COOPERATION AGREEMENT
BETWEEN
The President of the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
AND
The Director of Lithuanian State Medicines Control Agency
for the years 2012- 2015

The President of the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Director of Lithuanian State Medicines Control Agency

hereinafter referred to as the "Parties",

AFFIRMING their wish to promote the relations between the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Lithuanian State Medicines Control Agency,

STATING their commitment to support joint efforts to provide efficacious and safe medicinal products to their respective populations,

SHARING the objective of developing knowledge on medicinal products for human use,

RECOGNISING the need to strengthen effective exchange of knowledge and experience between the Polish and Lithuanian experts,

CONFIRMING the need for cooperation to minimize impact of medicinal products shortages,

SUPPORTING the objective to enforce bilateral cooperation on field of medicinal products authorization, clinical trials and pharmacovigilance,

HEREBY ADOPT the following Cooperation Agreement for the years 2012-2015:

ARTICLE 1

The Parties shall develop and enhance cooperation in the area of medicinal products for human use as set out in this Cooperation Agreement.

ARTICLE 2

The Parties shall cooperate in the area of medicinal products for human use with particular focus on the following issues:

1. sharing of knowledge in the field of medicinal products assessment and authorization and clinical trials authorization,
2. mutual support in activities related to clinical trials inspections,
3. mutual support in activities related to pharmacovigilance and safety of medicinal products,
4. exchange of information about medicinal products shortages and appointing respective contact persons in both Agencies.

ARTICLE 3

The cooperation, referred to in Article 2, shall consist of:

1) Exchange of information and experts visits related to the criteria and methods of assessment of quality, safety and efficacy of medicinal products in the process of granting marketing authorization,
2) Study visits, joint inspections and yearly meetings of the Polish and Lithuanian clinical trials inspectors,
3) Study visits, joint inspections and yearly meetings of the Polish and Lithuanian pharmacovigilance inspections inspectors,
4) Appointing contact point to exchange of information on new, serious cases of new adverse reactions,
5) Appointing contact point persons in both Agencies to exchange information about medicinal products shortages,
6) Organizing joint scientific workshops and trainings,
7) **Cooperation** in the area of labelling of the medicinal products.

2. Particulars of the cooperation referred to in point 7 above shall be agreed upon by the Parties in the annex to this Agreement.

ARTICLE 4

1. The Parties shall exchange annually on a reciprocal basis up to two experts referred to in Article 3 point 1, 2, 3 for a period of 10 days per each expert visit, with the purpose of exchanging experience and improving qualifications.

The Parties shall agree on the number of expert visits for a given year by the end of March.

2. The exchange of experts, referred to in Article 3, shall be financed in the following manner:

1) the Sending Party shall cover the costs of travel to and from the capital of the Receiving Party, accommodation and daily allowances.

2) the Receiving Party shall cover the costs of preparing and carrying out of the visit of expert.

ARTICLE 5

In case of health emergencies involving the delegated persons during their stay in the territory of the other Contracting Party under this Agreement, the Receiving Party shall ensure they receive medical assistance. The Sending Party shall ensure that a person delegated under this Agreement holds a valid insurance policy which meets the criteria stipulated by regulations in force in the territory of the Receiving Party. The policy shall guarantee coverage of the cost of necessary medical treatment in case of a sudden illness or an accident, as well as coverage of the cost of ambulance transport to the country of residence.

ARTICLE 6

1. This Agreement shall enter into force on the day of its signature and shall be valid for the period of three years.
2. If none of the Parties terminates the Agreement by means of a written notification, three months prior to its expiration, the Agreement shall be automatically extended for the next three years period.

ARTICLE 7

The termination of this Agreement shall not affect the execution of the programmes and undertakings, which was initiated during the operation of this Agreement, unless both Parties decide otherwise.

Signed in..Warsaw.....on.....19 November....2012, in two original copies, each in Polish, Lithuanian and English, all of which are equally authentic.

In the event of discrepancies in their interpretation, the English text shall prevail.

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

Grzegorz Cessak

FOR THE STATE MEDICINES CONTROL AGENCY OF LITHUANIA

Gintautas Barcys