



Ministry of Health  
Republic of Latvia



efpia

European Federation of Pharmaceutical  
Industries and Associations

Siffa

## **LETTER OF INTENT between the Government of Latvia and the pharmaceutical industry**

The Government of Latvia represented by the Ministry of Health (hereinafter – the Ministry) and Latvian Academy of Sciences (hereinafter – the Academy) and the research-based pharmaceutical industry (hereinafter – the Industry) represented by European Federation of Pharmaceutical Industries and Associations (hereinafter – the EFPIA) and Association of International Research-based Pharmaceutical Manufacturers (hereinafter – the SIFFA) (hereinafter all together referred to as the Parties) by this Letter of Intent, the Parties foresee the gradual development of mutual cooperation, implementing individual projects and concluding agreements, and thus agreeing on:

1. Fostering the access to medicines in, and thus improving Latvian health outcomes.
2. Developing capacity for the conclusion of the agreements directed towards the management of the introduction of specific medicines that correspond to diseases with an aim to enable any mid-term-increase in payment for medicines to be spent wisely, specifically for new medicines.
3. Within the agreements mentioned in Clause 2, to explore innovative payment models, such as paying for outcomes. Oncology is to be considered as a priority area, considering the updated National Cancer Program.
4. A methodology shall be agreed upon by the Ministry and Industry for both the provision of transparency within the compensated medicine system, availability of medicines, result-oriented uptake of medicines, and the Industry's support to ensure the availability of medicines.
5. This collaboration is directed to facilitate stable and predictable business conditions and the access to innovative medicines and investments in research.
6. To implement the above Clauses, the Ministry and the Industry agree to set up a working group involving representatives of the competent institutions and Industry, which will be authorized to develop specific proposals for this step-wise collaboration.
7. The Parties agree to support the research and development of new medicines in Latvia, as well as activities to promote the participation of Latvian

researchers in Horizon 2020 and other financial instruments offered by the Industry.

8. A precise procedure of ensuring the introduction of Clause 7 can be agreed upon by additional sub-agreements between participants of the Industry and the Academy.

9. As for clinical research, the Parties undertake to fully comply with the requirements set in Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

10. The present Letter of Intent is concluded for an indefinite term and enters into force on the day of the signing thereof.

11. Each Party may terminate validity of the Letter of Intent, giving written notice to all the other Parties. Should this be the case, the Letter of Intent expires one (1) month after the date when the relevant Party has sent the written notice of termination of the Letter of Intent.

12. The present Letter of Intent can be amended and supplemented by a written agreement of the Parties. Any amendment and supplement thereto enters into force under the procedure defined in Clause 10.

13. Responsible authorities of the Parties may conclude additional agreements stipulating a specific procedure of the executing provisions of the Letter of Intent.

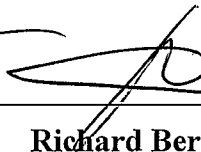
The Letter of Intent is executed in Riga, Latvia, on June 29, 2015, in eight (8) copies in Latvian and English. All copies are of equal legal force. Should interpretation differ, the version in English shall be the dominant version.




**Dr. Guntis Belevičs**  
Minister of Health



**Dr. Ojārs Spārītis**  
President of  
Latvian Academy  
of Sciences



**Richard Bergström**  
Director General of  
European Federation  
of Pharmaceutical  
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**Imants Sinka**  
Chairman of the  
Board of Association  
of International  
Research-based  
Pharmaceutical  
Manufacturers