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COFECE: off-patent drugs have not translated into sufficient competitive pressure in the markets

- *The Commission published a market study on competition and free market access in the markets in off-patent drugs.*
- *Among the problems identified: expiry of patents has not been translated into sufficient competitive pressure; delays in the entry of generic medicines into the markets; furthermore, two years, on average, must pass for price reductions to take effect, and these are less pronounced than in other countries.*
- *For competition to be fully advantageous, the legal framework needs to be modified, as well as the criteria for public policy.*

Mexico City, August 9, 2017.- The Federal Economic Competition Commission (COFECE or Commission) published the *Market study on competition and free market access in the off-patent drug markets* which finds competition problems derived from regulatory and public policy failures, that hamper the participation of a greater number of economic agents in the market as well as the incentives to ensure more options of drugs at competitive prices for Mexican families.

These competition problems generate added costs up to 2.5 billion pesos in medicines annually, which is the equivalent to two times the Hospital Juarez de Mexico's budget or the construction of four general hospitals with 180 beds each.[1]

Patents on active substances are mechanisms that aim to promote knowledge development and innovation[2] and grant pharmaceuticals the right to exclusively sell new drugs for 20 years. This non-renewable period is essential for pharmaceuticals to recuperate research and development costs, and obtain economic returns. Once patents granted by the Mexican Institute of Industrial Property (IMPI) have expired, other pharmaceutical companies may

[1] Hospital Juarez de Mexico's Budget and Construction costs of a general hospital with 180 beds available at: http://pef.hacienda.gob.mx/work/models/PEF2017/docs/12/r12_aae.pdf y http://portaltransparencia.gob.mx/pot/contrataciones/consultarContrato.do?method=consultaContrato&id.idContrato=1092701MA443331_27_11&_idDependencia=641 accordingly. Reports in Spanish.

[2] Active substances are defined as the substance contained in a drug that gives it its therapeutic effect.

produce and sell the same active substance in a generic version with the same therapeutic effect. For the generic drugs to be marketed, it is necessary to have a health registration from the Federal Commission for the Protection against Sanitary Risks (Cofepris), which is obtained once bioequivalence[3] between the generic and original drug is ensured.

Once the patent has expired, having a greater number of competitors promotes a quality supply of medicines at the lowest possible prices, as pharmaceuticals must compete for consumer preference to ensure profits. Hence the importance of guaranteeing entry, without undue delays, to all economic agents interested in participating in the generic drug market. However, the *Market study on competition and free market entry of off-patent drugs markets* identified a series of distortions that prevent conditions conducive to the efficient development of this market. Among the most important are:

I. **The entrance of generic drugs into the market is late and slow.** There are some drugs that are not produced and marketed even when the health registration was obtained from Cofepris. In Mexico, on average, more than two years elapse between the expiration of a patent and the launching of the first generic. In contrast with the cases of the United States and the European Union, in the former, generics of best-selling drugs are sold immediately, in the case of the latter, the average time is seven months.

II. **Off-patent drugs have not translated into competitive market pressure.** The market study identifies 22 innovative drugs, with annual sales estimated at six thousand 285 million Mexican pesos, whose patents have expired, yet no competitor has applied for a health registration, these have no generic competitor, nor are there legal disputes to hamper their marketing. In the case of new generics, their launch has not translated into more competitive prices.

III. **The entrance of alternative generic products does not translate into better prices for consumers.** Two years after the entrance of the first generic drug, the average price of these is 28% below that of the original drug. Even so, the reduction in prices in Mexico is less pronounced, compared to a 40% reduction in the European Union.

IV. **Industry regulation affects competition conditions:**

[3] Relation between two equivalent pharmaceuticals or alternative pharmaceuticals that when administered under similar conditions produce similar bioavailability. (http://www.dof.gob.mx/nota_detalle.php?codigo=5314833&fecha=20/09/2013)

- Health regulations restrict the possibility to substitute original drugs for generic drugs when the prescribing doctor does not explicitly indicate the generic name in the prescription.

- The possibility to protect the same drug with more than one patent favors exclusivity because competitors are forced to become involved in legal disputes in order to market the original formula. Recently, an average increase of 1.2 almost 2 patents per active substance have been registered, which in turn increase the market power of the drug.

- Public, complete and updated information on health registrations is lacking as well as the link between reference medicinal products and the patents that protect them, which generate search and legal dispute costs among innovating and generic pharmaceuticals. At the end of December 2016, the Cofepris website offered full information on only 7% of the 486 authorized generic drugs. 68% did not appear on the website. The list of reference medicines does not contain patent information.

With the objective of strengthening competition conditions in the market of off-patent drugs, as well as reaping full benefits from competition in the market in generic drugs, modification of the regulatory framework and criteria of public policy are required:

1. **Greater transparency to increase certainty.** Cofepris has undertaken important measures to expedite the entrance of generic drugs in the market, which should be accompanied by actions that increase public access to relevant information which is complete and updated which in turn permit the identification of the universe of drugs with patents, their main characteristics as well as the information on patents that protect approved reference medicines. The promotion of the "Bolar"[4] clause and the periodic publication of innovative drugs with patents that will expire in the next three years.

2. **Ensure and disseminate regulation that is more favorable to competition.** Establish in the Regulation on Health Inputs the obligation for doctors to prescribe the generic denomination and promote that the pharmacy provides public information on

[4] The "Bolar" clause allows a producer of generic drugs to request and begin the authorization or health registration procedure, including the presentation of evidence of bioequivalence, up to three years before the expiration of the patent of the innovative drug.

available generic drugs. On the other hand, in line with international practices, it would be relevant to restrict granting certain types of patents in the Regulation under the Industrial Property Law, said patents are prone to be used in an abusive manner by the patent holders to block the entrance of competitors. For example: restriction on second uses of inventions, process innovation or different chemical forms of the active ingredient.

3. **Promote the use of generic drugs in the consumption basket.** To stimulate competition and diminish spending of consumers, the Ministry of Health could develop communication strategies directed at doctors and families to enhance confidence in regards to the quality of generic drugs.

4. **Make generic drugs competitive for public tenders.** Improve procurement and payment times in the public sector because the entrance of small and medium laboratories that sell generic drugs to the health sector could generate the scale needed for greater entrance and competition of generics in commercial markets.

The market in drugs is relevant because of its impact in life expectancy and family welfare, in addition to its participation in the national economy and family expenses. Last year, the market value of drugs in Mexico was estimated at 200 billion Mexican pesos. From this stems the relevance to enact legal reform and change in the criteria of public policy, to improve competition conditions in this market.

The *Market study on competition and free market access of off-patent drugs markets* developed as an initiative from the Commission, with information provided by federal authorities, regulators, economic agents and sectorial associations, among others- contribute to the specialization of COFECE, benefitting the analysis of markets in drugs in Mexico. Consequently, it facilitates our work to oversee and prosecute potential anticompetitive conducts.

See the full study or its summary in Spanish

Case infographic

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The Federal Economic Competition Commission is entrusted with safeguarding competition and free market access. Through this, it contributes to consumer welfare and the efficient functioning of markets. Through its work, COFECE seeks better conditions for consumers, greater output, better services and a "level playing field" for businesses.