medicines for europe
better access. better health.

15th Legal Affairs CONFERENCE

26-27 MARCH 2019
HOTEL OKURA, AMSTERDAM

TUESDAY 26 MARCH

	18:00 19:00	REGISTRATION AND WELCOME COCKTAIL
	19:00 20:00	**SESSION I - THE EUROPEAN PATENT SYSTEM AND PATENT QUALITY**

CHAIR
Jules Fabre, Senior Counsel, European IP & Regulatory Litigation, Teva

PANELLISTS
Sjoerd Hoekstra, Director Patent Examination, EPO
Imre Gonda, Head of IP, Gedeon Richter
Karin Pramberger, IP Director, Polpharma Group

Questions & answers

	20:00 22:00	NETWORKING DINNER WITH SPEAKERS AND LEGAL EXPERTS

WEDNESDAY 27 MARCH

	09:00	WELCOME NETWORKING COFFEE	
	09:30	OPENING ADDRESS	**Adrian van den Hoven** Director General, Medicines for Europe
	09:40	**SESSION II - A HIGH LEVEL DISCUSSION ON: "THE PHARMA SECTOR INQUIRY: 10 YEARS ON & THE FUTURE"**	

CHAIR
Andreas Schillack, Head Legal Europe, Sandoz International GmbH

PANELLISTS
- **Kees Schillemans**, Partner, Allen & Overy LLP
- **Agnieszka Deeg-Tyburska**, Legal Director, Polpharma Group
- **Tomos Shillingford**, Associate General Counsel IP, Insud Pharma
- **George Moore**, Assistant General Counsel-Europe, Australia & Asia, Mylan

Questions & answers

Medicines for Europe
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
www.medicinesforeurope.com

	10:30	NETWORKING COFFEE BREAK
	11:00	**SESSION III - 45-MINUTE ROUNDTABLE DISCUSSIONS**

Delegates may attend two of the discussion tables below for a period of 45 minutes per session:

1. **The 505(b)(2) approval pathway system in the US**
   Moderator: **Jeffrey Francer**, Senior VP & GC, Association for Accessible Medicines (AAM)
   Co-moderator: **Kenneth V. Phelps**, President and Founder, Camargo Pharmaceutical Services

2. **Second medical use patents**
   Moderator: **Ignace Vernimme**, Partner, Stibbe

3. **The legal impact of non-compliance with FMD**
   Moderator: **György Thaler**, Development Director, Gedeon Richter
   Co-moderator: **Johan Verhaeghe**, National Policy Liaison, Medicines for Europe

4. **Policies to stimulate competition**
   Moderator: **Harald Mische**, Official DG Competition, European Commission

5. **Confidentiality of data**
   Co-moderator: **Vincenzo Salvatore**, Of Counsel, Leader of the Healthcare and Life sciences Focus Team, BonelliErede
   Co-moderator: **Miguel Vidal-Quadras Trias de Bes**, Legal Expert, AESEG

6. **The concept of plausibility**
   Co-moderator: **Tomos Shillingford**, Associate General Counsel IP, Insud Pharma
   Co-moderator: **Sascha Stolzenberger**, Director of Biotech IP, Gedeon Richter Pharma GmbH

7. **New technologies in pharma**
   Co-moderator: **George Moore**, Assistant General Counsel-Europe, Australia & Asia, Mylan
   Co-moderator: **Kristof Roox**, Partner, Crowell & Moring

8. **The new Trade Secrets regime**
   Moderator: **Benjamin May**, Partner, ARAMIS Société d'Avocats

	12:40	NETWORKING BUFFET LUNCH

medicines for europe
better access. better health.

15th Legal Affairs CONFERENCE

26-27 MARCH 2019
HOTEL OKURA, AMSTERDAM

14:00	**SESSION IV - THE SPC MANUFACTURING WAIVER: WHERE DO WE STAND?**

CHAIR
Kristof Roox, Partner, Crowell & Moring

PANELLISTS
- **Alfonso Calles-Sánchez**, Administrator, DG Grow, European Commission
- **Beatriz Díaz de Escauriaza**, Senior IP Counsel, Insud Pharma
- **Corinna Sundermann**, Senior Vice President Intellectual Property, Fresenius Kabi

Questions & answers

14:50	**SESSION V – THE SPC REGULATION: THE LEGAL REVIEW OF THE MAX PLANCK INSTITUTE**

CHAIR
Kristof Roox, Partner, Crowell & Moring

PANELLISTS
- **Alfonso Calles-Sánchez**, Administrator, DG Grow, European Commission
- **Roberto Romandini**, Max Planck Institute
- **Karin Pramberger**, IP Director, Polpharma Group

Questions & answers

15:40	NETWORKING COFFEE BREAK

16:10	**SESSION VI – THE PHARMA INCENTIVES REVIEW: WHAT CAN WE EXPECT NOW?**

CHAIR
Adrian van den Hoven, Director General, Medicines for Europe

PANELLISTS
- **Sven J. R. Bostyn**, Associate Professor of Biomedical Innovation Law, University of Copenhagen
- **Marcel van Raaij**, Director Pharmaceutical Affairs & Medical Technology, Dutch Ministry of Health, Welfare and Sports
- **George Moore**, Assistant General Counsel-Europe, Australia & Asia, Mylan
- **Ellen 't Hoen**, Director, Medicines Law & Policy

Questions & answers

medicines for europe
better access. better health.

15th Legal Affairs CONFERENCE

26-27 MARCH 2019
HOTEL OKURA, AMSTERDAM

17:00	SESSION VII – WHAT'S NEW ON BIOSIMILARS: OPPORTUNITIES OR CHALLENGES FOR BIOSIMILAR MEDICINE DEVELOPERS	
	CHAIR **Floris ten Have**, Partner, Stibbe **PANELLISTS** • **Alexander Ott**, Senior Patent Attorney, Sandoz/Hexal AG • **Kristin Cooklin**, Global Head of Patents, Zentiva • **Jacek Myszko**, Senior Counsel, Sołtysiński Kawecki & Szlęzak • **Jeffrey Francer**, Senior VP & GC, Association for Accessible Medicines (AAM) Questions & answers	
17:50	CONCLUDING REMARKS	**Sergio Napolitano**, Director Legal and External Affairs, Medicines for Europe
18:00	END-OF-CONFERENCE COCKTAIL	

GOLD SPONSORS

crowell moring

Stibbe

CONFERENCE SPONSORS

Aramis Société d'Avocats

BarentsKrans

BonelliErede

MEDIA PARTNERS

Clarivate Analytics

www.gabionline.net • www.gabi-journal.net
GaBi GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

Generics Bulletin
Pharma intelligence | informa

IMS Health & Quintiles are now IQVIA™

PHARMA BOARDROOM

FOLLOW THE EVENT ON TWITTER #LAC19

For further information https://www.medicinesforeurope.com/events2019/LAC19/