



CONCLUSIONS

PARIS - 12 NOVEMBER 2012









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THE PHARMACEUTICAL INDUSTRY AND THE FIGHT AGAINST DOPING:

NEW PARTNERSHIPS FOR CLEAN SPORT

EXECUTIVE SUMMARY

The International Conference on "The Pharmaceutical Industry and the Fight Against Doping: New Partnerships for Clean Sport," was the first event of its kind, bringing together biopharmaceutical companies and their representative associations with the authorities in charge of the fight against doping in sports. The key objective of the conference was to strengthen and develop the efforts between these entities to better prevent misuse of drugs in development with doping potential in sports.

The many successful collaborations in recent years between individual pharmaceutical/ biotechnology companies and the World Anti-Doping Agency (WADA) demonstrate the feasibility of a mutually beneficial partnership model to develop anti-doping tests for new drugs with doping potential to deter their abuse by athletes.

Based upon such experiences, practical tools have been developed jointly by the biopharmaceutical industry and WADA to facilitate information transfer. Encapsulated under the 2 FIELDS 1 GOAL Campaign launched in July 2012, these tools are available to biopharmaceutical companies willing to address the risk of doping potential of any drug in their developmental pipelines.

This conference led to strong support from all participating parties of the innovative, collaborative partnership model. Several recommendations and initiatives were highlighted to further strengthen and expand the model in the near future, for the benefit of biopharmaceutical companies and anti-doping authorities – WADA in particular – and with the full backing of the international public authorities attending.



PROGRAMME

CO-ORGANISED BY

Ministry of Sports, Youth, Non Formal Education and Voluntary Organisations of France

Council of Europe

UNESCO

World Anti-Doping Agency

FRENCH PARLIAMENT HOUSE

Immeuble (Building) Chaban-Delmas Salle (Room) Victor Hugo 101 rue de l'Université 75007, Paris (FRANCE)

12 NOVEMBER 2012

8:30 - 9:30 Welcoming of participants

> 9:30 - 12:00 First session

14:00 - 17:00 Second session



THE PHARMACEUTICAL INDUSTRY AND THE FIGHT AGAINST DOPING:





Paris - 12 November 2012

First Session - 9:30 to 12:00

THE PHARMACEUTICAL INDUSTRY AND THE WORLD ANTI-DOPING AGENCY: UNITING FOR CLEAN SPORT

OPENING

- Ms Valérie Fourneyron, Minister of Sports, Youth, Non Formal Education and Voluntary Organisations, France
- Ms Gabriella Battaini-Dragoni, Deputy Secretary General, Council of Europe
- M. Getachew Engida, Deputy Director General, UNESCO
- Hon. John Fahey, President, World Anti-Doping Agency (WADA)
- Dr Jacques Rogge, President, International Olympic Committee (IOC)

PART 1 Societal and economic risks of doping

- M. David Howman, Director General, WADA
- Dr Timothy Armstrong, Coordinator Surveillance and Population-based Prevention Unit, World Health Organisation (WHO)
- M. Philippe Lamoureux, Director General, LEEM, and Council Member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

PART 2 Health industry and anti-doping authorities: what is at stake in the cooperation?

- **Prof. Arne Ljungqvist**, Vice President, WADA
- M. Philip Thomson, Senior Vice President, Global Communications, GlaxoSmithKline
- M. James C. Greenwood, President and CEO, Biotechnology Industry Organisation (BIO)

PART 3 Health industry and anti-doping authorities: past experiences and lessons learnt

- Dr Olivier Rabin, Science Director, WADA
- Dr Philippe Van Der Auwera, Global Head of Drug Safety, Roche

CLOSE The way forward

- Hon. John Fahey, President, WADA



THE PHARMACEUTICAL INDUSTRY AND THE FIGHT AGAINST DOPING:

NEW PARTNERSHIPS FOR CLEAN SPORT





Second session - 14:00 to 17:00

PRESENTATION OF THE OPERATIONAL FRAMEWORK TO THE PARTIES CONCERNED (PUBLIC AUTHORITIES AND PHARMACEUTICAL FIRMS) TO ENSURE THEIR EFFECTIVE INVOLVEMENT

ROUND TABLE 1 From the political concept to raising awareness among those involved:

what kind of network to build and how to include all the stakeholders?

Moderator: - Prof. Arne Ljungqvist, Vice President, WADA

- M. Jean-Pierre Bourely, Head of Office "Promotion of Health, Protection of Population, and Rapporteur:

Prevention of Doping", French Ministry of Sports

Panelists: Dr Laetitia Bigger, Senior Manager Vaccines Policy, IFPMA

- Dr Timothy Armstrong, Coordinator Surveillance and Population-based Prevention Unit, WHO

- M. Andy Parkinson, Chair of the Ad Hoc European Committee for the World Anti-Doping Agency

(CAHAMA) and Chief Executive, UK Anti-Doping

- M. Andrew Emmett, Managing Director, Science and Regulatory Affairs, US BIO

- M. Alexander Schischlik, Team-Leader Anti-Doping and Sports Programme, UNESCO

ROUND TABLE 2 What framework is needed for co-operation between the World Anti-Doping Agency

and stakeholders in the health sector?

Lessons learnt: from awareness raising to implementation

Moderator: - **Dr Steve Elliott**, Scientific Executive Director, Amgen (Retired)

Rapporteur: - M. Marc de Garidel, Chairman & CEO, Ipsen and Chairman, G5 Group

Panelists: - Ms Barbara Leishman, Head of Safety Science Quality Risk Management, Roche

> - Ms Melodi McNeil, Director Regulatory Policy and Intelligence, Abbott - M. Mark Luttmann, WADA Cooperation Coordinator, GlaxoSmithKline

- Dr Anne-Marie Duliège, Chief Medical Officer, Affymax

- Dr Olivier Rabin, Director Science, WADA

SUMMARY How to build on the work already done and further develop co-operation through

an action programme?

- M. David Howman, Director General, WADA General rapporteurs:

- M. Bruno Genevois, President, Agence française de lutte contre le dopage (AFLD)



Paris - 12 November 2012

CLOSE: THE WAY FORWARD

Hon. John FAHEY

President, World Anti-Doping Agency (WADA)

I would like to thank the speakers for their contributions. They have confirmed that today we find ourselves in a unique situation. In the early days of the fight against doping, the partnership established had many detractors, but the results of the last few years have shown that it has produced positive outcomes. However, the need to go further and expand our network will always exist.

It is therefore obvious that sample analysis is not sufficient. We also need to identify the substances that exist and are distributed.

Over the last few years, partnerships have therefore extended to other stakeholders, including law enforcement agencies. For example, INTERPOL in Lyon has an agent working exclusively on this issue. We have also made contact with the customs authorities.

Finally, you have seen how we have developed partnerships with the pharmaceutical industry. The contributions from Roche and GSK have clearly demonstrated the effectiveness of this work in preventing the illicit use of compounds that are perfectly legitimate in other circumstances.

We know that doping is not confined to elite athletes. We want our young people to live healthy lives. This is also the objective of the pharmaceutical industry, and we have seen this morning that it is possible to produce positive results in this area.

I think that these presentations have effectively prepared the ground for the discussions we will have this afternoon on the methods we need to implement and develop.

Any doubts I might have had on the willingness of the pharmaceutical industry to cooperate have been swept aside by this morning's contributions.

At the WTO Doha Ministerial Conference, governments and the pharmaceutical industry agreed to provide access to AIDS drugs for all patients. This clearly demonstrates the willingness of the pharmaceutical industry to take action that leads to results when the stakes are high enough.

We also need to involve the small companies that are making discoveries and scientific advances. We must collaborate with them. I would like to thank Philip Thomson, who responded to those who have concerns about respect for intellectual property rights in the context of the fight against doping.

We have demonstrated this morning that if we have the will to do so, we can all work together to combat substance abuse, wherever it takes place.

Thank you very much. Your contributions have demonstrated your willingness to do the right thing. The time has now come to transform good intentions into concrete actions.

Paris - 12 November 2012



From the political concept to raising awareness among stakeholders: What kind of network to build and how to include all stakeholders?

Moderator: Prof. Arne LJUNGQVIST, Vice President, World Anti-Doping Agency (WADA).

Reporter: Jean-Pierre BOURELY, Head of Office "Promotion of Health, Protection of Population, and Prevention of Doping," French Ministry responsible for Sport.

Dr. Laetitia BIGGER, Senior Manager, Vaccines Policy, IFPMA.

Dr. Timothy ARMSTRONG, Coordinator, Surveillance and Population-based Prevention Unit, World Health Organization (WHO).

Andy PARKINSON, Chair of the Ad Hoc European Committee (CAHAMA) for WADA, and Chief Executive, UK Anti-Doping.

Andrew EMMETT, Managing Director, Science and Regulatory Affairs, US BIO.

Alexander SCHISCHLIK, Team-Leader, Anti-Doping and Sports Programme, UNESCO.

Jean-Pierre BOURELY

I will now draw some conclusions from this round table discussion.

We can use as our starting point the UNESCO Convention, which is now 17 years old and has been ratified by 172 out of 193 States.

Doping is an important issue that motivates governments to act, because it affects not only sport, but society as a whole. It is also an issue of public health, as it concerns not only elite athletes, or even athletes generally, but the entire population. We have seen how the pharmaceutical industry was particularly sensitive to the problem of doping, because it raised questions of responsibility for the sector. It cannot disassociate itself from the way in which drugs are consumed.

The whole of society is therefore affected. This should be underlined. Educating patients and consumers is an important aspect of the fight against doping. We also need to identify appropriate procedures for early detection of substances that are being misused. The intervention of AFNOR is an interesting one from this point of view, as we can draw a parallel with dietary supplements: Their consumption is not essential, and we must ensure that they are not harmful. We need to use the lessons learned from this experience.

Doping is bad for sport, but also for public health. Elite athletes employee highly sophisticated and technologically advanced doping practices.

The challenge is to convince the parties involved, and initiate a win-win dialogue based on cooperation willingly given. We have to jointly create a mechanism so that all aspects of this collaborative process are capable of providing what the parties involved need.

The authorities that work to combat doping want more effective investigation resources. The pharmaceutical industry must be convinced of the positive benefits of its involvement in the fight, particularly in terms of PR and the prevention of illicit drug use. The pharmaceutical industry is involved in a public health initiative that will also require prevention and education.

We also need to guarantee the preservation of industrial secrets for the pharmaceutical industry, both in technical and legal terms. In this regard, the IFPMA has allotted the resources to construct this kind of cooperation by distributing information, while also preserving confidentiality.

We need an intelligent dialogue between WADA and international pharmaceutical groups, but also at a local level, and with the same guarantees. Through its role of global cooperation, WADA will ensure the overall consistency of the project.

Finally, the Council of Europe must play a structural role by inviting its members to become actively involved in this cooperation between the pharmaceutical industry and its Member States.



Paris - 12 November 2012

ROUNDTABLE 2: CONCLUSIONS

What framework is needed for cooperation between the World Anti-Doping Agency and stakeholders in the health sector?

Lessons learned: From raising awareness to implementation

Moderator: Dr. Steve ELLIOTT, Scientific Executive Director, Amgen (Retired)
Reporter: Dr. Patrick DELAVAULT, SrVP, Chief Medical Officer, IPSEN Group
Barbara LEISHMAN, Head of Safety Science Quality Risk Management, Roche
Melodi MCNEIL, Director, Regulatory Policy and Intelligence, Abbott
Mark LUTTMANN, WADA Cooperation Coordinator, GlaxoSmithKline

Dr. Anne-Marie DULIEGE, Chief Medical Officer, Affymax

Dr. Olivier RABIN, Science Director, WADA

Patrick DELAVAULT

It seems to me that there are four key challenges that have been highlighted by our discussions.

You spoke about war, but who is the enemy? This has yet to be determined. I don't have a firm opinion on this question. The first message is therefore to identify the enemy, and to realize that doping is a threat to health. Today, performance is very highly valued in our societies, and some are willing to do anything to achieve it. So it's a serious social issue that is no longer confined to elite sport.

Doping is the use of drugs for purposes other than their original intention, which leads to health risks. It's our responsibility, as the pharmaceutical industry, to act with WADA to combat doping.

The pharmaceutical industry is a key player but the regulatory authorities also have a role to play.

The second message consists of integrating the fight against doping into the culture of the pharmaceutical industry. It's not so much a question of resources or time, but more a

change of culture. The issue of the doping potential of a product should be integral to discussions throughout the development of a compound, within the context of risk management. This is especially important, as doping also harms the image of the pharmaceutical industry and represents a counterfeiting risk.

The third point is that the organization of this conference is a sign of the progress made in cooperation to combat doping. The IFPMA and WADA are today working more closely together to identify drugs with doping potential, to exchange information and to explore testing methods. This cooperation has developed on a voluntary basis. It is simple to implement. The examples given today show us the steps we need to follow, and this document should be widely distributed in the pharmaceutical sector.

Finally, in order to promote this cooperation, we must expand it further. We need to identify pharmaceutical companies that want to set up information flows and cooperate with WADA. The network of contacts between the IFPMA and WADA should be strengthened. We should also capitalize on the results of this conference, which we could be repeated in 2014.



Paris - 12 November 2012

CONFERENCE SUMMARY

How to build on the work already accomplished, and further develop cooperation through an action program?

Bruno GENEVOIS

President, French Anti-Doping Agency (AFLD)

The debates have been full of interest and wide-ranging, and I will draw two conclusions from them: WADA has played an essential role in cooperation with the pharmaceutical industry, and should continue to do so. However, it cannot act alone.

WADA has acquired important experience since 2004, particularly in terms of centralizing information. In addition, it is capable of guaranteeing the requirement of confidentiality. It also has power of initiative, and because of its relations with national agencies, is able to provide the feedback that some contributors have requested.

However, it cannot act alone. It needs contact with representatives from the pharmaceutical industry, in particular the smaller companies. Cooperation must be extended to the entire sector. The difficulty lies in finding a sufficient motive through which to cooperate. Regarding the large firms, we have seen that they have understood the advantage of being involved in the fight against doping. There may be less motivation for a smaller organization, and we therefore need to encourage it.

Other partnerships are also necessary for WADA. These concern national stakeholders first. Here, I'm thinking about the laboratories accredited by WADA. The Chatenay-Malabry laboratory, for example, was entrusted with the specific task of detecting a given product. National medicines agencies can also spread WADA's work. They need to be made aware of the impact of products with doping potential when granting market authorizations. There's still progress to be made in this area.

National anti-doping agencies can also promote WADA's work. They should be able to benefit from the results obtained by WADA in its collaboration with the pharmaceutical industry.

ISO standards have been mentioned. I can't see what role they could play in terms of new compounds, but in the area of dietary supplements, they are indeed useful.

The European Union also has a medicines agency that could play the same role as the national bodies, but at European level.

I agree that the Council of Europe represents an excellent forum for extending WADA's action.

Finally, UNESCO also has a role to play in completing this work. Through the 10th anniversary of its Convention, we could plan to include an article on the usefulness of collaboration with the pharmaceutical industry for anti-doping purposes.

After hearing these debates, I am more than ever convinced of the usefulness of adding an SO line to the list of substances banned by WADA, which would include new compounds not yet tested.

Finally, if we succeed in developing this collaboration, we will at last be able to say that the fight against doping is one of yesterday's wars.



Paris – 12 November 2012



Director General, World Anti-Doping Organization (WADA)

From my point of view, this conference has been very positive. I would like to thank our hosts. It's unusual for governments to organize such an event for the private sector. I would like to congratulate the representatives from the pharmaceutical industry, who have come here at the invitation of public stakeholders.

It is significant for WADA that manufacturers felt it was important to participate in this work, and I would like to thank you for your collaboration.

We have been talking about doping athletes, but the vast majority of clean sportspeople that we support are hidden from view. Dopers are bad people, supported by bad teams. They do not respect our values, and all they think about is success, regardless of the price.

The pharmaceutical industry and WADA have produced a globally applicable operational model. We are working with multinationals, but also with smaller companies. We have learned to trust each other. This conference is the living proof of that.

I would like us to organize a new conference on this subject in a few years' time, and I would like to thank you for your participation and your contribution.