2 FIELDS 1 GOAL

Protecting the Integrity of Science and Sport

Implementation of the Joint Declaration on Cooperation in the Fight Against Doping in Sport

Frequently Asked Questions

1. GENERAL QUESTIONS

1.1 What is the World Anti-Doping Agency (WADA)?

The World Anti-Doping Agency was established in 1999 as an independent international agency composed and funded equally by the sport movement and governments of the world. The purpose of the Agency is to develop anti-doping capacities and to monitor the World Anti-Doping Code (Code), the document harmonizing anti-doping policies in all sports and all countries. WADA also provides an updated list of prohibited compounds and substances broken down by category on a yearly basis. The List of Prohibited Substances and Methods (List) identifies which substances and methods are forbidden in-competition, out-of-competition and in some cases, by specific sport.

The WADA list of prohibited substances can be found here.

1.2 Have there been prior agreements between WADA and the biotechnology and pharmaceutical industries regarding doping in sport?

In July 2010, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and WADA signed the Joint Declaration. The global Biotechnology Industry Organization (BIO) joined the collaboration in June 2011. The purpose of the Joint Declaration is to create a strong framework of collaboration and to encourage the voluntary cooperation of IFPMA and BIO member companies with WADA. This partnership with WADA will help identify compounds with the potential for doping as early as possible during development, help minimize the misuse during clinical trials, facilitate the sharing of information and development of detection methods, and support collaboration on communications when medicines are found to be associated with doping.

1.3 How are IFPMA, BIO and the member companies implementing the tenets of the Joint Declaration with WADA?

While cooperation is voluntary, IFPMA and BIO are strongly encouraging their member organizations to participate in implementation of the Joint Declaration. To this end, IFPMA and BIO are providing a number of resources to their members to support them in practical implementation. This includes the *2 FIELDS 1 GOAL* campaign and the *Points to Consider* booklet which notes best practices and includes templates for confidentiality agreements and other information-sharing agreements.

2. WHY PARTICIPATE?

2.1 Why is there a need for an industry-wide effort against doping and the identification of pipeline substances that have doping potential?

Doping is illegal in many countries and undermines the integrity of scientific innovation and competitive sport by misusing drugs intended for therapeutic use and artificially enhancing athletic performance. IFPMA and BIO member companies are driven by the concern for the welfare of patients and are committed to making safe medicines, as well as optimizing safe conditions for their use. Collaborative efforts between WADA and the biotechnological and pharmaceutical industries will help identify potential doping compounds at an early stage and will facilitate much faster development of detection methods. These actions will not only allow for detection of doping abuse, but will act as a deterrent to mitigate the problem of doping among athletes by having testing and detection methods in place prior to the commercial availability of the compound.

2.2 How much of a concern is doping worldwide?

Doping is considered a public health issue by the sports movement and public authorities worldwide, and it has an impact on every sport throughout the world. WADA was created out of the worldwide public concern regarding doping. Today, 170 countries and almost 700 sport organizations are now signatories to the Code, which came into force in 2004. In addition, many of these countries have created a national anti-doping agency to effectively implement anti-doping activities at a national level. The United Nations Educational, Scientific and Cultural Organization (UNESCO) International Convention against Doping in Sport represents the first time governments around the world have agreed to apply the force of international law to counter doping. The Convention helps to ensure the effectiveness of the Code.

3. IDENTIFYING COMPOUNDS WITH DOPING POTENTIAL

3.1 How will a company assess the likelihood and potential for the pipeline medicine to be misused for doping?

Best practices for the assessment of doping potential are described in the *Points to Consider* booklet, which details an approach for assessment of doping abuse potential based on structural characteristics, mechanisms of action and observed effects, and provides guidance as to when and how to contact WADA in case of suspected doping potential. This approach is designed to make use of information collected by a company's existing development and review process and does not call for additional screening procedures.

3.2 Is it useful to consult WADA about the doping potential for each compound or only those with high potential?

Sharing of information will be determined on a case-by-case basis and only for those compounds for which in-house assessment or external information indicates a probable or high likelihood of doping abuse potential. WADA will then conduct an assessment and confirm or refute the doping potential of the compound.

3.3 Should a company's assessment include compounds and products in all drug development stages or only those which achieve commercial viability?

The potential for doping abuse may be considered for any compound—even those that fail to complete all drug development stages and do not achieve commercial viability. In fact, the latter may appear particularly attractive to dopers because they are "unknown" and therefore believed to be "not detectable."

3.4 In what phase of clinical drug development is it advisable to contact WADA about a compound that may be a doping candidate?

This is not dependent on development stage, but on the reliability of the information available, and is at the discretion of the manufacturer. For some compounds, there may be early reliable indicators of doping potential such as membership in a class included in the List. For others, reliable data may not be available until later in the development process. Companies may apply internal criteria to rank doping potential, ranging from "no or negligible doping potential" to "high risk of doping potential." WADA recommends contacting them only in the case of compounds with probable or high likelihood of doping potential.

4. WHAT IF A PRODUCT IS CONSIDERED TO HAVE POTENTIAL FOR DOPING ABUSE?

4.1 How should a company inform WADA about a compound suspected of having probable doping potential?

If a compound is identified as having probable or high likelihood of doping potential, the company should contact the WADA Science Department using the dedicated mailbox address provided in the *Points to Consider* booklet to discuss next steps. On the basis of the information supplied by the company, WADA will then assess the doping potential of the compound. Should the doping potential be confirmed by WADA, subsequent steps would then be agreed upon by WADA and the company.

4.2 What data will WADA require for initial assessment of the doping potential of a compound?

Initial information to be shared with WADA will generally include data relevant to the prohibited activity in question and relevant pharmacokinetic and pharmacodynamics evidence. In many cases, the product Investigator Brochure (IB), or selected excerpts of the IB, will be suitable. Should WADA confirm the doping potential of a compound, further information will be requested from the manufacturer, such as clinical data and information required to develop detection methods.

4.3 Will WADA try to stop the development of a product if it has the potential to be doped?

No, WADA will not stop the development of a product that has the potential to be doped. It is not the role of WADA to intervene in development of new medicines, nor is it empowered to do so. WADA's role is to ensure that appropriate testing methods and procedures are put in place to ensure fairness in sport, which is most effectively achieved through collaboration with the manufacturer. However, WADA will work with the company and provide the manufacturer with information about potential channels to divert the misuse of medicines and aid the manufacturer in complying with regulatory requirements to minimize or avoid unauthorized use. These measures will be determined on a case-by-case basis and agreed upon by the company.

4.4 Will WADA disclose any information given to them by biotechnology and pharmaceutical companies?

Prior to sharing any proprietary information between a company and WADA, the two parties will sign a confidentiality agreement. WADA will be legally bound not to share proprietary information with any third party, unless mutually agreed upon in writing. Furthermore, any and all information shared between the companies and WADA is on a voluntary, case-by-case basis. Non-proprietary information may be shared or made public by either party by mutual agreement.