

4th Brazil-Japan Seminar of Regulations on Pharmaceuticals and Medical Devices

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Date : Monday 3 December, 2018 9h00 to 17h30

Venue: JETRO Tokyo HQ

Number of participants (limit): c.a. 200 people

Hosted by: MHLW/PMDA, ANVISA, JETRO

Supported by Industry of Pharmaceuticals and Medical Devices

- Brazil:
- The Brazilian Trade and Investment Promotion Agency (Apex-Brasil)
 - The Brazilian Pharmaceuticals Manufacturers Association (Abiquifi)
 - The Brazilian Fine Chemicals, Biotechnology and Specialty Industries Association (Abifina)
- Japan:
- The Federation of Pharmaceutical Manufacturers' Associations of JAPAN (FPMAJ)
 - Japan Pharmaceutical Manufacturers Association (JPMA)
 - Japan Federation of Medical Devices Association (JFMDA)

Agenda

Session	Presenter
9h00-9h30 Opening Remarks	MC: Katsuaki Ura, MHLW
▪ Representative of MHLW/PMDA	Mr. Kazuhiko Mori, Councilor, MHLW
▪ Representative of ANVISA	Dr. Alessandra Bastos, Director, ANVISA
▪ Representative of JETRO	Mr. Naoyoshi Noguchi, Executive Vice President, JETRO
▪ Representative of APEX	Ms. Maíra Leite Rezende, APEX Brasil
▪ Representative of Japanese Industry	Mr. Tadaharu Goto, Director General, JPMA Mr. Fumio Hirose, Vice Chairman, JFMDA
▪ Representative of Brazilian Industry	Dr. Norberto Prestes, International

	Business Manager, ABIQUIFI
9h30~9h45 Photo Session	
09h45~10h25 Japanese Health System from MHLW 30 min: Presentation (Including the following aspects: - Characteristics of the market - Description of the health system - Reimbursement System) 10 min: Question & Answer	Moderator: Dr. Bianca Zimon, ANVISA Dr. Takahide Hashimoto, Chief, General Division, Health Policy Bureau, MHLW
10h25~11h05 Brazilian Health System from ANVISA 30 min: Presentation (Including the following aspects: - Characteristics of the market - Description of the health system - Health Technologies Assessment) 10 min: Question & Answer	Moderator: Katsuaki Ura, MHLW Dr. Bianca Zimon, ANVISA
11h05-11h20 Coffee Break	
11h20 – 12h10 Opportunities from Industries 20 min: From Japan 20 min: From Brazil 10 min: Question & Answer	Moderator: Katsuaki Ura, MHLW Mr. Keiichi Iwase, Director Vice- President, Department of Institutional Relations, JETRO Sao Paulo Ms. Maíra Leite Rezende, APEX Brasil
12h10-13h10 Networking Lunch	
13h10-14h10 Session 1 Recent Regulatory Update and Regulatory Progress for Promoting Cutting-edge technology	Moderator: Dr Alessandra Bastos, ANVISA

<p>25 min: From Japan</p> <p>25 min: From Brazil</p> <p>10 min: Questions & Answer</p>	<p>Dr. Nobumasa Nakashima, Associate Executive Director, Office of International Programs , PMDA</p> <p>Dr. Ana Carolina Marino, ANVISA Dr. Leandro Pereira, ANVISA</p>
<p>14h10-14h55 Session 2 Expectation to International Harmonization from Industry [Pharmaceuticals] 15 min: Proposal from Japanese industry</p> <p>[Medical devices] 15 min: Proposal from Japanese Industry</p> <p>15 min: Q&A</p>	<p>Moderator: Dr Ana Carolina Marino, ANVISA</p> <p>Dr. Masafumi Yokota, Vice Chairperson of ICH Project Committee, JPMA</p> <p>Mr. Makoto Funabashi, Head of Brazil WG, Asia Subcommittee, JFMDA</p>
<p>14h55-15h10 Coffee Break</p>	
<p>15h10-16h10 Session 3 Strengthening cooperation between industry and regulator 20 min: Japanese industry activities in Brazil</p> <p>20 min: Brazilian industry's activities for international convergence</p>	<p>Moderator: Dr Patrícia Lamarão, ANVISA</p> <p>Dr. Koichiro Morihira, Chairperson of Intellectual Property Committee, JPMA</p> <p>Mr. Kenjiro Takayanagi, Medical Sub-department, Foreign trade dept. of the Japanese Chamber of Commerce and Industry in Brazil ,JFMDA</p> <p>Mr. Walker Lahmann Executive Director of Institutional Relations at EUROFARMA and Director of External Trade at ABIFINA</p>

<p>20 min: Panel Discussion</p>	<p>Panelists: Presenters & Mr. Naoyuki Yasuda, Director, Office of International Regulatory Affairs, Pharmaceutical Safety and Environmental Health Bureau, MHLW & Dr. Alessandra Bastos, ANVISA</p>
<p>16h10-17h20 Session 4: Quality Certification on Medical Devices and Pharmaceuticals</p> <p>20 min: PMDA - Recent Trend</p> <p>20 min: ANVISA – Recent Trend</p> <p>10 min: Proposal from Industry</p> <p>20 min: Panel Discussion</p>	<p>Moderator: Dr. Junko Sato, Office Director, Office of International Programs, PMDA</p> <p>Ms.Mami Yabuki, Principal Inspector, Office of Manufacturing/ Quality Compliance, PMDA Mr. Masahito Ogawa, Division Director, Office of Manufacturing/ Quality Compliance, Division of Medical Devices</p> <p>Dr. Patrícia Lamarão, ANVISA</p> <p>Dr. Susumu Harashima, Vice-Chairperson, GMP Expert Committee, Quality & Technology Committee, JPMA Mr. Koji Sekiguchi, Chairman of International Policy & Strategy Committee, JFMDA</p> <p>Panelists: Presenters</p>
<p>17h20-17h30 Closing Remarks</p> <ul style="list-style-type: none"> ➤ ANVISA ➤ PMDA 	<p>MC: Katsuaki Ura, MHLW</p> <p>Dr. Alessandra Bastos, Director, ANVISA</p> <p>Dr. Yoshikazu Hayashi, Senior Executive Director , PMDA</p>