POINTS TO CONSIDER

Identification of Compounds
with Potential for Doping Abuse
and Sharing of Information
with WADA

2 FIELDS 1 GOAL

Protecting the Integrity of Science and Sport

ACKNOWLEDGEMENTS:

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and Associations (IFPMA) Anti-doping Working Group

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TABLE OF CONTENTS PAGE

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

POINTS TO CONSIDER

Identification of Compounds with Potential for Doping Abuse and Sharing of Information with WADA

1. INTRODUCTION

1.1 Background and Rationale

With the increasing focus on assuring safe use provisions throughout the lifecycle of medicines, it is difficult for drug developers to believe that there is a growing group of users and their enablers for whom safe use provisions are irrelevant. With the increased rewards on offer to sportsmen and women in the modern era, athletes are under increasing pressure to achieve better, faster, longer and stronger performances. With the difference between being the best and the "also ran" becoming smaller and smaller, the temptation to look for alternative ways to achieve a competitive edge increases with every passing year. Performance-enhancing drugs have probably been a part of top-flight sport for decades in the modern Olympics era. In order to maintain a level playing field, drug testing is now an everyday part of the professional athlete's life. However, as tests have become more sophisticated so, too, have the cheats. Today it is not only the more traditional steroids and beta-blockers being abused. Almost any new drug is being viewed as possibly having the potential to enhance performance in one or more sports.

The World Anti-Doping Agency (WADA) is the independent international organization created in 1999 to promote, coordinate and monitor the fight against doping in sport in all its forms. In order to do this 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 detect illegal use.

Such collaboration has, until recently, been initiated on an ad hoc basis. To mark a formal commitment to the collaboration between the biotechnology and pharmaceutical industries and WADA, IFPMA and WADA signed a joint agreement in July 2010[1], followed shortly thereafter by similar agreements between WADA and a number of individual companies, as well as endorsement by U.S. BIO in June 2011.

1.2 Purpose of this *Points to Consider* Document

The purpose of this booklet is to provide practical guidance for identifying pipeline compounds with a potential for sports-related abuse and for sharing this information with the World Anti-Doping Agency (WADA). The advice provided in this booklet represents current best practices and has been agreed with WADA. This includes template documents for Confidentiality Agreements and a Memorandum of Understanding (Appendix 3) to facilitate interactions between companies and WADA, which are based on several years of experience in collaboration between WADA and industry. Signature of such an agreement, however, is not a prerequisite for collaboration with WADA.

This booklet also applies to compounds that fail to complete all drug development stages, and do not achieve commercial viability, since these fall into a less well-controlled "grey zone." While compounds that complete all stages of development and are granted marketing authorization are highly visible, well documented and well regulated, experience has shown that those for which development is discontinued may provide substantial doping abuse potential while having low visibility and less control and oversight. Such compounds are particularly attractive to "high-profile abusers" because they are thought to be unknown, hence undetectable, and are likely to be part of a tailor-made doping regimen, thus conferring significant competitive advantage.

To optimize the chances of adoption and implementation, any procedure developed by a company should provide a balance between theoretical stringency and the day-to-day realities of the work in both WADA and the biotechnology and pharmaceutical industries. Thus, the intention is to provide a simple, intuitive and transparent process that:

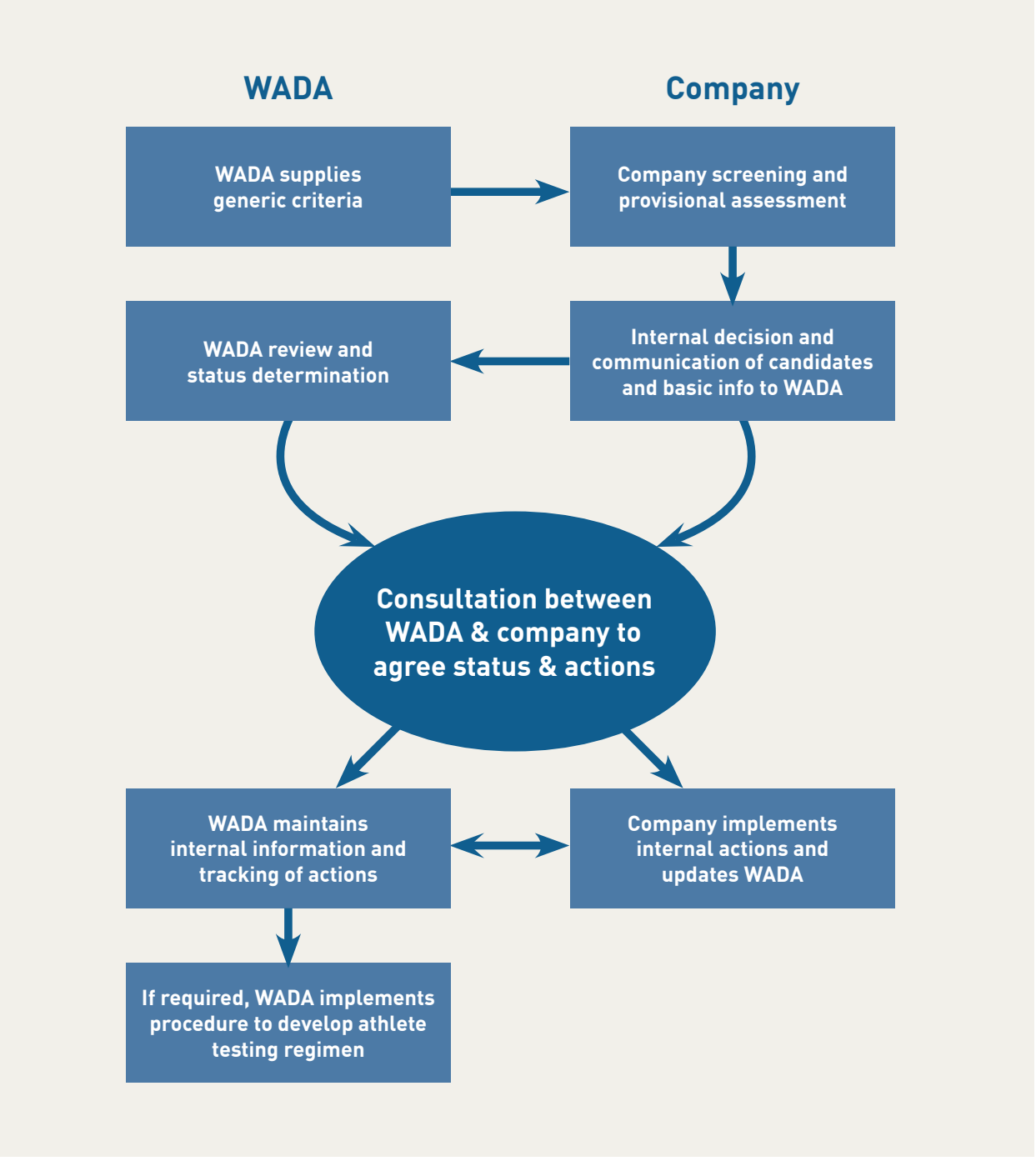
- Optimizes effectiveness and efficiency
- Avoids undue workload
- Protects proprietary information
- Ensures that time, effort and resources are focused on compounds with genuine abuse potential as opposed to hypothetical "noise"
- Avoids creation of a standalone bureaucracy

In keeping with these criteria, many of the processes described in this document can be integrated easily into a company's existing processes for assessing compounds for other kinds of abuse (e.g., physical and psychological addiction, misuse and diversion/counterfeiting).

2. PROCESS OVERVIEW

Figure 1 provides an overview of the process and information flow.

Figure 1 Process Flow Chart



3. IDENTIFICATION OF COMPOUNDS

3.1 Basis for Identification

The WADA Code (Section 4.3) defines the high-level criteria that determine whether a compound should be included in the Prohibited List. WADA Code Section 4.3 [2] and a summary of criteria based on the Prohibited List [3] are provided in http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129134.pdf, Appendix 1 and Appendix 2, respectively. This provides useful guidance in identifying the classes of agents that have a mechanism of action or effects that may be misused for performance enhancement. For novel compounds not covered by the Prohibited List, however, such potential is difficult to assess and is more reliant on observed effects. In this context, it is useful to consider the types of effects that may lead to enhanced performance in different types of sports. These effects vary according to the sport, and include, but may not be limited to, pro-cognitive or pro-cardiorespiratory effects. The in-house review process for individual compounds, depending on the stage of development (i.e., amount of data available), can apply one or more approaches:

- **Structure:** possibility for comparison with chemical structures of existing performance-enhancing agents
- **Mechanism of action:** identification of potential mechanisms likely to yield performance enhancement (e.g., various measures of enhanced physical or mental endurance, stimulatory effects, muscle growth, stimulation of haematopoietic cell production, reduced susceptibility to muscle or tendon injury)
- **Observed effects in animals or humans:** this may include unexpected effects such as CNS stimulatory effects (e.g., insomnia, euphoria, aggression), increased energy levels, reduction in fatigue, loss of appetite, increase of appetite, weight loss, etc., that may be indicative of potential for misuse

3.2 In-house Review Process and Assessment of Doping Abuse Potential

3.2.1 Rating of Doping Potential

Compounds should be assessed by biotechnology and pharmaceutical companies at different stages of development and rated for their potential for doping abuse. Subsequent actions would be determined on the basis of this rating, which may change during the course of nonclinical and clinical development. An example of such a rating system is provided in Table 1.

To minimize "noise" and unnecessary workload, WADA would be notified only of those compounds with likely or confirmed doping potential (categories C and D in the example).

Table 1 Doping Potential Ranking and Associated Actions (Example)

Status ranking*	Actions
A. No or negligible doping potential	• Routine monitoring during development; do not inform WADA
B. Possible doping potential	• Monitoring during development, with additional assessments to further evaluate risk; do not inform WADA
C. Probable doping potential	• Enhanced safety risk evaluation within company • Assessment of risk during formal in-house reviews • Consultation with WADA to further evaluate risk and supply additional data
D. High risk of doping potential	• Defined in consultation with WADA • "Task force" • Dedicated safety risk evaluation • Measures to control drug access • Detailed info to WADA on detection measures, clinical indicators and other support • Frequent communication between company & WADA

* A compound may switch ranking during the course of development depending on the accruing data

3.2.2 Products in Non-Clinical Development

It is anticipated that sufficient evidence for characterization of doping abuse potential would be provided by standard biochemical and *in vitro* and *in vivo* pharmacological characterization, without requiring additional studies.

To a great extent, consideration of risk at very early stages will be based on structure and mechanism of action (see Section 3.1).

It is recommended that consideration of doping abuse potential be included in routine review by internal bodies, such as a nonclinical safety review committee.

3.2.3 Products in Clinical Development

It is recommended that the review of data relevant to doping abuse potential be included prospectively in the standard safety risk evaluation and management for each compound, based on considerations under Section 3.1, and that regular safety review within the company address the question of doping abuse potential.

For compounds for which a doping abuse potential has been identified on the basis of nonclinical development, data collection and/or analysis in clinical trials can be adapted to make specific provision for adequate follow up, as would be the case for any nonclinical safety concerns.

For products proceeding to health authority filings, the absence of, or potential for doping abuse can be documented in regulatory submissions pertaining to misuse potential and risk management, e.g., EU Risk Management Plan Sections 1.9.3 (*Potential for Misuse for Illegal Purposes*) and 1.9.4 (*Potential for Off-label Use*).[4]

3.3 WADA Consultation

Information is shared with WADA on a voluntary basis. It is recommended that WADA be contacted only for those compounds for which in-house review indicates a likely or probable doping abuse potential. It is not intended to involve WADA in in-house review procedures or to share information on compounds without at least a probable doping risk potential (see Section 3.2.1).

4. SHARING OF INFORMATION WITH WADA

4.1 Procedure

1. A designated contact person from the company contacts the WADA Science Department in writing at its dedicated e-mail address: science@wada-ama.org.
2. An initial contact either in writing (documents) or verbally (teleconference) will allow WADA to rapidly assess the doping potential of the compound(s).
3. If the doping potential is confirmed by WADA, a confidentiality agreement (CDA) is signed, unless a blanket agreement covering multiple programmes is already in place, in which case the protections afforded by that agreement may be sufficient.
4. When the CDA is in place, specific confidential information is provided in order for WADA to complete its assessment process.
5. At the end of the assessment process, if deemed necessary, WADA will provide the company with a list of information and specific resources (i.e., reagents) needed to further develop an anti-doping method.

4.2 Timing

Initial and updated information is supplied as it becomes available. There is no requirement for routine reporting or updating to WADA, e.g., annual report.

4.3 Nature and Format of Information to be Shared with WADA and Technical Infrastructure

In WADA and for each company, it is recommended that a key contact person be designated to simplify and streamline general communications. All information exchanged between the company and WADA about compounds having doping potential would be conveyed via the identified contact persons.

If a compound is determined to have genuine doping potential, additional dedicated communication channels would be established.

The product Investigator Brochure (IB) may be a suitable vehicle for information, although it contains information that a company may not wish to share. Alternatives may be an extract from the IB or a standard form providing key information.

Information would be shared only with WADA and not with any third parties such as other biotechnology or pharmaceutical companies. Security of the information within WADA to prevent unauthorized access would be assured.

Protection of proprietary information would be achieved by means of a confidentiality agreement. To minimize administrative workload, a generic template, to cover all compounds of interest at the company, has been developed with WADA for use as a starting point (Appendix 3). This may be adapted or added to, as appropriate, for a given situation.

4.4 Decision on Doping Potential

On the basis of the review process defined above, the company performs an internal assessment of doping abuse potential. An example of a ranking system and associated actions is provided in Table 1. For those agents with at least a probable assessment, the information described in Section 4.3 is supplied to WADA.

Based on the information received, WADA will define the doping potential of the compound(s) and will agree on the next steps with the company. If a genuine doping abuse potential is confirmed by WADA, the actions described in Section 5 will be undertaken.

5. ACTIONS IN CASE OF GENUINE DOPING ABUSE POTENTIAL

5.1 In-house Measures

Once a genuine doping risk has been identified in agreement with WADA, it may be useful to set up within the company a dedicated subteam of the product team for each compound with an identified doping risk potential. This group would be responsible for sharing information and materials with WADA.

It may be of utility to maintain a "reference resource centre" with examples of best practices, etc., within the appropriate department within each company. This would advise and support product teams as they review and evaluate compounds, act as the initial go-between for the company and WADA and support a product team in setting up the dedicated task force, if this is called for.

5.2 WADA Needs for Testing Strategy

WADA will provide the list of information and specific resources needed in order to develop an anti-doping method, and will identify the process and anticipated timeline to be followed. Particular emphasis will be placed on the intervention, if needed, of external parties (e.g., WADA accredited laboratories).

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

- Full information on mechanism of action, structure, receptor targets, abuse potential, preclinical and clinical indicators, pharmacokinetic and pharmacodynamic characteristics, as required by the individual case
- Information on detection (concentrations in blood or tissue, surrogate indicators, diagnostic tests, etc.)
- Support in validating detection methods (e.g., excretion studies to validate anti-doping methodology)
- Supply of materials requested for testing (e.g., specific reagents, reference samples, etc.)
- Information on anti-doping test development, any potential improvement in the detection method and the implementation of the method in anti-doping activities (provided by WADA to the company)

5.3 Company Actions to Control Access

Storage and transport of bulk materials or finished product, including both commercial and clinical trial supplies, represent potential vulnerabilities that can be exploited to divert materials for inappropriate use.

5.3.1 Control of Manufacturing Information

This is governed by internal company-specific procedures.

5.3.2 Bulk Materials

Access to bulk materials is governed by internal company-specific procedures.

If development is discontinued, secure storage or secure destruction measures should be developed and communicated to WADA.

5.3.3 Clinical Trial Supplies

Experience has shown that clinical trial facilities may be vulnerable to diversion of clinical trial supplies with doping potential from their intended use in clinical trials to misuse for doping purposes by athletes or their entourage.

Existing company standard operating procedures for control of clinical trial supplies may provide sufficient protection. However, in the case of compounds where, for example, unused material could be collected from containers discarded after administration (e.g., residue in used vials), additional measures may be required to collect and destroy such material. Additional information to the staff at the investigational site on the doping potential of a new drug in clinical trials and recommendations for enhanced vigilance in control of drug dispensing, storage conditions or supply management, may be helpful under such circumstances. Such measures would be determined on a case-by-case basis.

5.3.4 Access to Commercial Product

Special measures may be required to ensure that commercial product is used only for the authorized purpose. Examples of such measures include controlled dispensing and prescription measures, or patient registries. Such measures would be determined on a case-by-case basis.

WADA should be notified if drug supplies disappear or are stolen, including information on quantity, location, batch numbers, etc.

6. IMPLEMENTATION

Each company should define its own internal process for review of doping abuse potential for compounds, consistent with applicable regulatory requirements and the company's Standard Operating Procedures.

In terms of WADA interaction, implementation of this *Points to Consider* booklet can be staged to prioritize late-phase development compounds (Phase IIb-III), progressing to early development phase compounds in the later stages of implementation.

7. REFERENCES

1. International Federation of Pharmaceutical Manufacturers & Associations. Doping in Sport. Available at: http://www.ifpma.org/ethics/doping-in-sport.html. Accessibility verified July 12, 2012.
2. World Anti-Doping Agency. World Anti-Doping Code. Available at: http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code/. Accessibility verified July 12, 2012.
3. World Anti-Doping Agency. Prohibited List. Available at: http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/International-Standards/Prohibited-List/. Accessibility verified July 12, 2012.
4. European Medicines Agency Committee for Medicinal Products for Human Use. Guideline on Risk Management Systems for Medicinal Products for Human Use. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129134.pdf Published November 20, 2005. Accessed July 12, 2012.

APPENDIX

APPENDIX 1
WADA CRITERIA FOR INCLUSION IN PROHIBITED LIST

The following is extracted from the World Anti-Doping Code 2009: http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/The-Code.

4.3. Criteria for Including Substances and Methods on the Prohibited List

WADA shall consider the following criteria in deciding whether to include a substance or method on the *Prohibited List*.

4.3.1 A substance or method shall be considered for inclusion on the *Prohibited List* if *WADA* determines that the substance or method meets any two of the following three criteria:

4.3.1.1 Medical or other scientific evidence, pharmacological effect or experience that the substance or method, alone or in combination with other substances or methods, has the potential to enhance or enhances sport performance;

4.3.1.2 Medical or other scientific evidence, pharmacological effect or experience that the *Use* of the substance or method represents an actual or potential health risk to the *Athlete;*

4.3.1.3 *WADA's* determination that the *Use* of the substance or method violates the spirit of sport described in the Introduction to the *Code*.

[Comment to Article 4.3.1.1: This Article anticipates that there may be substances that, when used alone, are not prohibited but which will be prohibited if used in combination with certain other substances. A substance which is added to the Prohibited List because it has the potential to enhance performance only in combination with another substance shall be so noted and shall be prohibited only if there is evidence relating to both substances in combination.]

4.3.2 A substance or method shall also be included on the *Prohibited List* if *WADA* determines there is medical or other scientific evidence, pharmacological effect or experience that the substance or method has the potential to mask the Use of other *Prohibited Substances* or *Prohibited Methods*.

[Comment to Article 4.3.2: A substance shall be considered for inclusion on the Prohibited List if the substance is a masking agent or meets two of the following three criteria: (1) it has the potential to enhance or enhances sport performance; (2) it represents a potential or actual health risk; or (3) it is contrary to the spirit of sport. None of the three criteria alone is a sufficient basis for adding a substance to the Prohibited List. Using the potential to enhance performance as the sole criterion would include, for example, physical and mental training, red meat, carbohydrate loading and training at altitude. Risk of harm would include smoking. Requiring all three criteria would also be unsatisfactory. For example, the Use of genetic transfer technology to dramatically enhance sport performance should be prohibited as contrary to the spirit of sport even if it is not harmful. Similarly, the potentially unhealthy abuse of certain substances without therapeutic justification based on the mistaken belief they enhance performance is certainly contrary to the spirit of sport regardless of whether the expectation of performance enhancement is realistic. As part of the process each year, all Signatories, governments and other interested Persons are invited to provide comments to WADA on the content of the Prohibited List.]

APPENDIX 2
OVERVIEW OF PROHIBITED SUBSTANCES AND METHODS

The following is based on Prohibited List (List) 2012. For the most up-to-date version, please consult the WADA website: http://www.wada-ama.org/en/World-Anti-Doping-Program/Sports-and-Anti-Doping-Organizations/International-Standards/Prohibited-List/.

The Prohibited List aids in prospective identification of substance classes or mechanisms of action that have known potential for doping abuse.

SUBSTANCES AND METHODS PROHIBITED AT ALL TIMES (in and out of competition)	
Prohibited Substances	
S0.	Non-approved substances
	Any pharmacological substance which is not addressed by any of the subsequent sections of the List and with no current approval by any governmental regulatory health authority for human therapeutic use (e.g., drugs under pre-clinical or clinical development or discontinued, designer drugs, veterinary medicines) is prohibited at all times.
S1.	Anabolic agents
	1. Anabolic androgenic steroids (AAS) a) Exogenous b) Endogenous, when administered exogenously 2. Other anabolic agents
S2.	Peptide hormones, growth factors and related substances
	1. Erythropoiesis-Stimulating Agents 2. Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) in males 3. Insulins 4. Corticotrophins 5. Growth Hormone (GH), Insulin-like Growth Factor-1 (IGF-1), Fibroblast Growth Factors (FGFs), Hepatocyte Growth Factor (HGF), Mechano Growth Factors (MGFs), Platelet-Derived Growth Factor (PDGF), Vascular-Endothelial Growth Factor (VEGF) as well as any other growth factor affecting muscle, tendon or ligament protein synthesis/degradation, vascularisation, energy utilization, regenerative capacity or fibre-type switching; and other substances with similar chemical structure or similar biological effect(s).
S3.	Beta-2 agonists
S4.	Hormone antagonists and metabolic modulators
	1. Aromatase inhibitors 2. Selective estrogen receptor modulators (SERMs) 3. Other anti-estrogenic substances 4. Agents modifying myostatin functions 5. Metabolic modulators
S5.	Diuretics and other masking agents

SUBSTANCES AND METHODS PROHIBITED AT ALL TIMES (in and out of competition) *(continued)*	
Prohibited Methods	
M1.	Enhancement of oxygen transfer
	1. Blood doping, including the use of autologous, homologous or heterologous blood or red blood cell products of any origin
	2. Artificially enhancing the uptake, transport or delivery of oxygen
M2.	Chemical and physical manipulation
	1. Tampering, or attempting to tamper, in order to alter the integrity and validity of Samples collected during Doping Control is prohibited. These include but are not limited to urine substitution and/or adulteration (e.g., proteases)
	2. Intravenous infusions and/or injections of more than 50 mL per six-hour period are prohibited except for those legitimately received in the course of hospital admissions or clinical investigations
	3. Sequential withdrawal, manipulation and reintroduction of any quantity of whole blood into the circulatory system
M3.	Gene doping
	1. The transfer of nucleic acids or nucleic acid sequences
	2. The use of normal or genetically modified cells
SUBSTANCES AND METHODS PROHIBITED IN COMPETITION *in addition to S0-S5 and M1-M3*	
Prohibited Substances	
S6.	Stimulants
	a: Non-Specified Stimulants
	b: Specified Stimulants
S7.	Narcotics
S8.	Cannabinoids
S9.	Glucocorticoids (oral, intravenous, intramuscular, rectal routes)
SUBSTANCES PROHIBITED IN PARTICULAR SPORTS	
P1. Alcohol	
P2. Beta-blockers	

APPENDIX 3
TEMPLATE MEMORANDUM OF UNDERSTANDING AND CONFIDENTIALITY AGREEMENT

Memorandum of Understanding

This memorandum of understanding is entered into with effect as of the Effective Date

(as defined below)

by and between

Company X

with an office and place of business _____ ("Partner")

and

World Anti-Doping Agency

Stock Exchange Tower 800 Place Victoria (Suite 1700), P.O. Box 120, Montreal (Quebec) H4Z 1B7, Canada ("WADA")

WHEREAS doping in sport relies primarily on misuse and abuse of commercially available medicines as well as newly discovered Compounds entering/having entered clinical development.

WHEREAS doping does not only affect the fairness of sport competitions by illegally enhancing athletic performance, but also causes potentially harmful side effects for the health of doped athletes.

WHEREAS WADA is the international agency mandated to fight against doping in sport in all its forms.

WHEREAS Partner is willing to support WADA in its fight against doping in sports by establishing an internal process in order to identify Compounds in development with a potential for sports-related abuse as early as possible.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Affiliate

The term "Affiliate" shall mean any individual, corporation, association or other business entity which directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of "Affiliate," the term "control" means the direct or indirect ownership of more than fifty percent (>50%) of the stock, having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.

1.2 Agreement

The term "Agreement" shall mean this document, including any and all appendices and amendments to it as may be added and/or amended from time to time in accordance with the provisions of this Agreement.

1.3 Appendix

The term "Appendix" shall mean an appendix to this Agreement.

1.4 Compound

The term "Compound" shall mean any compounds in development by Partner.

1.5 Confidential Information

The term "Confidential Information" shall mean any and all information, data or know-how, whether technical or non-technical, oral or written, that is disclosed by Partner or its Affiliates ("Disclosing Party") to WADA ("Receiving Party"). The term "Confidential Information" is not deemed to include any information, data or know-how which:

a) was generally available to the public at the time of disclosure, or information which becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party,

b) can be shown to have been in possession or control on a non-confidential basis of the Receiving Party prior to its receipt from the Disclosing Party,

c) is obtained at any time lawfully from a third Person under circumstances permitting its use or disclosure,

d) is developed independently by the Receiving Party as evidenced by written records other than through knowledge of Confidential Information,

e) is required to be disclosed by the Receiving Party to comply with a court or administrative order providing the Receiving Party furnishes prompt notice (in no event less than three (3) days) to the Disclosing Party to enable it to resist such disclosure, or is approved in writing by the Disclosing Party for release by the Receiving Party.

1.6 Effective Date

The term "Effective Date" shall mean _____.

1.7 Information Manager

The term "Information Manager" shall have the meaning as set forth in section 3.1 of this Agreement.

1.8 Inventions

The term "Invention" shall mean an invention whether patentable or not related to, including or referencing a Compound that is conceived or discovered in connection with any activity carried out pursuant to this Agreement. Under this definition, an Invention may be made by employees of WADA, by employees of Partner or its Affiliates solely or jointly with a Third Party, or jointly by employees of WADA and Partner or its Affiliates with or without a Third Party.

1.9 Party

The term "Party" shall mean WADA or Partner, as the case may be, and "Parties" shall mean WADA and Partner collectively.

1.10 Third Party

The term "Third Party" shall mean a person or entity other than (i) WADA or (ii) Partner or any of its Affiliates.

2. SUPPORT OF WADA IN ITS FIGHT AGAINST DOPING

2.1 Principle

Partner is willing to support WADA in its fight against doping in sports by establishing a Partner internal process in order to identify Compounds in development with a potential for sports-related abuse. For the avoidance of any doubt, it is understood by WADA that Partner shall establish such internal process at Partner's sole discretion.

2.2 Process

Partner's internal process will assess in-house Compounds at different stages of development as to their potential for doping abuse. In order to align such internal assessment, Partner may notify WADA only of those Compounds for which Partner in its sole discretion identifies a likely or confirmed doping potential. For the avoidance of any doubt, it is understood by WADA that it is not intended to involve WADA in any in-house review procedures or to share any information or Confidential Information for Compounds for which Partner did not identify a likely or confirmed doping potential.

WADA may draw the attention of the Partner to a substance with suspected doping potential in the Partner's pipeline of drugs in development. The Partner should act diligently with WADA in order to further assess the doping potential of such a drug.

3. SHARING INFORMATION WITH WADA

3.1 Voluntary Basis

Any sharing of information and Confidential Information between WADA and Partner occurs on a purely voluntary basis. Nothing in this Agreement shall stipulate any binding obligation of Partner to share any information or Confidential Information with WADA. Each Party shall appoint an Information Manager.

The Information Manager shall be the point of contact within each Party with responsibility for facilitating information exchange between the Parties.

3.2 Initial Information to WADA

If Partner identifies a Compound for which in-house review indicates a likely or probable doping abuse potential, then Partner's Information Manager shall provide written notice to WADA's Information Manager. Upon receipt of such initial notice the Parties shall initiate a first discussion in order to allow WADA to rapidly assess the doping potential of the affected Compound. Such first discussion may occur in writing or verbally, as agreed to by the Information Managers of both Parties.

3.3 Information Sharing by Partner with WADA

If the doping potential of the affected Compound is confirmed by WADA, then prior to any further exchange of information, the Parties shall execute a confidentiality agreement, a template of which is attached to this Agreement as Appendix 1. Upon execution of such confidentiality agreement specific, Compound-related Confidential Information of Partner may be shared with WADA in order for WADA to complete its assessment of the doping potential of the affected Compound. If the doping potential is confirmed by WADA, then the Parties shall agree on further measures.

3.4 Ownership of Inventions

All Inventions shall be the sole, exclusive and unburdened property of Partner. WADA shall promptly disclose in writing to Partner each Invention and provide to Partner all information known to WADA reasonably relating to such Inventions. WADA agrees to sign all necessary documents or take such other actions as Partner may reasonably request in order to perfect any and all such rights. In particular, WADA shall assign to Partner all of WADA's right, title and interest in and to each such Invention. All costs and expenses for perfecting and enforcing its rights in such Invention shall be borne by Partner.

Partner hereby grants to WADA a non-exclusive and free license for non-commercial purposes to use Inventions related to newly-developed detection methods for sport-related abuse of Compounds. WADA shall have the right to grant sublicenses to WADA accredited anti-doping laboratories for their routine and research anti-doping activities.

4. REPRESENTATIONS AND WARRANTIES OF WADA

4.1 Authorization

The execution, delivery and performance of this Agreement by WADA and all instruments and documents to be delivered by WADA hereunder:

a) are within the corporate power of WADA,

b) have been duly authorized by all necessary or proper corporate action,

c) to the best knowledge of WADA, will not violate any law or regulation or any order or decree of any court of governmental instrumentality, and

d) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously.

4.2 No Claims

There are no claims or investigations pending or threatened against WADA or any of its Affiliates, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially adversely affect WADA's ability to perform its obligations hereunder.

4.3 No Other Representations

EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THIS AGREEMENT.

WADA specifically acknowledges that the internal process established by Partner may not enable Partner to identify each Compound with likely or confirmed doping potential and that Partner does not give any related representation or warranty of any kind.

4.4 Disclaimer

NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

5. OBLIGATION NOT TO DISCLOSE CONFIDENTIAL INFORMATION

5.1 Non-Use and Non-Disclosure

During the Term of this Agreement and for ten (10) years thereafter WADA shall:

a) treat Confidential Information provided by Partner as strictly confidential and at least as it would treat its own information of a similar nature,

b) use its best efforts not to disclose such Confidential Information to Third Parties, without Partner's prior written consent, and

c) not use such Confidential Information other than for fulfilling its obligations under this Agreement.

5.2 Press Releases

5.2.1 Principle

In the context where it is necessary to communicate with media, on any given situation, a Party shall contact the other Party prior to responding to the media and both Parties will agree to the public information to be shared. Whenever possible, advance notice of all such communications should provide for at least five working days prior to publication.

Each Party shall only issue press releases related to the activities contemplated by this Agreement that either:

a) have been approved by the other Party or

b) are required to be issued by a Party as a matter of law.

In all circumstances, a Party shall provide the other Party (hereafter the "Reviewing Party") with a draft press release at least two (2) weeks prior to its intended publication for the Reviewing Party's review.

During such period the Reviewing Party shall either:

a) approve the draft press release and permit the other Party to issue the press release,

b) contact the other Party to discuss modification to the draft press release, or

c) contact the other Party and disapprove the press release.

If the Reviewing Party asks for modification, then the other Party shall either make such modification or work with the Reviewing Party to arrive at a press release that the Reviewing Party approves.

6. TERM AND TERMINATION

6.1 Commencement and Term

This Agreement shall enter into force as of the Effective Date. The Agreement shall remain in force for a period of 5 (five) years (the Initial Term). Unless the Agreement is terminated by either Party by a 6 (six) months' prior written notice, the Agreement shall be automatically extended by 2 (two) years after the Initial Term or after any subsequent extension term.

6.2 Termination

Each Party shall have the right to terminate this Agreement at any time and for any reason by giving the other Party a six (6) months' prior written notice.

6.3 Survival

Sections 3.4 (Ownership of Inventions), 5.1 (Non-Use and Non-Disclosure) and 7.1 (Governing Law) shall survive any expiration or termination of this Agreement for any reason.

7. MISCELLANEOUS

7.1 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of _____, without reference to its conflict of laws principles.

The competent courts of _____ shall have the exclusive jurisdiction.

7.2 Disputes

In the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or their designees, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For WADA: Director General

For Partner: _____

7.3 Assignment

Neither Party shall have the right to assign the present Agreement or any part thereof to any Third Party without the prior written approval of the other Party.

7.4 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions which will achieve as far as possible the economic business intentions of the Parties. However, the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e., the Parties would presumably have concluded this Agreement without the unenforceable provisions.

7.5 Waiver

The failure by either Party to require strict performance and/or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance and/or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition.

7.6 Entire Understanding

This Agreement contains the entire understanding between the Parties hereto with respect to the within subject matter and supersedes any and all prior agreements, understandings and arrangements, whether written or oral.

7.7 Amendments

No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

7.8 Notice

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested and addressed as follows:

if to WADA, to:	World Anti-Doping Agency Attn. Director Legal Department Stock Exchange Tower 800 Place Victoria Box 120 Montreal, Quebec, H4Z 1B7 CANADA Facsimile No: +1 514 904 8754
if to Partner, to:	(Address and Contact of Partner)

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

World Anti-Doping Agency

By:

Name: Hon. John Fahey
Title: WADA President

By:

Name: Mr. David Howman
Title: WADA Director General

By:

Name: Dr. Olivier Rabin
Title: WADA Director, Science

Partner

By:

Name:
Title:

By:

Name:
Title:

APPENDIX 1

CONFIDENTIALITY AGREEMENT

between

_____

(hereinafter "PARTNER")

and

World Anti-Doping Agency, Stock Exchange Tower 800 Place Victoria (Suite 1700), P.O. Box 120, Montreal (Quebec) H4Z 1B7, Canada ("WADA") (hereinafter "WADA").

_____

WHEREAS, PARTNER has developed and possesses certain proprietary information relating to _____ (hereinafter called "INFORMATION");

WHEREAS, WADA desires to obtain access to such INFORMATION for the purpose of evaluating and assessing its potential for sports-related abuse (hereafter the Purpose);

WHEREAS, PARTNER is willing to disclose to WADA said INFORMATION for the Purpose;

NOW, THEREFORE, the parties hereto agree as follows:

1. PARTNER should, after execution of this Agreement by both parties, provide WADA with the INFORMATION.

2. The INFORMATION will be disclosed to WADA with the express understanding that neither WADA nor PARTNER will be obligated to enter into any further agreement relating to INFORMATION. In addition, nothing in this Agreement shall be construed as granting any license or right in and to INFORMATION to WADA.

3. It is understood that such INFORMATION is proprietary to PARTNER and WADA will treat such INFORMATION for a period of ten (10) years after its disclosure hereunder in strict confidence and will not divulge the INFORMATION to third parties or use any INFORMATION for any other purpose than the Purpose except as follows:

   a) to the extent such INFORMATION is public knowledge or after disclosure hereunder becomes public knowledge through no fault of WADA; or

   b) to the extent such INFORMATION can be shown by WADA to have been in its possession or control on a non-confidential basis prior to the date of disclosure hereunder; or

   c) to the extent such INFORMATION is received by WADA from any third party without any obligation to PARTNER.

4. WADA will advise PARTNER within six (6) months from the date of the disclosure of INFORMATION hereunder whether WADA is interested in negotiating a further agreement. Should WADA not be interested in negotiating a further agreement, all INFORMATION disclosed to WADA by PARTNER under this Agreement shall be returned to PARTNER, if so requested by PARTNER, except that one copy may be kept for archive purposes.

5. This Agreement shall be governed in all respects by the laws of _____ and the competent courts of _____shall have the exclusive jurisdiction.

Place, _____(date)

Partner

_____

[name]

Place, _____(date)

World Anti-Doping Agency

_____

[name]

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