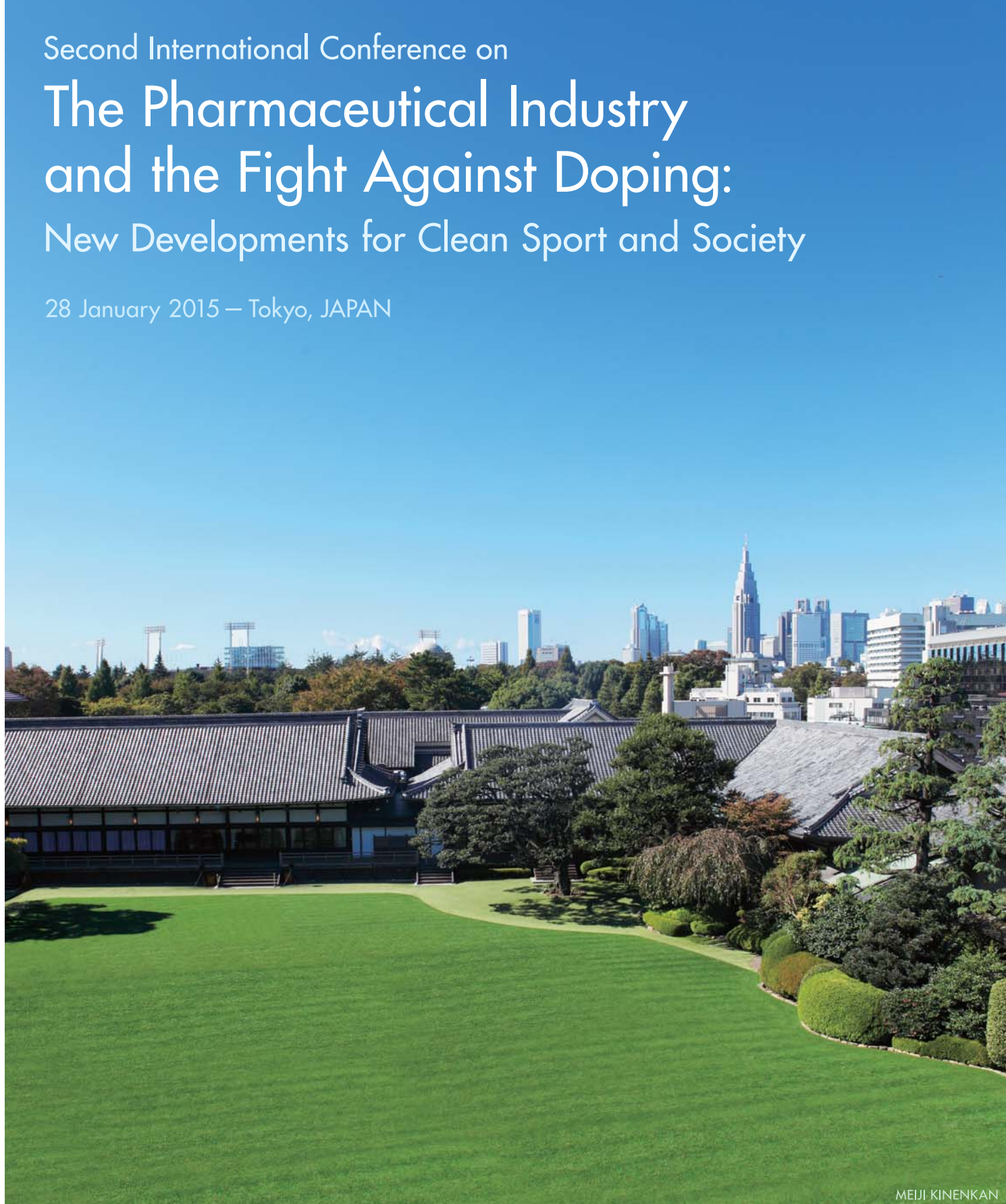


Second International Conference on  
**The Pharmaceutical Industry  
and the Fight Against Doping:**  
New Developments for Clean Sport and Society

28 January 2015 — Tokyo, JAPAN



MEIJI KINENKAN



Supported by :  The Federation of Pharmaceutical Manufacturers' Associations of JAPAN (FPMAJ)  
Japan Pharmaceutical Manufacturers Association (JPMA)

# Second International Conference on The Pharmaceutical Industry and the Fight Against Doping: New Developments for Clean Sport and Society

## Outline

### "The Pharmaceutical Industry and the Fight Against Doping: New Developments for Clean Sport and Society"

was held at Meiji-Kinenkan, Tokyo, Japan on 28 January 2015. This Tokyo-based Conference included more than 300 representatives from across pharmaceutical, anti-doping and sport communities as well as the media.

It was organised by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) of Japanese Government, the World Anti-Doping Agency (WADA), the Japan Anti-Doping Agency (JADA) and UNESCO.

The Tokyo Conference was also supported by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) and the Japan Pharmaceutical Manufacturers Association (JPMA). The represented presenters came from international organisations such as the World Health Organisation (WHO), INTERPOL and pharmaceutical companies, some of whom had previously signed MOUs with WADA.

The event was broken into morning and afternoon sessions, with the press conference taking place at lunchtime.

The Conference focused on the latest steps in the increased cooperation between the anti-doping and pharmaceutical industries. It explored new ways to help protect the rights of clean athletes and the integrity of sport as well as the ways that help restrict the abuse of licensed and unlicensed medicines and ensure the promotion of public health.

## Background

The Tokyo Conference on "The Pharmaceutical Industry and the Fight Against Doping: New Developments for Clean Sport and Society" was held following the groundbreaking inaugural event in Paris, France, in November 2012.

This first event was based on the joint initiative by WADA and IFPMA who signed the "Joint Declaration on Cooperation in the Fight against Doping in Sport" in July 2010, which in turn was endorsed by the global Biotechnology Industry Organization (BIO) in June 2010.

In July 2013, WADA and IFPMA launched the "2 Fields, 1 Goal" campaign along with the Points to Consider booklet.

This has helped companies to establish a voluntary process for determining the potential doping risk of compounds in their development pipelines. Global partnerships have since been formed with leading pharmaceutical industries such as Amgen, GlaxoSmithKline, Roche, and more recently, Pfizer and Novartis.

Following on from this global initiative, Japan stepped up to take a 'local' approach, and WADA, JADA and FPMAJ signed a Joint Declaration on Cooperation in the "Promotion of Anti-Doping Activity & Declaration of Integrity of Sport" on 26 June 2013.

Recognising doping as a public health and significant societal issue, this joint declaration aspired to prevent the risk of misuse of medicines with doping potential and aimed to identify potential doping compounds at an early stage of clinical trials as well as the development of research in detection methods.

Doping is an issue that permeates other areas of the society, too.

It has become imperative to prevent the abuse and misuse of sport-related drugs and to establish a collaborative relationship between the international and national governmental and non-governmental agencies for their mutual benefit.

Information sharing is at the heart of such partnerships.

The pharmaceutical companies share information with WADA regarding pipeline products that have potential for athletes performance misuse, so that WADA can quickly and effectively develop suitable prevention and detection strategies.

In turn, WADA exchanges information with the pharmaceutical companies on substances in development that could be abused by athletes as well as the risk of illegal manufacturing or counterfeiting in the field of sport.

# Timetable

First Session 9:30 ~ 12:00

## The Pharmaceutical Industry and the World Anti-Doping Agency: Uniting for Clean Sport and Society

Opening:	Mr. Hideki Niwa	State Minister of Education, Culture, Sports, Science and Technology (MEXT), Japan	Executive Committee, World Anti-Doping Agency (WADA)
	Sir. Craig Reddie	President, WADA	
	Ms Angela Melo	Director, Ethics, Youth and Sport Division, Sector for Social and Human Sciences, UNESCO	
Part 1:	<b>Societal and Economic Risks of Doping</b>		
	Mr. David Howman	Director General, WADA	
	Dr. Tatsuya Kondo	Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)	
	Dr. Temo Waqanivalu	Team Leader, World Health Organization (WHO)	
	Mr. Clément De Maillard	Criminal Intelligence Officer, INTERPOL	
Part 2:	<b>Challenges in Anti-Doping and Role of the Biopharmaceutical Industry</b>		
	Dr. Valérie Fournayron	Chair of Health, Medical & Research Committee, WADA	
	Dr. Steven Elliott	Scientific Executive Director (retired), Amgen	
	Mr. Masafumi Nogimori	Vice President IFPMA, President FPMAJ	
Part 3:	<b>Biopharmaceutical Industry and Anti-Doping Authorities: Expectations and Perspectives for the future</b>		
	Dr. Olivier Rabin	Senior Director, Science, WADA	
	Mr. Richard Bergström	Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA)	
Close:	<b>Conclusions and Perspectives</b>		
	Sir. Craig Reddie	President, WADA	

Lunch 12:00 ~ 14:00

Press Conference held during the participants' lunchtime (12:15-13:00).

Second Session 14:00 ~ 17:00

## From Concepts to Achievements to Progressing Partnerships for Clean Sport and Society

Round table 1 From the political concept to developing partnerships: what kind of network to build and how to include all the stakeholders?

Moderator	Prof. Hidenori Suzuki	President, Japan Anti-Doping Agency (JADA)
Rapporteur	Mr. Marcellin Dally	Secretary, Anti-Doping Convention Youth and Sport Section Division of Ethics, Youth and Sport, UNESCO
Panelists	Ms Barbara Leishman	Chair, Anti-Doping Working Group, IFPMA
	Mr. David Verbraska	Vice President, Pfizer
	Mr. Haruhiko Hirate	Corporate Officer, Takeda Pharmaceutical Company Ltd.
	Mr. Michael K Gottlieb	National Program Director, White House Drug Policy Office, Executive Office of the President, USA

Round table 2 Effective collaboration between the World Anti-Doping Agency and the Biopharmaceutical Industry

Moderator	Ms Barbara Leishman	Chair, Anti-Doping Working Group, IFPMA
Rapporteur	Dr. Steven Elliott	Scientific Executive Director (retired), Amgen
Panelists	Mr. Mark Luttmann	WADA Cooperation Coordinator, GlaxoSmithKline
	Mr. Christian de la Tour	VP Corporate Projects, Public Affairs & Corporate Communications, Ipsen
	Mr. Tatsuya Kamiuchi	Group Manager, Drug Safety Division, Chugai Pharmaceutical Co., Ltd.
	Dr. Olivier Rabin	Senior Director, Science, WADA

Concluding Remarks: How to further develop co-operation in the future?

General rapporteurs	Mr. Masafumi Nogimori	Vice President IFPMA, President FPMAJ
	Mr. David Howman	Director General, WADA
	Prof. Ichiro Kono	President, Japan Sport Council Vice-President, Tokyo 2020 JADA Board member

★ Facts & Figures

303 participants / 11 countries

31 pharmaceuticals

336 min presentations & discussions



# 1st Session

The morning session aimed to share each organisations' expertise and progress and highlight ongoing collaborations, topics of which included: Societal and Economic risks of doping; Challenges in anti-doping and the role of the Biopharmaceutical Industry; and collaborative perspectives for the Biopharmaceutical Industry and anti-doping authorities in the future.

## Opening

State Minister Hideki Niwa opened the conference by emphasising the significance to protect fairness in sport and to prevent the abuse and misuse of sport-related drugs. Mr. Niwa expressed the further necessity to strengthen the collaboration between the pharmaceutical industry and anti-doping. Sir Craig Reddie also echoed Mr. Niwa, in mentioning: "Doping and its correlation to drug abuse is an issue that has a negative impact on society as a whole." He went on to stress that "partnerships with pharmaceutical companies are crucial" and a 'win-win' solution

for both the anti-doping and pharmaceutical communities. Ms. Angela Melo highlighted that such 'win-win' collaborative approaches aim to improve the exchange of information and promote education programmes.

## Part 1: Societal and Economic Risks of Doping

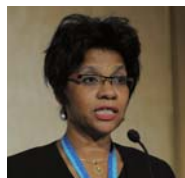
Part 1 focused on how doping affects and tarnishes all individuals in society and discussed how its consequences are not limited to elite athletes. Mr. David Howman emphasised the continuing and increasing engagement of the criminal underworld and black market in providing prohibited substances through trafficking and distribution as well as the increasing sophistication of cheating at the high end of sport which trickles down to the amateur and youth levels.



**Mr. Hideki Niwa**  
State Minister of Education, Culture, Sports, Science and Technology (MEXT), Executive Committee, WADA



**Sir Craig Reddie**  
President, WADA



**Ms Angela Melo**  
Director, Ethics, Youth and Sport, UNESCO



**Mr. David Howman**  
Director General, WADA



**Dr. Tatsuya Kondo**  
Chief Executive, Pharmaceuticals and Medical Devices Agency (PMDA)



**Dr. Temo Waqanivalu**  
Team Leader, WHO



## Welcome Cocktail

In his opening remarks, Mr. Hakubun Shimomura, Minister for Education, Culture, Sports, Science and Technology and Tokyo 2020 Minister, wished for a successful International Conference and for further enhancement of anti-doping programmes and the importance of promoting public health. The Welcome Cocktail was a kick-off event attended by two State Ministers of MEXT, public officials, the speakers, the representatives from industry, sport and the anti-doping community in Japan and beyond.



Backstage

Dr. Tatsuya Kondo highlighted that anti-doping activity is based on Regulatory Science (RS) and that international collaboration based on this ethical science between industry-government-academia will further promote the health of citizens. Dr. Temo Waqanivalu discussed the social cost of illicit substance use and identified the vital need for health, education and sport collaboration and partnerships. Mr. Clément De Maillard raised the alarm of the reality of mass consumption of doping products and stated that this "presents a major challenge for public health," and is also seen as a threat to the security and stability of society.

## Part 2: Challenges in Anti-Doping and Role of the Biopharmaceutical Industry

The central theme of Part 2 was to highlight how the stronger collaboration between the anti-doping community and the biopharmaceutical industry can help in dealing with the challenges of today and the future. Dr. Valérie Fourneyron emphasised the importance of scientific research and the approaches required: to further collaborate with WADA-accredited laboratories for detection analysis; the police force for countering 'pharmaceutical crime'; and the pharmaceutical industry for forecasting the arrival of molecules with doping potential.

With the past examples illustrating the avoidance strategies by doped athletes and supportive doctors and scientists, Dr. Steven Elliott stressed the vital need to sustain the fight through the application of new methods to deter the doping cheats. Mr. Masafumi Nogimori illustrated the success of growing collaborative relationships between IFPMA and WADA which has ensured the information sharing on the potential doping risk of compounds in the development pipelines and misuse and abuse of substances. The collaboration, Mr. Nogimori mentioned, has assisted "in achieving our mission", and has ultimately led "to protect the value and trust of the companies."

## Part 3: Biopharmaceutical Industry and Anti-Doping Authorities: Expectations and Perspectives for the future

Dr. Olivier Rabin discussed the regular contact that has recently been made with investigators on the status of new drugs, new doping strategies or suspicious websites. The responsibilities of government regulatory bodies were highlighted and thereby the efficient sharing of

knowledge and exchange of information that must be accompanied by appropriate human and financial resources. Both Dr. Rabin and Mr. Richard Bergström emphasised the "Innovative Medicines Initiative (IMI)". According to them, the IMI will represent a significant step forward fostering the knowledge sharing and health worldwide. Mr. Bergström discussed how the IMI can allow providing a framework and funding for public private consortia to address unmet medical needs and deliver tools for research that optimise translation of new science, technology and knowledge into healthcare products and solutions for patients.

## Conclusions and Perspectives:

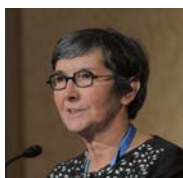
Sir Craig Reddie summarised how the improved alliances can assist both communities to:

- a) Identify medicinal substances of potential interest to dopers and therefore, assist anti-doping in the early identification of detection techniques; and
- b) Minimise the misuse and abuse of substances by athletes, and thereby ensure that these substances are only used for their original medicinal purpose.

He concluded that it is the responsibility and duty of all of us to protect the rights of the clean athletes and of society at large from the broader dangers of doping.



Mr. Clément De Maillard  
Criminal Intelligence Officer, INTERPOL



Dr. Valérie Fourneyron  
Chair of Health, Medical & Research  
Committee, WADA



Dr. Steven Elliott  
Scientific Executive Director (retired),  
Amgen



Mr. Masafumi Nogimori  
Vice President IFPMA, President FPMIAJ



Dr. Olivier Rabin  
Senior Director, Science, WADA



Mr. Richard Bergström  
Director General,  
European Federation of  
Pharmaceutical Industries and  
Associations (EFPIA)



## Press Conference

Attended by approximately 50 media, the Press Conference was opened by Minister Hideki Niwa, followed by remarks from Sir Craig Reddie and Prof. Hidenori Suzuki. In opening up the Press Conference to media, a wide range of questions were asked, including how and where collaborations will be extended in the future, and the significance of values-based education from an anti-doping perspective.



# 2nd Session

## Round table 1:

**From the political concept to developing partnerships: what kind of network to build and how to include all the stakeholders?**

Round table 1 explored the value and importance of partnerships, and discussed the need to find a practical way to step forward from being reactive to more proactive with the support and commitment of the various actors. Led by Prof. Hidenori Suzuki, the panelists discussed a wide range of topics, including how to build partnerships, cooperation, trust and resources, and they shared the successful examples from the viewpoints of public authorities and industries.

Mr. Michael Gottlieb introduced a new legislation in the US, the "Designer Anabolic Steroid Control Act" signed by President Obama in December 2014, which proactively adds specified substances to the list of those included within the definition of 'anabolic steroid'. Mr. David Verbraska illustrated how Pfizer enthusiastically came to a formal agreement with WADA because of their corporate commitment to the integrity of science and public health.

Ms Barbara Leishman emphasised how communication and awareness are some of the most important aspects and ones that require further collaboration, especially development from the regulatory aspect of proper risk management plans for new medicines which encompass the risk of doping in sports. Illustrating 'uniqueness' of the Japanese pharmaceutical industry with their grounded social responsibility, Mr. Haruhiko Hirate suggested the possible collaboration between pharmaceutical industry and public authority particularly in the area of promoting information campaigns with a health message against the misuse of drugs for doping purposes. Round table 1 was wrapped up by Mr. Marcellin Dally on future perspectives on partnerships and collaborations aiming for the same goal.



## Round table 2:

**Effective collaboration between the World Anti-Doping Agency and the Biopharmaceutical Industry**

The main focus of Round table 2 was on the practical implementation of anti-doping strategy and how proactive measures and actions can be taken. Introduced by Ms Barbara Leishman, the panelists, who are the IFPMA Working Group members from different companies, discussed their respective experiences, different models for collaboration with WADA and the way forward in the future.

The panelists agreed that the responsibility of the industry to deal with the problem and the process for collaboration has already been installed. Mr. Christian de la Tour and Dr. Steven Elliott mentioned the necessity to have a "champion" - somebody who cares - and stated that the process for continuity should be embedded within the company, not just individuals. Mr. Tatsuya Kamiuchi followed with promoting a national-level awareness-raising activity as the industry's critical obligation.

Encountered with the objections at an early stage on intellectual property (IP), Mr. Mark Luttmann illustrated how the confidentiality agreement with WADA can completely address this issue. Giving a recent example of GW50516 which is discontinued and never manufactured due to toxicity but became available on illegal websites, Dr. Olivier Rabin highlighted how imperative it is to adopt a proactive approach by allowing WADA access to relevant information within the Investigator's Brochure in order to conduct an early assessment of the doping potential and to eventually "access to a few milligrams of the drugs" to develop anti-doping tests.

The panel also stressed the regulatory authority's responsibility in relation to the Safety Risk Management of new medicines and Benefit Risk Assessment as a global requirement which would add a minimum amount of additional work.



## Concluding Remarks:

From the perspectives of the pharmaceutical industry, anti-doping and sport respectively, the conference concluded by agreeing on the need to further advance cooperation for the benefit of clean sport, clean athletes and clean society. Welcoming the concrete developments, strengthened relationships and joint initiatives between the pharmaceutical industry and anti-doping community, Mr. Masafumi Nogimori, Mr. David Howman and Dr. Ichiro Kono all reminded the participants of their collective responsibility for the benefit of society as a whole.

At the end of the conference, Dr. Kono concluded that as shown in the Tokyo 2020 government legacy commitment 'PLAY TRUE 2020', "We share the value of sport and integrity of sport, and we share the passion in sport and passion to advance society in a credible way."



## Key phrases:

*"As with every good sport's team, we all have a different role to play. We all need to play to our strengths and contribute if we were to succeed."*  
— Mr. David Verbraska

*"...the future gives us every reason to hope."*  
— Mr. Clément De Maillard

*"Health, Education and Sport collaboration and partnerships are vital."*  
— Dr. Temo Waqanivalu

*"Combining our efforts will make a difference in sport for today's and tomorrow's athletes, also for the public and society at large."*

— Dr. Olivier Rabin

*"We all need to get involved. None of us should be sitting on the sidelines thinking, 'This is somebody else's job.'"*  
— Dr. Steven Elliott

*"...it (success) only happens when there is leadership and when there is commitment."*

— Mr. Michael Gottlieb

*"...your drugs could be targeted, and it is better prepared if you have a policy, a strategy, and a process in place."*

— Ms. Barbara Leishman

*"FPMA Working Group and WADA representatives can guide you for putting a plan in place."*

— Mr. Mark Luttmann

## SUMMARY POINTS / CONCLUSION:

1. Strengthened commitment in partnership between the pharmaceutical industry and the anti-doping community ;
2. Coordinated global and local approaches bring new initiatives to the collaboration for protecting the clean athletes, integrity of sport and public health ;
3. The Regulatory Science is proposed as a point to consider for integration in anti-doping activity ;
4. The regulatory agencies have an active role to play in collaboration with anti-doping authorities ;
5. WADA and the Innovative Medicines Initiative (IMI) will develop a new form of partnership looking at new and future research topics to foster new ideas and new initiatives for a cleaner and healthier society.



*SPORT  
FOR  
TOMORROW*

