Regional Workshop on Trade Secrets and Undisclosed Information Relating to Registration of Agricultural Chemical Products and Veterinary Medicines

organized by
the World Intellectual Property Organization (WIPO)

in cooperation with
the Agency for Agriculture and Livestock (SAG), Ministry of Agriculture
with the support of the National Institute of Industrial Property (INAPI), Ministry of Economy

Chile, November 28 and 29, 2023

PROVISIONAL PROGRAM

prepared by the International Bureau of WIPO
Speakers should allocate 10 minutes for Q&A within their scheduled time slots.

Tuesday, November 28, 2023 (Chile time)

9.00 – 9.30  Registration

9.30 – 9.45  Opening Ceremony

Welcome Address by:

Representative of the Ministry of Agriculture
Representative of WIPO

9.45 – 10.30  Topic 1  Overview of Trade Secrets and Undisclosed Information

Speaker: WIPO

10.30 – 10.45  Coffee Break

10.45 – 11.45  Topic 2  Protection of Trade Secrets and Undisclosed Information under the TRIPS Agreement

Speaker: WTO

11.45 – 12.45  Topic 3  FAO’s Activities and Perspective: Registration of Agricultural Chemical Products and Veterinary Medicines, including Protection of Confidential Data

Speaker: FAO

12.45 – 13.45  Lunch

13.45 – 14.45  Topic 4  Protection of Trade Secrets and Undisclosed Information Relating to Registration of Agricultural Chemical Products and Veterinary Medicines: Legal Framework in Chile

Speaker: INAPI

14.45 – 15.45  Topic 5  IP Provisions in Free Trade Agreements (FTA) Relevant to Registration of Agricultural Chemical Products and Veterinary Medicines

Speaker: WTO

15.45 – 16.05  Coffee Break

16.05 – 16.50  Topic 6  Overview of the Various Mechanisms under National/Regional Laws on Protection of Undisclosed Test and other Data relating to Registration of Agricultural Chemical Products
Speaker: Prof. Sven Bostyn, Associate Professor of Innovation Law, University of Copenhagen, Denmark

16.50 – 17.30  **Topic 7**  Overview of the Various Mechanisms under National/Regional Laws on Protection of Undisclosed Test and other Data relating to Registration of Veterinary Medicines

Speaker: Dr. Jonathan J. Darrow, Assistant Professor, Harvard Medical School, United States of America

17:30 – 18.10  **Topic 8**  Overview of the Various Legal Mechanisms under National Laws of Latin American Countries on Protection of Undisclosed Test and other Data relating to Registration of Agricultural Chemical Products and Veterinary Medicines

Speaker: Mr. Benny Spiewak, Partner at SPLAW, Brazil, São Paulo

**Wednesday, November 29, 2023**

9.00 – 10.00  **Topic 9**  Regional Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Agricultural Chemical Products and Veterinary Medicines in Europe

Speaker: European Food and Safety Authority (EFSA)
European Medicines Agency (EMA)

10.00 – 11.00  **Topic 10**  Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Agricultural Chemical Products [and Veterinary Medicines] in [the Republic of Korea][Japan]

Speaker: From [the Republic of Korea][Japan]

11.00 – 11.20  Coffee Break

11.20 – 12.20  **Topic 11**  Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Agricultural Chemical Products and Veterinary Medicines in the United States of America

Speaker: Environmental Protection Agency (EPA)
Federal Drug Administration (FDA)

12.20 – 13.30  Lunch
13.30 – 14.10 **Topic 12**  
Trade Policy Reviews: Selected cases of Protection of Undisclosed Information  
Speaker: WTO

14.10 – 14.40 **Topic 13**  
Roundtable: Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Agricultural Chemical Products and Veterinary Medicines in Latin American Countries  
Presentations by the participants from the region and Q&A

14.40 – 15.00 **Coffee Break**

15.00 – 15.40 **Topic 13 (Cont’d)**  
Roundtable: Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Agricultural Chemical Products and Veterinary Medicines in Latin American Countries

15.40 – 16.20 **Topic 14**  
Roundtable: Practical Challenges and How We Can Address Them – Lessons Learned  
Discussion among All participants and speakers, including WTO, WHO and WIPO speakers

16.20 – 16.40 **Closing**

16:40 – 17:00  
Evaluation survey  

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NATIONAL WORKSHOP

National Workshop on Trade Secrets and Undisclosed Information relating to Registration of Pharmaceutical Products

organized by
the World Intellectual Property Organization (WIPO)

in cooperation with
the Institution of Public Health (ISP)
with the support of the National Institute of Industrial Property (INAPI), Ministry of Economy

Chile, November 30, 2023

PROVISIONAL PROGRAM

prepared by the International Bureau of WIPO

Speakers should allocate 10 minutes for Q&A within their scheduled time slots.
Thursday, November 30, 2023 (Chile time)

9.00 – 9.30  Registration

9.30 – 9.45  Opening Ceremony

Welcome Address by:

Representative of ISR
Representative of WIPO

9.45 – 10.15  **Topic 1**  Overview of Trade Secrets and Undisclosed Information
Speaker: WIPO

10.15 – 11.00  **Topic 2**  Protection of Trade Secrets and Undisclosed Information under the TRIPS Agreement
Speaker: WTO

11.00 – 11.15  Coffee Break

11.15 – 12.00  **Topic 3**  Intersection of the Trade Secret System and Health (TBD)
Speaker: WHO

12.00 – 12.40  **Topic 4**  Protection of Trade Secrets and Undisclosed Information Relating to Registration of Pharmaceutical Products: Legal Framework in Chile
Speaker: INAPI

12.40 – 13.40  Lunch

13:40 – 14.20  **Topic 5**  Overview of the Various Mechanisms under National/Regional Laws on Protection of Undisclosed Test and other Data relating to Registration of Pharmaceutical Products
Speaker: Dr. Jonathan J. Darrow, Assistant Professor, Harvard Medical School, United States of America

14.20 – 15.00  **Topic 6**  Overview of the Various Legal Mechanisms under National Laws of Latin American Countries on Protection of Undisclosed Test and other Data relating to Registration of Pharmaceutical Products
Speaker: Mr. Benny Spiewak, Partner at SPLAW, Brazil, São Paulo
15.00 – 15.15  Coffee Break

15.15 – 16.00  **Topic 7**  Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Pharmaceutical Products in Europe

Speaker:  European Medicine Agency (EMA)


Speaker:  Federal Drug Administration (FDA)

16.40 – 17.20  **Topic 9**  Legal Framework and Practices for Protection of Data and Confidentiality in the Registration Procedures of Pharmaceutical Products in Japan

Speaker:  The Pharmaceuticals and Medical Devices Agency (PMDA)

17.20 – 18.00  **Topic 10**  IP Provisions in Free Trade Agreements (FTA) Relevant to Registration of Pharmaceutical Products

Speaker:  WTO

18.00 – 18.20  Roundtable:  Practical Challenges and How We Can Address Them – Lessons Learned

Discussion among All participants and speakers, including WTO, WHO and WIPO speakers

18.20 – 18.30  Closing

18.30 – 18.40  Evaluation survey

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NATIONAL WORKSHOP

National Workshop on Intellectual Property, Public Health and Trade

organized by
the World Intellectual Property Organization (WIPO)

in cooperation with
the Ministry of Health (MINSAL)
with the support of the National Institute of Industrial Property (INAPI), Ministry of Economy

Chile, December 1, 2023

PROVISIONAL PROGRAM

prepared by the International Bureau of WIPO
Speakers should allocate 10 minutes for Q&A within their scheduled time slots.

Friday, December 1, 2023 (Chile time)

9.00 – 9.30 Registration
9.30 – 9.40 Opening Ceremony
   Welcome Address by:
   Representative of MINSAL
   Representative of WIPO

9.40 – 10.30 **Topic 1** Health-related provisions in the TRIPS Agreement (TBD)
   Speaker: WTO

10.30 – 11.20 **Topic 2** Patent-related Flexibilities and their Implementation and Use at the National Level
   Speaker: WIPO

11.20 – 11.35 Coffee Break

11.35 – 12.25 **Topic 3** Promoting Innovation and Access to Medical Technologies: Public Health Perspective
   Speaker: WHO

12.25 – 13.15 **Topic 4** Work of INAPI on the issues related to Inventions in the Pharmaceutical Field
   Speaker: INAPI

13.15 – 14.30 Lunch

14:30 – 15.00 **Topic 5** Health-related provisions in Bilateral and Regional Trade Agreements
   Speaker: WTO

15.00– 16.00 **Topic 6** Recent Developments in the Field of IP and Health in WTO, WHO and WIPO
   Speakers: WTO
   WHO
   WIPO

16.00 – 16.15 Coffee Break
16.15 – 16.40  Q & A session
Speakers: All participants

16.40 – 16.50  Closing

16.50 – 17.00  Evaluation survey

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