



# British Chamber of Commerce

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## Dear Members:

It is no real coincidence that healthcare is high on the agenda of both the Mexican and British Governments. Demographic trend statistics in developed countries indicate a growing population of the elderly, in some cases faster than the birth rate, and an increasing demand for better healthcare by the consumer; the pressure is on, therefore, not only to improve healthcare services, but to do so with better allocation of funds. Mexico has a very experienced team in the Health Secretariat who are already starting to implement changes, especially in the public sector, through decentralisation and involving the private sector in the process. As the article from Paul Doulton explains, this opens up many opportunities for British enterprise in the hospital sector, in nursing training and in infrastructure. There has already been a lot of interest shown from Britain, as Ken Newnham, President of British Healthcare, describes and the British Healthcare Working Group (BHWG) is British Healthcare's first overseas associate. Of course, without the active part played by the Embassy, especially in its sterling work in developing close working ties with Mexican Ministry of Health officials, many of whom studied in Britain, much of what has been and is being achieved would not have been possible.

The major British players in healthcare are from the Pharmaceutical Industry, competing in a market worth close to US\$9 Billion here in Mexico in both the private and public sectors. Both GlaxoSmithKline and AstraZeneca are strong here in Mexico and have shown consistent annual growth in recent years. Both companies are the result of mergers within the Industry, to try to improve and strengthen their market share and R&D capabilities. Ricardo Alvarez-Tostado, General Manager of AstraZeneca, talks about the challenges facing the Industry in this issue and Dr. Jorge Tanaka, Medical Director, GSK, highlights some of the achievements that pharmaceutical companies, GSK included, have accomplished in demonstrating their role as good corporate citizens. None of us can have failed to be aware of the battle going on at the moment in the generics sector of the market; this is also mentioned in the AstraZeneca article and developed in more depth in Dr. Herfried Wöss' article on patents.

**Roy Bateman**  
Chairman BHWG

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# The Protection of Pharmaceutical Patents in Public Tender Proceedings in Mexico

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The pharmaceutical industry in Mexico has been subject to different forms of unfair competition such as the existence of Mexican companies dedicated to copy patented pharmaceutical drugs ("patent forfeiters"). There are several ways to fight against such practices. One is to use the remedies provided under the Mexican Law for Industrial Property. The other one is to force the health authorities not to grant sanitary authorisations to notorious patent forfeiters of pharmaceutical drugs (see: Herfried Wöss: *The Application of TRIPS to the Authorisation by Health Authorities of the Using, Making and Selling of Pharmaceutical Drugs*, *Journal of International Trade Law & Regulation*, Sweet & Maxwell, London, 8 (2002) 3, p. 79-84).

Finally, there are means to defend against forfeiters of pharmaceutical patents in public tender proceedings. This is of importance with respect to the public market as public entities are obliged to purchase medicaments through public tender proceedings. It has to be mentioned that patent forfeiters in Mexico are often companies of significant size and market power.

Several provisions contained in the Mexican federal and local legislations and in free trade agreements ("FTAs") help to establish strategies to defend patents in public tenders: According to

article 50, section X, of the Federal Public Procurement Law ("Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público"), the purchasing authority has to refuse bids from entities that are not entitled to offer a product because of the lack of the corresponding intellectual property rights. A provision in that sense has to be included in the bidding guidelines (article 29, section X, of the Federal Public Procurement Law). However, this provision normally is not applied automatically and therefore the lawful patent owner has to present the appropriate legal remedies at a very early stage of the tender proceeding (e.g. immediately after the purchase of the bidding guidelines) to make sure that his rights are safeguarded.

Special provisions are contained in the Public Tender Rules for NAFTA and other FTAs ("*Acuerdo por el que se dan a conocer las Reglas para la aplicación de las reservas de compras del sector público establecidas en el Tratado de Libre Comercio de América del Norte y para la determinación del contenido nacional en los procedimientos de contratación de obras públicas*", DOF 6 de octubre de 2000). According to Rule 7.b.4 of the Public Tender Rules, the authorities have to verify the existence of a patent with the Mexican Institute of Industrial Property ("IMPI" for its acronym in Spanish). Apart from that, since January 1, 2002 the purchase of patented drugs has to be exclusively through international tenders. In order to determine

the right venue, the tendering authority has to request a ruling from the Ministry of Economy which has to hear SECODAM for its decision.

Article 28, section II, of the Federal Public Procurement Law, establishes that public tenders have to be international if so established in FTAs such as in Annex XI, para. 6, to Article 25 of Decision 2/2000 of the EU-Mexico Association Agreement (so-called FTA on Goods, DOF, June 26, 2000). It has to be mentioned that according to a recent judgement of the Mexican Supreme Court international treaties apply also in the sphere of competence of the federal entities of the Mexican Republic.

As can be observed in practice, public tenders for pharmaceutical drugs are often called on a national and not an international level in violation of the aforementioned rules. Such violation can be remedied through a declaration of inconformity ("*manifestación de inconformidad*") and the corresponding judicial procedures with the effect that the drugs in question be excluded from such national tender. As a consequence, the patent holder may negotiate a direct adjudication of the drugs under article 41, section I, of the Federal Public Procurement Law or the respective local acquisition laws.

Therefore, there is sufficient room for pharmaceutical companies to establish strategies for the defence of their patents in public tenders in Mexico. Other legal measures not discussed herein, aim to impede the Mexican Health Ministry under national and international law (for the latter see article cited above) to grant sanitary authorisations to notorious patent forfeiters for the production of pharmaceutical drugs, or to force the Ministry to withdraw them, which is even more difficult to achieve.