MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS (IFPMA) AND THE WORLD ANTI-DOPING AGENCY (WADA)

Preamble

Doping in sport primarily involves the misuse and abuse of new chemical entities in development and of commercially available medicines. Doping affects the fairness of sport competitions by illegally enhancing athletic performance, causes potentially harmful health effects and violates the spirit of sport. Not only the elite athlete population is affected, but also larger groups of amateur and young athletes, as well as people aiming at improving their physical appearance. That's why today, doping is declared a public health issue by national and international authorities.

The international fight against doping in sport produces tangible/concrete results through cooperation between multiple stakeholders. The results of several collaborations between the research-based pharmaceutical industry and anti-doping authorities clearly demonstrate the mutual benefit in developing anti-doping capacity for newly developed and commercially available medicines thus limiting access to drug abuse in sport and reducing the health risk of exposed populations.

Scope

Recognizing the role of the World Anti-Doping Agency (hereafter referred to as "WADA") as the international authority for promoting, coordinating, and monitoring the fight against doping in sport in all its forms;

Considering the role of the International Federation of Pharmaceutical Manufacturers & Associations (hereafter referred to as "IFPMA") representing the innovative pharmaceutical industry, which is committed to the development of anti-doping capacity for medicines as a further contribution to improving global public health;

Pursuant to the longstanding <u>Joint Declaration on Cooperation in the Fight Against Doping in Sport</u> established between IFPMA and WADA in July 2010;

WADA and IFPMA have decided to develop this MoU to enhance their partnership and coordinated efforts in supporting the fight against doping in sport, in encouraging the reduction of drug abuse in sport and society, and in facilitating a better use of innovative medicines within the athletic populations.

Objectives

The aim of this MoU is to encourage the development and sustain voluntary cooperation between WADA and IFPMA member companies in support of the following activities:

- 1. Systematically identifying compounds with a potential for sport-related doping abuse and establish mechanisms to inform member companies and WADA.
- 2. Supporting Risk Management Plans and minimizing the risk of misuse of medicines with doping potential to avoid any opportunities for abuse by considering:
 - Informing investigators of the risks of doping abuse;
 - Including clauses in contractual agreements between pharmaceutical companies and investigators;
 - Emphasizing the importance of the control of unused medicinal products while in research and clinical trials.
- 3. Facilitating, on a need basis, the transfer of information relevant to doping abuse under specific agreements in conformance with the Principles described below.
- Supporting the continuous development of anti-doping tests in WADA-accredited laboratories for newly developed compounds and commercial medicines with doping potential.
- 5. Exploring potential collaborations within the framework of a joint IFPMA-WADA *ad-hoc* Working Group in the following areas:

<u>Education</u>: Contributing to educational programs by providing accurate information on new medicines, educating on distinguishing between safe and unsafe medicines;

<u>Science & Medical</u>: Supporting research for anti-doping tests, facilitating transfer of methodologies to anti-doping laboratories, supporting development of new tests (e.g., biomarkers);

<u>Testing</u>: Facilitating development and implementation of innovative methods for large scale testing worldwide;

<u>Compliance</u>: Improving on compliance coverage to better ensure adherence to anti-doping rules and promote reduction of substance abuse;

<u>Intelligence and Investigations</u>: Supporting WADA's endeavor to reduce trafficking of counterfeit drugs and medicines. Contributing to investigations involving drugs/medicines.

- 6. Facilitating the transfer between IFPMA member companies and WADA of relevant information to improve on the treatment of athletes with innovative medicines requiring a Therapeutic Use Exemption.
- 7. Collaborating on appropriate communication plans when medicines are associated with doping cases.
- 8. Collaborating on the establishment of international conferences highlighting the role of pharmaceutical industry in the fight against doping in sport and society.

Principles

- 1. Any and all information to be shared between companies and WADA is on a voluntary basis under the principle of *bona fide* support to the cause.
- 2. Sharing of information will be determined on a need basis, either by IFPMA or IFPMA member company or WADA, and focused on compounds or medicines identified with doping abuse potential.
- Protection of any proprietary or confidential information will be achieved by means of a confidentiality agreement. Information will be shared only with WADA or company employees and not with any third parties, unless mutually agreed in writing.
- 4. A key contact person will be designated in WADA and in each company to simplify and streamline general communication. All information exchanged between the company and WADA about compounds having doping potential will be conveyed via the identified contact persons. IFPMA may play a role to facilitate communication as need be.
- 5. In case of genuine doping abuse potential of a compound, exchanges between the company and WADA will be further developed:

WADA will provide the list of information sought in order for it to develop an anti-doping method;

The company and WADA will exchange, at a frequency to be jointly agreed by the two parties, information on the drug development and on the development and implementation by WADA of the anti-doping method(s).

6. WADA and IFPMA will monitor jointly the implementation of this declaration through annual reviews.

IFPMA President

WADA President

Mr. David A. Ricks Chairman and CEO, Eli Lilly and Company Mr. Witold Banka