the quality, safety and efficacy of the drugs present in the market, and that this will inure to the benefit of the general health of the population. Furthermore, the issuance of a Mexican official standard dealing with good practice in the storage and distribution of drugs may reduce drug adverse-effect risks.

LOGISTICS TO BE FOLLOWED IN ORDER TO MARKET FOREIGN DRUGS AFTER SANITARY REGISTRATION HAS BEEN OBTAINED

I. Submission of notice of proper warehousing of foreign drug or application for sanitary registration for a warehouse for controlled foreign drugs

Applicant is required to provide proof that it has facilities that are suitable for the safe handling of drugs. In this regard, the observation to be made in the light of the regulatory reform is that the authorities may limit themselves to just documentary oversight not only during the process to obtain sanitary registration but also during the marketing stage, since the only requirement for this stage is that of giving notice of the start of operations, exception made of controlled substances, and this may imply significant risks for the health of the population as a whole. Consequently, the Mexican health authorities must be very careful in exercising the discretionary powers that they were granted in maintaining oversight of foreign drugs, for them not to betray the very reason for which they exist, which is to exercise effective control over sanitary risks.

II. Designation of a liable responsible person or entity that will be in charge of the quality, safety and efficacy of the drugs and for their proper sanitary control at the relevant facilities[8]

The provisions applicable to this matter in the HSR were not amended and therefore we would just like to comment that the executive power decided not to address the issue of foreign drug manufacturing processes in the reform that was enacted in 2008. We are therefore of the opinion that the purposes for which the figure of a liable or responsible person was created, which were those of overseeing the manufacturing processes of medicinal products, will now in fact hardly be achieved.

III. Compliance with import requirements

Import requirements are not only contemplated in the General Health Law and in the HSR but also in the applicable provisions included in foreign trade laws and regulations and other legal, regulatory and administrative guidelines which, although not part of health regulatory laws, are closely related to them.

As to this aspect, the challenge for the authorities is even greater. The question that comes to mind is if the authorities will actually have the technical and human capabilities to efficiently review the more than 15,000 applications that have been filed for sanitary registration renewal,[9] in order to check compliance with all the specific requirements that have to be met by a foreign drug to be granted registration. The authorities would be required, for example, to have Mexican public officials inspect the various manufacturing facilities which the foreign manufacturer has in different countries to ascertain that they comply with GMP, even if they require that the costs involved in doing so be borne by the applicants.[10]

As far as we know, inspections of this kind have never occurred in the past and the application of this provision will no doubt subject the initial applicants to its consequences (trial and error). It is therefore of the utmost importance for applicants to fully comply with all

[8] Articles 257 to 261 of the General Health Law and articles 121 to 128 of the HSR.

[9] Which were the result of the amendments made to article 376 of the General Health Law, discussed elsewhere in this article.

[10] Under article 167 of the HSR, if a foreign manufacturer submits a GMP certificate issued by the proper authority of the country of origin, Mexican authorities would have the obligation or checking

We would therefore recommend that Mexican health authorities follow the international trend in this regard, which is to issue registration if the country of origin that issues a GMP certificate has legal provisions in place that properly guarantee the quality, safety and efficacy of the drugs, at least to the same degree as these are ensured by Mexican laws; and that when the regulatory framework of the country issuing the certificate does not do so, to supervise manufacturing practices *in situ*, before issuing the relevant sanitary registration. Although the HSR allow the authorities to act in a discretionary manner by allowing them the option of *in situ* inspection, the truth is that should they fail to do so and then refuse registration, they would not be providing proper legal grounds for such rejection, and should they grant registration without having inspected the facilities, they would fail to meet their obligation of ensuring and protecting the health of the more than 100 million Mexicans. In addition, such actions, by not undertaking an effective inspection of good manufacturing practice, would give rise to unequal treatment among foreign and Mexican manufacturers.

requirements and to file their application sufficiently in advance to allow them to meet the date scheduled for launching their products in Mexico. Since as a general rule the processing for renewal of registration takes less time than that required to obtain first-time registration, the information requirements in each individual case will depend on the completeness of the original file for which the authorities initially granted registration. In order words, registration renewal will be more expedite to the degree the original file was complete. In this regard it is important to clarify that the five-year term provided by the regulations applies to the time granted for *filing* the application for renewal, and is not a term within which renewal must be obtained, and therefore, drug business concerns will be able to continue marketing their drugs legally, regardless of the time the authorities take to resolve on their renewal applications.

The topic of sanitary liability is no doubt a challenge for both the manufacturers and the authorities, but also for the third parties that are involved in the process of manufacturing health supplies. This is the case of the figure known in Mexico as the health compliance officer (*responsable sanitario*). Briefly, this is the person or party who is liable for, and is in charge of supervising the quality, safety and efficacy of medicinal drugs (articles 121 through 128 of the HSR).[11] In Mexico this is a professional who endorses the products that are to be registered and marketed in Mexico.

Perhaps the HSR before they were amended forced in an unorthodox manner, by means of the Mexican-plant requirement, the party who held the sanitary registration (the Mexican manufacturer) to assume all liability deriving from a product of foreign origin that did not meet identification, purity, conservation, formulation, dosage or manufacturing standards (article 261 of the General Health Law). The investment made by the title holder in the Mexican plant led to the undertaking of measures to control, oversee and when make any corrections in the formulation of drugs of foreign origin.

Now, with the reform, this liability will fall on a manufacturer that is located in Germany, China or India, where Mexican health authorities will not be able to take immediate action, and in the best scenario will have to resort to the international agreements to which Mexico is a party.

Given the scenario described above, the other figure contemplated in the current Mexican laws which is jointly and severally liable in regard to the sanctions that are to be applied in the event of actions or omissions resulting from non-compliance with the standards applicable to the product, is the health compliance officer (*responsable sanitario*) assigned to the facility. The questions which arise in relation to this matter are the following: What authority will those who have acted in this capacity up to date have to assume such liability? Has there even been any action undertaken against any such person?

As a result, it seems that there is an urgent need for additional, more concise and detailed regulations on the general matter of sanitary liability that should be more of a preventive rather than a reactive nature, involving all those who take part in the drug manufacturing and marketing

[11] We must keep in mind that in accordance with article 194 of the General Health Law a health supply is any medicinal drug or psychotropic substance, narcotic, or the raw materials and additives used in their manufacture, as well as the medical equipment, prostheses, orthoses, functional aid devices, diagnostic agents, dentistry supplies, dressing and surgical materials and hygiene products.

process. These regulations should specify the authority that must be vested in the party who assumes sanitary liability, to enable this person to adequately perform his or her duties, and should also provide for the creation of a professional pharmacovigilance department at each facility for which a sanitary registration is granted; this department to be entrusted with the proper supervision of the quality, safety and efficacy of the drugs, not only at the time they are developed and manufactured, but also after they have been marketed in order to avoid adverse effects of the drugs among the population that consumes them.

We must remember that both the party who assumes sanitary liability and the legal representative of a facility that engages in the manufacture of drugs are only individuals and therefore have only limited assets to redress any harm or injury caused to the population as a result of a drug. It is for this reason that the concept of preventive general sanitary liability should be applied more extensively, in order for the party assuming this liability to have both internal and external support to adequately perform his or her duties and also to orient his or her actions towards prevention rather than on the redress of damages.

CLOSING REMARKS

The authorities of all countries must ensure that all the people have access to the drugs they require. In Mexico it is estimated that at least 50% of medicinal drug demand originates in the two largest social security institutions, the Mexican Social Security, and the Government Employee Social Security Institute.

The effort to provide a wider range of medicinal drugs, at better prices to make them affordable for the population is to be applauded, provided that their quality, safety and efficacy continues to be ensured, otherwise the price to be paid for not doing so, will be borne by the population. The reforms enacted must be understood as consistent with this perspective, and consequently the authorities must not ignore the issues regarding sanitary control over drugs from their point of origin, that is, from the time products that are to be sold in Mexico are manufactured to the time they are consumed. From this perspective, the regulations that provide for monetary sanctions for infringement of health regulatory laws must be improved.

Despite the amendments made to articles 131, 153, 166, 167, 168 and 170 of the HSR, the rest remained in effect, thus leaving the decision of inspecting a plant located in other country to the discretion of the authorities. We believe this should not be so, and that the regulations should be changed to make such inspection obligatory, at least in the case of plants in countries whose health regulatory systems are not at least on a par with that of Mexico.

Moreover, we believe that the following issues should be subject to the review of the regulatory authorities:

The characteristics of the legal representative domiciled in Mexico must be clearly defined, as well as the responsibilities which such representative will assume before the Ministry of Health and the manner in which he/she will interact with the health compliance officer. In addition we believe that authority should be vested in health compliance officers to enable them to perform their obligations in a manner consistent with the scope of the liability they assume.

The issuance of a Mexican official standard governing good practices as regards the handling, storing and distribution of health supplies, which does not exist at present and seems to be necessary.

The issuance of concise and in-depth regulations dealing with health-related liability in general, applicable to all of those that take part in the chain of production and to the authorities, of a preventive rather than a reactive nature; and in addition, a clear delimitation of the liability assumed by each or else, providing that the holder of the sanitary registration assumes total liability.

The issuance of a Mexican official standard establishing all the requirements, both general and specific, that must be met by the parties applying for sanitary registration of a foreign drug.

Providing for the obligatory requirement of having a professional pharmacovigilance department in each facility. In this regard we believe that such a department should provide assistance to the health compliance officer in carrying out this task, because frequently it is not until after the drugs are sold to the public when adverse reactions are detected by means of the reports by consumers. This would be a way of ensuring that sufficient tests are conducted to determine if such reactions are in effect produced by the drug, because it must be kept in mind that when this is the case the authority must take controlling action commensurate with the reactions caused, and can even have the product withdrawn from the market. This measure would also serve as a tool for the authorities to take all action necessary to prevent the marketing and sale of drugs that do not provide proof of their quality, safety and efficacy and would mitigate the negative effects these may have on the population that consumes them, as has already been the case in other countries.

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