MEMORANDUM OF UNDERSTANDING BETWEEN THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES, THROUGH THE FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY RISKS, AND THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS OF THE REPUBLIC OF POLAND, ON MEDICINAL PRODUCTS AND MEDICAL DEVICES.

The Ministry of Health of The United Mexican States (SSA), through the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland (URPLWMiPB), hereinafter the "Parties", have agreed the following:

ARTICLE 1.- OBJECTIVE

The purpose of this Memorandum of Understanding is to establish a cooperation mechanism by which the "Parties", according to the powers given to them by their corresponding law and regulation, and on the basis of equality and reciprocity, facilitate the exchange of information and cooperation on medical devices and medicinal products, including herbal medicinal products, vaccines, biological and blood-derivatives.

This Memorandum of Understanding represents the agreement reached by the "Parties", in particular:

(i) Each "Party" has jurisdiction on medicinal products and medical devices.

(ii) This Memorandum of Understanding intends to allow a meaningful collaboration between the "Parties", and

(iii) Each "Party", under certain circumstances may limit the disclosure of information provided by the other "Party" in regard of this Memorandum of Understanding, particularly if the disclosure of it can be detrimental to the commercial interests of a third party, can be a breach of confidentiality or privacy, reveals trade or industrial secrets, is contrary to the public interest or of the "Parties", violates or contravenes legal obligations or requirements or other obligations under the respective laws of Poland or Mexico.

ARTICLE 2.- MODALITIES AND AREAS OF COOPERATION

The activities in which cooperation will be provided will be defined in the program of cooperation and specific projects jointly agreed by the "Parties", depending on the availability of material, human and financial resources of the "Parties" and the legal, budgetary, rationality, austerity and social communication provisions that are applicable.

2.1. The cooperation program will include, among others, the following:

a) exchange of information and experiences;

b) interchange of professionals;

c) organization of joint workshops, conferences, teleconferences and study visits;

d) technical assistance;

e) any other modality of cooperation agreed by the "Parties".

2.2 The cooperation activities under this Memorandum of Understanding may include but not limited to the following areas:

a) authorization, surveillance of safety of use and efficacy of medicinal products and clinical trials;

b) legal acts, technical requirements regarding clinical trials, marketing authorization of medicinal products on the territories of Poland and Mexico;

c) requirements regarding assessment of documentation in the process of marketing authorization of medicinal products for human use;

d) raw materials and active pharmaceutical ingredients used in the manufacturing process of pharmaceuticals;

e) withdrawal of medicinal product marketing authorization, known by the COFEPRIS to have been manufactured in Poland, and known by the URPLWMiPB to have been manufactured in Mexico;

f) surveillance and pharmacovigilance especially on new serious adverse incidents;

g) legal acts, recommendations and guidelines in scope of reporting and surveillance of adverse reactions and in scope of assessment of reports;

h) medicinal products shortages and mutual support to counteract these shortages;

i) medicinal products clinical trial inspections, medicinal devices clinical trial inspection, pharmacovigilance inspection;

j) medical devices surveillance in the scope of:

1) organization and surveillance structure of the market of medical devices;
2) medical devices imported in both countries;

3) broad cooperation and exchange of information regarding medical devices noncompliance with relevant requirements;
4) exchange of information regarding incidents with medical devices.

k) assistance to the holders of the marketing authorization of medicinal products from both countries by providing timely and comprehensive information on the legal provision that regulates clinical trials, marketing authorization and pharmacovigilance of drugs in the Republic of Poland and the United Mexican States.

l) promotion of the establishment of cooperation between stakeholders associations active in the scope relevant to the COFEPRIS and URPLWMiPB's responsibilities;

m) international cooperation activities in scope of the subject of cooperation possibly influenting on public health.

ARTICLE 3.- FINANCING

1. The financing of the cooperation activities developed under this instrument shall be subject to the available budget of the "Parties".

2. Each Party will bear its own costs in relation to the cooperative activities under this Memorandum of Understanding.

ARTICLE 4.- PERFORMING AND MONITORING

The "Parties" shall conduct the monitoring and evaluation of the commitments acquired under this Memorandum of Understanding. The final report will be sent to heads of both "Parties".

1. Working-level Consultation Meetings will be held annually, alternately in Mexico and the Republic of Poland.
2. The co-chairs heads of the Working-level Consultation Meetings and representatives to carry out cooperation activities will be appointed by the heads of the two Parties.
3. Where deemed necessary for the implementation of this Memorandum of Understanding , the Working-level Consultation Meetings may involve private experts or stakeholders from the industry with the mutual consent of the "Parties".
4. The composition and agenda of the Working-level Consultation Meetings will be jointly decided upon by the "Parties" in advance.
5. The "Parties" will designate their respective contact points to ensure the efficient operation of the Working-level Consultation Meetings.

ARTICLE 5.- CONFIDENTIALITY

1. Neither "Party" will disclose or distribute to a third party any confidential information provided by the other "Party" in the process of cooperative activities under this Memorandum of Understanding, except as and to the extent authorized in writing to do so by the providing "Party".

2. Any confidential information to be exchanged between the Parties will be clearly identified as confidential.

ARTICLE 6. WORKING RELATIONS

The officials assigned by each of the "Parties" to carry out cooperation activities will continue under the direction of the institution to which they belong, so it will not create any labor relation with the other "Party", which shall not be considered a substitute or solidary employer.

ARTICLE 7. – ENTRANCE AND DEPARTURE OF OFFICIALS

The "Parties" shall coordinate with the competent authorities, in order to facilitate the entry, stay and departure of the official personnel involved in collaborative activities under this Memorandum of Understanding. This personnel shall comply with the immigration, tax, customs, health and national security laws of the hosting country and shall not engage in any activity unrelated to their functions. Official staff shall leave the host country, in accordance with the laws and provisions established.

ARTICLE 8.- INSURANCE

Each Party shall ensure that the officials involved in cooperation activities representing this Party have medical, personal injury and life insurance, in order that, in case of an accident resulting from its development, which deserves repair or compensation, shall be covered by the corresponding insurance company.

ARTICLE 9.- AMENDMENTS

Any part of this Memorandum of Understanding can be modified at any time by mutual written consent of the "Parties" by the respective signatories. If it is not otherwise proposed, the amendments shall enter into force from the moment of the signing.

ARTICLE 10. – UNFORESEEN CIRCUMSTANCES

The "Parties" shall have no liability for damages or losses that may arise as a consequence of an unforeseen circumstance or force majeure, that can prevent the execution of all or part of the obligations of the object of this instrument.

Once these events have past activities will resume in the form and terms set forth by the "Parties".

ARTICLE 11. – VALIDITY

This Memorandum of Understanding will enter into force at the date of signature by both "Parties" and will continue its validity until it is determined in accordance with Article 13 of this Memorandum of Understanding.

ARTICLE 12. – CONTACT POINTS

The liaison officers responsible for the administration of this Memorandum of Understanding are:

a. For the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of the Republic of Poland, the person holding the position of Head of the International Cooperation Unit; and
b. For the COFEPRIS, the person holding the position of Executive Director of International Affairs.

ARTICLE 13. – CONCLUSION

Either "Party" may, at any time, conclude this Memorandum of Understanding by a written notice to the other "Party". This Memorandum will terminate one month after the date of receipt of the notice of termination.

The Article 5 concerning to CONFIDENTIALITY shall continue in force.

The termination of this Memorandum of Understanding will not affect any commitments given under or as a consequence of this Memorandum in respect of any arrangement or action taken during the period before the termination takes effect.

ARTICLE 14.- DISPUTES SETTLEMENT AND INTERPRETATION

Any dispute, claim or controversy arising between the "Parties" under this Memorandum of Understanding shall be settled by agreement between the "Parties".

Signed in Mexico City on February 25th, 2015, in English, Polish and Spanish, in two counterparts of each, being all of them equally valid. In case of any divergence of interpretation, the English text will prevail.

BY THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES, THROUGH THE FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY RISKS

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Mikel Andoni Arriola Peñalosa

Federal Commissioner

BY THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS OF THE REPUBLIC OF POLAND

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Grzegorz Cessak

President