

Doping is considered a public health issue by the sport movement and public authorities worldwide, and is characterized primarily by the misuse and abuse of medicines. To address this, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has developed the *Points to Consider: Identification of Compounds with Potential for Doping Abuse and Sharing of Information with WADA (Points to Consider)* booklet in collaboration with the World Anti-Doping Agency (WADA) to aid the industry in early identification of compounds with the potential for sports-related abuse before they are commercially available.

The *Points to Consider* booklet is an extension of the Joint Declaration on Cooperation in the Fight against Doping in Sport signed by IFPMA and WADA in July 2010, and endorsed by the global Biotechnology Industry Organization (BIO) in June 2011. The *Points to Consider* booklet is a tool for biotechnology and pharmaceutical companies to play a role in the fight against doping in sport.

KEY FEATURES OF THE POINTS TO CONSIDER BOOKLET

The *Points to Consider* booklet serves as a "how to" manual to help companies establish a voluntary process for determining the potential doping risk of compounds in their development pipelines.

The intention of the booklet is to provide a simple, routine, and transparent process that:

- Optimizes effectiveness and efficiency
- Avoids undue workload
- Protects proprietary information
- Ensures that time, effort and resources are focused on compounds with genuine abuse potential as opposed to hypothetical "noise"
- Avoids creation of a standalone bureaucracy

Through the *Points to Consider*, biotechnology and pharmaceutical companies are encouraged to assess compounds and substances and rate their potential for doping abuse—even those compounds that fail to complete all drug development stages and do not achieve commercial viability. Sufficient evidence for

characterization of doping abuse potential can be provided during standard in-house processes and in vitro and in vivo pharmacological characterization, without requiring additional studies.

Sharing of information between the company and WADA will be determined on a case-by-case basis and only for those compounds for which in-house screening or external information indicates a likely or probable doping abuse potential. Based on the information received, WADA will assess and define the doping potential of the compound(s) and will agree on next steps with the company. If deemed high risk, WADA will guide the key contact person at the company regarding further information and resources needed to develop an anti-doping strategy and, if needed, will define further anti-doping testing plans for the compound.

The booklet provides additional useful background information from WADA along with contact information for the appropriate members at WADA.

WHY INDUSTRY SHOULD PLAY A ROLE IN THE FIGHT AGAINST DOPING

Doping undermines the integrity of scientific innovation and competitive sport. Biotechnology and pharmaceutical companies serve patients and develop and deliver innovative life-saving and lifeenhancing medicines to improve the health of people everywhere. While these medicines are regulated, doping athletes across various sports arenas have abused these medicines to boost athletic performance. Without exception, doping represents an unsafe and unapproved use of any medicine and is illegal in most countries. While the misuse of well-established products is well known and detection methods are often available, medicines in pre-clinical or clinical development are very attractive options to cheating athletes and their entourages because authorities are less aware of them and there is a delay in the

implementation of detection methods. The *Points* to *Consider* booklet provides the biotechnology and pharmaceutical industries with the opportunity to strengthen oversight of their compounds, help address the public health concern and mitigate doping of their products.

WADA is an independent international organization created to promote, coordinate and monitor the fight against doping in sport in all its forms. However, as drug testing has become more sophisticated, so too has the misuse of medicines. In order to combat doping in sport effectively, WADA needs the cooperation of the biotechnology and pharmaceutical industries to proactively identify products with the potential for abuse, and to develop testing methods to help detect illegal or illicit use.





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