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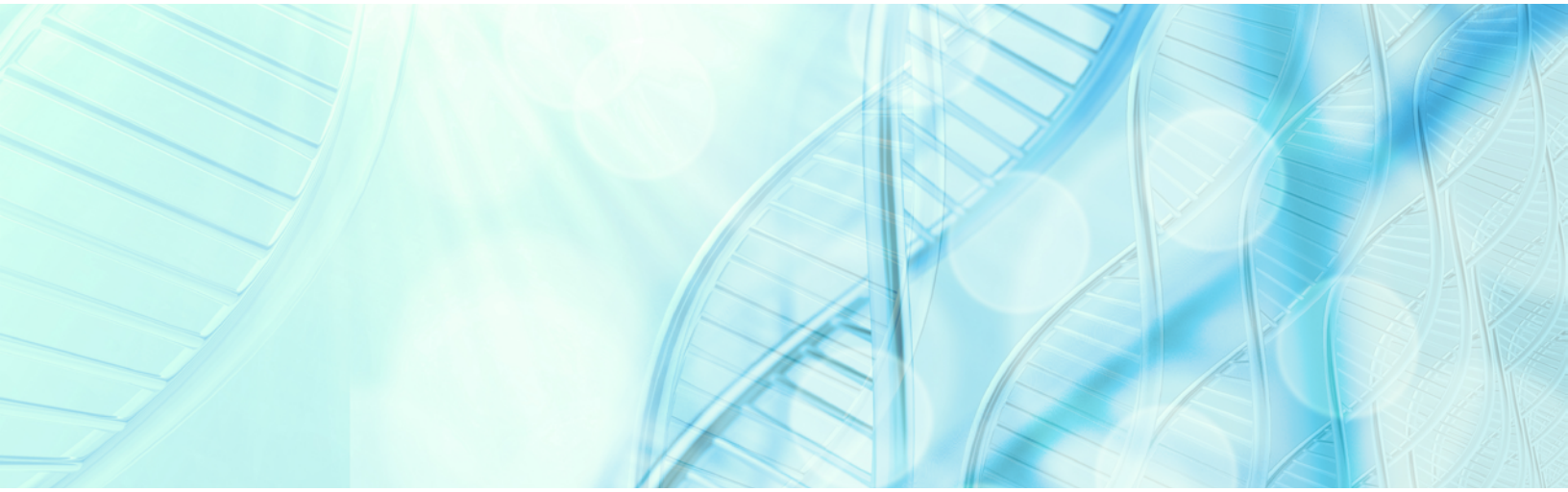
# Life Sciences Industry Group Newsletter



## Modifications to the General Health Law (GHL) and the Law of National Health Institutions (LNHI)

*Several modifications to the GHL and the LNHI have come into force on January 1st, 2020. In this newsletter, we highlight those changes which will have the biggest impact to our clients in the Life Sciences space.*

The modifications to the GHL and the LNHI follow two main policy purposes; to ensure the constitutionally ordered free universal healthcare, regardless of social security status, and to eliminate the former People's Insurance ("Seguro Popular"), substituting it for the Institute of Health for Well-being ("Instituto de Salud para el Bienestar" or "INSABI").

Below are some of the main aspects of the bill:

» **INSABI will act as a public health services provider instead of an insurer.**
Under the former structure, the People's Insurance provided health insurance for access to several different federal and local health institutions; people who weren't covered by Social Security would have access to this insurance, which would gradually increase covered illnesses.

With this change, INSABI will cease acting as an insurer, and will absorb administrative responisibilities over health care provision.

» **The former National Formulary of Health Supplies (Cuadro Básico) is substituted by a National Compendium. All National Health Institutions will have to adhere to this Compendium.**
The main impact that this change will have is to speed up the ongoing process of concentration and centralization of drug/device access mechanisms. With the former National Formulary, Institutions such as ISSSTE and IMSS had the possibility to create their own specific sub-formularies for supply purchases.

» **Innovator and follow-on biologic drug (Biocomparables) products will be subject to the same code in the National Compendium.**
This provision will have the effect of creating price-based competition between innovator biologic products and any relevant biosimilars.

» **Packaging of drug products will have to be different for drugs intended for sale in the public and private markets.**
This is a return to a policy position that had been abandoned a few years ago; It will likely increase costs associated to products in Mexico due to the need to produce differentiated packages.

*Our firm's Life Sciences team commonly acts as advisor to companies on relevant legal aspects both on Regulatory and Access issues. Please contact us with any queries on the above.*

This newsletter was prepared by Juan Luis Serrano-Leets (jlserrano@sanchezdevanny.com).

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## Contact


*Daniel Maldonado-Alcántara*
dmaldonado@sanchezdevanny.com

*José Alberto Campos-Vargas*
jacampos@sanchezdevanny.com

*Ricardo León-Santacruz*
rls@sanchezdevanny.com

*Ernesto Silvas-Medina*
esm@sanchezdevanny.com

*Juan Luis Serrano-Leets*
jlserrano@sanchezdevanny.com

*Turenna Ramírez-Ortíz*
tramirez@sanchezdevanny.com

*Humberto Morales-Barrón*
hmorales@sanchezdevanny.com

*Mariana Eguiarte-Morett*
meguiarte@sanchezdevanny.com

**Ciudad de México:**
Av. Paseo de las Palmas #525 Piso 6
Col. Lomas de Chapultepec, 11000
Ciudad de México
**T.** +52 (55) 5029 8500

**Monterrey:**
José Clemente Orozco #335 Piso 4
Despacho 401 Col. Valle Oriente, 66269
San Pedro Garza García N.L.
**T.** +52 (81) 8153 3900

**Querétaro:**
Blvd. Bernardo Quintana #7001
Torre 1 Oficina 1109 Col. Centro Sur, 76090
Querétaro, Qro.
**T.** +52 (442) 296 6400


 Sánchez Devanny Eseverri S.C.  @SanchezDevanny  /sanchezdevannymx **www.sanchezdevanny.com**