IFPMA-TFDA WORKSHOP ON COUNTERFEIT MEDICINES

INTEGRATED APPROACH AGAINST FAKE MEDICINES

FRIDAY, FEBRUARY 6, 2015

TICC - TAIPEI INTERNATIONAL CONVENTION CENTER
TAIPEI, CHINESE TAIPEI
07:30 - 08:15 REGISTRATION & WELCOME COFFEE

08:15 - 08:55 OPENING SESSION – INTEGRATED AND HARMONIZED APPROACH AGAINST FAKE MEDICINES
Dr Ming-Kung Yeh, Ministry of Health and Welfare of Taiwan
• Opening Remarks
Cyntia Genolet, IFPMA
• Introduction by Moderator
James Dahl, Partnership for Safe Medicines

08:55 - 11:00 SESSION 1: CURRENT REGULATORY LANDSCAPE & INITIATIVES AGAINST FAKE MEDICINES
• Transcontinental approach - APEC
Mark Paxton, US Food and Drug Administration
• Regional approach - "EU legislation and strategy to fight fake medicines"
Patrick Deboyser, Delegation of European Union
• Questions and Answers

11:00 - 11:30 COFFEE BREAK

11:30 - 12:30 SESSION 2: SUPPLY CHAIN INTEGRITY
• Complexity of the supply chain
Scott Kammer, RX360
• Serialization and Traceability – GS1 Standards: A Manufacturer’s Perspective
Michael P. Rose, Johnson & Johnson Health Care Systems Inc.
• Questions and Answers

12:30 - 14:00 LUNCH

14:00 - 14:05 OPENING BY MODERATOR
James Dahl, Partnership for Safe Medicines

14:05 - 16:00 SESSION 3: PRACTICES AND TECHNOLOGIES FOR PREVENTION, DETECTION, CONTROL AND MONITORING OF FAKE MEDICINES
• Implementation of Good Practices (GDP, GPP, and GMP) for safe medicines
  – Fu-Wen Chang, International Federation of Pharmaceutical Wholesalers (IFPW)
  – Ivan Ho, Pfizer
  – Chyn-Liang (Cindy) Huang, Food and Drug Administration, Taiwan
• Perspective of Healthcare professionals and patients
  – Sheuan Lee, International Council of Nurses
  – Kin P Tsang, International Alliance of Patients’ Organizations
• Monitoring fake medicines: “Case Study – Public-Private Sector Cooperation”.
  Panel discussion
  – Salmah Bahri, Malaysia Ministry of Health
  – Raymond Velez, Eli Lilly
  – Thomas Kubic, Pharmaceutical Security Institute (PSI), Panel Moderator
• Questions and Answers

16:00 - 16:30 Coffee Break

16:30 - 18:00 Session 4: Collaboration within and between countries
• Single Point of Contact Model
Domenico Di Giorgio, Italian FDA (AIFA)
• Conducive legislative framework to collaboration - Medicrime Convention
Sabine Waiser, Council of Europe
• Working together against fake medicines
Bejon Misra – Partnership for Safe Medicines (PSM) INDIA
• Questions and Answers

18:00 - 18:15 Closure
James Dahl, Partnership for Safe Medicines
OPENING SESSION

INTEGRATED AND HARMONIZED APPROACH AGAINST FAKE MEDICINES

**DR. MING-KUNG YEH**
Counselor at the Ministry of Health and Welfare of Taiwan

Dr Ming-Kung Yeh is presently Counselor at the Ministry of Health and Welfare of Taiwan, Professor at the School of Pharmacy of the National Defense Medical Center and a Board member of the Taiwan Blood Services Foundation. Dr Yeh is an expert on drug delivery inside the body.

Dr Yeh obtained a Bachelor and Master of Science from the School of Pharmacy of the National Defense Medical Center of Taiwan in 1986 and 1988 respectively. Subsequently, he went to the UK, where he obtained a PhD at the School of Pharmacy of the University of Nottingham in 1996. From 1999 to 2001, Dr Yeh worked as a clinical pharmacist at the Tri-service General Hospital in Taiwan. In 2002, he then went to the US, where he was a visiting professor at the University of Cincinnati in Ohio. In parallel, he was in the period 2001-2003 chief of the Logistic Department of the Tri-service General Hospital. After returning from the US, he became Chief of Pharmacy in the same hospital. In 2007, Dr Yeh became Professor at the School of Pharmacy, of the National Defense Medical Center, while keeping until 2009, in parallel, his position as Chief of Pharmacy. In 2013, Dr Yeh became Director-general of the Food and Drug Administration of the Ministry of Health and Welfare, becoming one year Counselor in the same ministry. Dr Yeh is also a very productive scientist, who has published over 60 papers in journals that are followed by the science citation index.

**MS. CYNTIA GENOLET**
Policy Analyst, Regulatory and Health Policy, IFPMA

Ms. Cyntia Genolet joined IFPMA in 2012 where she is responsible of the anti-counterfeiting portfolio. Cyntia also works on policy issues related to biotherapeutics and regulatory.

Prior to joining the IFPMA, Ms. Genolet has worked in Geneva for Sanofi in the Relations with International Institutions office. She previously accrued professional experience in Africa, South America and Switzerland for NGOs, international organizations and governments. She holds a MA in International Relations from the Graduate Institute of International and Development Studies in Geneva and a MAS in Health Economics and Management from HEC Lausanne.
MR. JAMES DAHL
Board of Director, Partnership for Safe Medicines

Mr. Jim Dahl is an independent product security consultant with significant experience in the public and private sectors. He is considered a subject matter expert in pharmaceutical crime and malicious product tampering. Jim is a retired federal law enforcement agent with 30 years’ experience having spent his last nine years in government as the Assistant Director of the FDA’s Office of Criminal Investigations (OCI). Mr. Dahl also served five years as the Global Product Security Director at Eisai Company Ltd., a research based pharmaceutical manufacturer with operations throughout the world. His experience includes managing his own independent consulting company and as senior managing director for crisis management at an international security consulting firm. Mr. Dahl currently serves as a member of the Board of Directors for the Partnership for Safe Medicines (PSM), a Washington, DC based non-profit organization dedicated to keeping unsafe medicines out of the global supply chain.

MR MARK PAXTON
Regulatory Counsel, Center for Drug Evaluation and Research, US Food and Drug Administration

Mr Mark Paxton is a Regulatory Counsel at Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA). Previously, he served as the Associate Vice President for International Regulatory Affairs for Pharmaceutical Research and Manufacturers of America (PhRMA) in Washington, DC. In this role, Mr. Paxton served as the primary industry person responsible for establishing global regulatory priorities and works with high level, company regulatory experts in a number of regulatory and technical committees to develop and implement global regulatory strategies, and engaged foreign Regulatory Authorities from Japan, Europe, Pacific Rim, and Latin America to position PhRMA objectives. Before joining PhRMA, Mr. Paxton was a pharmaceutical consultant providing expertise in approval requirements for 505(b)s and 505(j)s, Citizen/Suitability petitions, as well as manufacturing compliance requirements. Mr. Paxton received a BS in Business and Economics and a MS in Economics from the University of Kentucky and a JD from the University Of Dayton School Of Law.
MR. PATRICK DEBOYSER
Minister-Counsellor (Health and Food safety), Delegation of the European Union

Mr. Patrick Deboyser received his law degree from the University of Louvain, and was called to the Brussels Bar in 1979.


The author of several books and articles, Mr. Deboyser has taught European Law at the University of Brussels (ULB) and the University of Louvain (UCL). He is currently Professor of ‘food safety’ and ‘pharmaceutical policy’ at the European College of Parma.

SESSION 2
SUPPLY CHAIN INTEGRITY

MR. SCOTT KAMMER
Director, Global Product Security at Takeda Pharmaceutical

Mr. Scott Kammer is responsible for leading the Global Product Security for Takeda Pharmaceutical. Mr. Kammer provides 25 years corporate security experience in the pharmaceutical industry working for Abbott Laboratories and Takeda Pharmaceutical. He has been instrumental in the development and implementation of the global strategy to combat illicit trade for Takeda using a multi prong approach working with internal functions within the company, and responsible for coordinating the Global Product Protection Operations and Global Brand Protection Steering Committee. The multi-prong approach involves enforcement, product protection technologies, forensics, supply chain security, and education.

Previously Mr. Kammer had extensive experience in conducting complex international investigations that have led to successful prosecution and has built strong relations to monitor and detect illicit trade within the global supply chain. Scott has moved through the ranks and held various positions throughout his career within Security Operations, Investigations, and Product Security.

Mr. Kammer holds a BS in Political Science and MA in Business and Organizational Security Management.
MR. MIKE ROSE
Vice President, Supply Chain Visibility, Customer & Logistics Services, Johnson & Johnson Health Care Systems Inc.

Mr. Mike Rose is responsible for leading Johnson & Johnson’s supply chain visibility program that is an enabler to delivering exceptional customer experience while improving supply chain effectiveness and integrity. Mr. Rose’s responsibilities include product identification and traceability, which includes serialization and traceability, GS1 standards adoption, Unique Device Identification and e Capability.

In his 39 years with Johnson & Johnson, Mr. Rose has held various positions of responsibility across discovery research, information management, and supply chain. While in information management, Mike was the CIO and a Board Member of Ortho Biotech.

Recently, Mr. Rose is the chairman of European Federation of Pharmaceutical Industries and Associations Serialization & Coding Senior Oversight Group. He is a Board Member of the Pharmaceutical Distribution Security Alliance. He serves on PhRMA’s Supply Chain Security Workgroup.

Previously, Mr. Rose was a member of the GS1 Healthcare US and GS1 Healthcare Global leadership teams; served as a tri-chair of EPCglobal’s Healthcare and Life Sciences Business Action Group; Vice Chairman of the EPCglobal Board of Governors; and served as past co-chair of HDMA’s Industry Relations Council.

Mr. Rose serves on La Salle University’s Council of President’s Associates and the Executive Board of the Boy Scouts of America’s Bucks County Council.

Mr. Rose graduated from La Salle University with a BA in Biology, and received an MSE in Computer Science from the University of Pennsylvania.
Mr. Fu-Wen Chang is at the moment senior Quality Assurance manager of Zuellig Pharma, Inc. in Taiwan. Zuellig Pharma is a company that specializes in pharmaceutical and healthcare distribution and logistics and that proposes solutions to keep counterfeit medicine out of the distribution chain. Mr. Chang’s job is among other things to optimize the flow of products.

Mr. Chang studied Biology at the Fu-Jen Catholic University in Taipei (1985-1989). He subsequently did a master study in neuroscience at Yang-Min Medical College in Taipei (1989-1991). After obtaining his master’s degree, he spent a year at Chi Sheng Chemical Corporation as an R&D Researcher (1993-1994) followed by a year as Assistant Researcher at the National Defense Medical Center where he studied Parkinson-like syndromes. End of 1998 he started a 2-year stint as senior quality control analyst at Parke-Davis Pharmaceutical Company in Taiwan. In 1999 he moved to Eli Lilly and Company in Taipei where he first was a QA/Technical Service Specialist and subsequently a Regulatory Affairs Administrator. In April 2006, Mr. Chang moved to Center Laboratories, Inc. in Hsin-Chu where he first worked as QA/QC manager and subsequently as Production Manager. Finally, in 2011, he obtained his present job as Senior QA manager at Zuellig Pharma, Inc. in Taoyuan.
MR. IVAN HO
APAC Region, Pfizer Global Security

Since joining Pfizer in January 2005, Mr. Ivan Ho has devoted a significant portion of his time to Global Security’s pro-active anti-counterfeiting program, the goal of which is to detect and deter major manufacturers and distributors of counterfeit Pfizer products. Based in Hong Kong, he is responsible for such efforts in Hong Kong, Taiwan and Macau.

Prior to joining Pfizer, Mr. Ho served in Syngenta, a leading Swiss-based agri-business company as the Regional Head of Corporate Security for the Asia Pacific region, with responsibility for coordinating security activities and resources across the region. Before that, he worked for Proctor & Gamble as Greater China Security Manager position, responsible for managing security and anti-counterfeit operations in China, Taiwan, Hong Kong and Macau.

Mr. Ho began his professional career in 1982, when he joined the Royal Hong Kong Police Force where he served as an Inspector of Police. He later joined the British Columbia Provincial Police of Canada, where he served in the Coordinated Law Enforcement Unit and Organized Crime Agency. During his 17 years’ service in the law enforcement, he specialized in investigation of white-collar and organized crimes, as well as VIP protective security. Mr. Ho, who received technical trainings from United States Secret Service and Thomas De La Rue & Company Limited, was the resident counterfeit expert on forged banknotes and security document in the Commercial Crime Bureau. He testified as an expert witness in courts of Hong Kong while serving in the Royal Hong Kong Police Force. He holds a Bachelor of Social Sciences degree, majoring in Economics and Management Studies, and a Masters in Criminology from the University of Hong Kong. He is a member of ASIS International and has been certified as a Certified Protection Professional (CPP). From 2010 and 2013, he served as a member of the Steering Committee in the Overseas Security Advisory Council (OSAC) Board, Hong Kong Chapter.

Mr. Ho has played a critical role in Pfizer’s success in addressing the counterfeiting problem in Taiwan, including:

• Forging and maintaining effective partnership with enforcement and regulatory authorities
• Initiating pro-active investigations and referring investigate leads (including identification of targets) to enforcement authorities – such as MJIB, CIB, IPR Special Police and Coast Guard -- for their action
• Conducting joint operations with authorities to shutdown dishonest retail outlets and distribution networks of upstream suppliers
• Conducting market surveys and online test purchases to monitor the market, and coordinating pro-active enforcement (raids) and education campaigns (high profile press conferences)
• Coordinating lab analysis of samples seized by authorities and providing results for use in prosecutions
• Partnering with ICE to train Customs investigators to enhance awareness and identification of counterfeit packaging
• Partnering with ICE and PSI in Operation Medifake, conducting regional training workshops for Taiwan Customs to enhance awareness and enforcement of counterfeit drugs smuggling. Immediately after the regional training workshops, Taiwan Customs reinforced their inspection of shipments/parcels at check points, particularly at their mail facilities.
**MS. CHYN-LIANG HUANG**  
*Chief Inspector & Section Chief, GMP Inspectorate, Division of Risk Management, Food and Drug Administration of Taiwan*

Ms. Chyn-Liang (Cindy) Huang is at the moment Chief Inspector and Section Chief of the GMP Inspectorate, which is a part of the Division of Risk Management of the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare of Taiwan. One of the responsibilities of the TFDA is supply chain integrity, i.e. the prevention of fake medicine into the supply chain and the implementation of good manufacturing practices (GMP) by the pharmaceutical industry.

Ms Huang obtained a Bachelor of Science in Pharmacy from the Taipei Medical University in Taiwan and subsequently a Master of Science in Pharmacy from the University of Louisiana in Monroe (USA). Ms Huang started her career as a Specialist/GMP inspector in the Division of Drug Analysis of the Department of Health in 1998. In 2004, she promoted to Section Chief in the same Division. In 2007 she became Section Chief of the GMP Inspectorate. In 2010 she obtained her present position in the Division of Risk Management of the TFDA.

**DR SHEUAN LEE**  
*Board Member, International Council of Nurses*

Prof Dr Sheuan Lee plays a central role within the nursing community in Taiwan. She is at present Professor at the School of Nursing of Chung Shan Medical University (since 2001), Board Director of the Taiwan Nurses Association (since 1989), standing board director of the Taiwan Nursing Management Association (since 2011), ICN board member (since 2013) and Minister without portfolio (since 2008). She is particularly interested in and an expert of nursing and mental health, women’s health, counseling by nurses, the administration and management by nurses and nursing education. Her election to the board of the International Council of Nurses in 2013 can be seen as a crowning achievement of her career and is also a compliment to the Taiwanese nursing community.

Prof Lee obtained a BSN of the School of Nursing of the National Defense University in 1973. In 1980, she went to the School of Nursing of the University of Texas in Austin, where she obtained an MSN in 1982; she stayed on, and obtained a PhD at the same university in 1987. After her return to Taiwan she became Professor and Dean of the School of Chang Kung Medical University (1989-1996). In 1996 she moved to Huangkuang Institute of Technology where she held the same position. In 2000, she became professor at the School of Nursing of Taipei Medical University, but moved already in 2001 to the College of Nursing of Chung Shan Medical University, where she became Professor and Dean, a position she holds till this day.
MR. KIN P TSANG
President, Retina Hong Kong (International Alliances of Patients Organization)

Mr. Kin Ping Tsang, a retired business executive and patient suffering from Retinitis Pigmentosa, has been actively volunteering in Hong Kong and international patients’ movements in the past decades.

Mr. Tsang has founded Retina Hong Kong, a self help organization of patients suffering from retinal degenerative diseases with fellow patients in March, 1995, and has been serving President of the Association since then. He is member of Management Committee of Retina International and Board Member of AMD Alliance International.

Mr. Tsang was elected to Governing Board of International Alliance of Patients’ Organizations (IAPO) in 2008 and is the current Chair of IAPO. He has been engaging in planning and organizing of regional patients workshops in Africa, Latin America and Asia, and the Global Patients Congresses. His main advocating issues are access to treatment, patient safety, drug safety, medical ethics and patients engagement in healthcare sector.

Mr. Tsang was the Chairman of Hong Kong Alliance of Patients’ Organizations (HKAPo), from 2009 to 2013 and has been serving a number of committees for Food and Health Bureau and Labor and Welfare Bureau of the Hong Kong SAR Government. He is Honorary Fellow of Hong Kong Academy of Pharmacy, and Vice President of Hong Kong Guide Dogs Association.

DR. SALMAH BAHRI
Director of Pharmacy Enforcement, Malaysian Ministry of Health

Dr. Salmah Binti Bahri is currently the Director of Pharmacy Enforcement, Pharmaceutical Services Division, Ministry of Health Malaysia (MOH). She graduated with a B.Sc in Pharmacy from the University of Baghdad, Republic of Iraq in 1981. She received her M.Sc (Pharmacy) and Ph.D in Drug Policy and Management from the University Sains Malaysia in 2002 and 2007, respectively.

Her areas of expertise include Medicines Policy and Management, Quality Use of Medicines, Medicines Pricing and Good Governance in Medicines and the chairman for various committees in MOH such as the National Pharmacy Research & Development Committee, Implementation Committee for Comprehensive National Project on the Quality Use of Medicines by Consumers, Implementation Committee for Good Governance in Medicines, Advisory Group for the Medicine Price Monitoring Program in Malaysia, and Technical Committee for Implementation of National Drug Policy. Internationally, she is a member of the ASEAN Working Group on Pharmaceutical Development and WHO panel member for the development of the WHO Guideline on Pharmaceutical Pricing Policies.

Dr Salmah Bahri is also an active researcher in her fields of expertise in MOH. Among her important national research projects are the Drug Utilization in the Treatment of Diabetes Mellitus in the Ministry of Health Facilities and National Survey on the Use of Medicines by Malaysian Consumers (2007) and (2012). She has also published some international peer reviewed articles, proceedings, compendiums, research reports, articles, bulletins and newsletters for the MOH. She has also co-authored a few book chapters and was recently the main author of a book entitled National Medicine Policy-A Malaysian Perspective.
MR. RAYMOND VELEZ  
Regional Manager, Asia, Global Security, Eli Lilly

Mr. Raymond H. Velez has worked for Eli Lilly and Company for over ten years. He is currently the Regional Manager, Asia, Global Security, Eli Lilly & Company. In this role, he manages security and anti-counterfeiting operations in the Asia Pacific region. He is based in Bangkok.

He is a Certified Fraud Examiner (CFE) and is currently on the Board of Directors of the “Transported Asset Protection Association (TAPA) Asia”, a global supply chain association and “The Society For The Policing Of Cyberspace (POLCYB)”, a global cybercrime organization.

Prior to his current employment, Mr. Velez worked as the Senior Investigator for the Microsoft Corporation, Law and Corporate Affairs, responsible for IPR investigations in South Asia Pacific.

Mr. Velez enjoyed a career at the US Federal Bureau of Investigation (FBI). During his career he was assigned to various offices in the United States as well as Thailand, India and Pakistan. He has broad experience in complex investigations to include fraud, drug trafficking and terrorism. He has also conducted training of government agencies to include drug regulatory agencies, customs and the police throughout Asia and the United States.

MR. THOMAS KUBIC  
President and CEO, Pharmaceutical Security Institute

Mr. Thomas Kubic is a former Deputy Assistant Director of the Federal Bureau of Investigation, United States Department of Justice, with national and international investigative experience.

Selected as PSI’s president in October 2008, he has worked closely with the Security Directors from twenty-eight manufacturers to insure the integrity of pharmaceuticals and, most importantly, to protect public health. The Institute emphasizes information sharing and private-public sector cooperation.

Mr. Kubic represents the Institute at numerous international meetings, conferences and seminars. In 2013, PSI’s collaborations included work with the Global Fund, Interpol, the U.N. Office on Drugs and Crime, and the World Customs Organization. He has written extensively on the topic of public and private partnerships needed to address the global problem of pharmaceutical crime.

He has provided testimony concerning the international nature of counterfeiting before senior government officials around the world. He currently serves as an officer with the Partnership for Safe Medicines, and as an advisor to the Permanent Forum on International Pharmaceutical Crime and Interpol’s newly launched Pharmaceutical Industry Initiative to Combat Crime (PIICC).
SPEAKERS BIOGRAPHY

DR. DOMENICO DI GIORGIO
Dirigente dell’Unità di Prevenzione della Contraffazione, Italian Medicines Agency (AIFA)

Dr. Domenico Di Giorgio, Ph. D., is Director of the Counterfeit Prevention Unit for the Italian Medicines Agency (AIFA). Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention. He is the editor of the books “Counterfeit medicines: facts and case studies” (CoE/EDQM, 2009, 2011), The IMPACT Handbook (IMPACT/AIFA, 2011), and of the related publications series about investigators training and risk communication. He chaired the EDQM/Council of Europe Committees dealing with pharmaceuticals products and counterfeiting, and coordinates FAKESHARE I and II (2013), projects of shared IT intelligence co-funded by the Prevention of and Fight against Crime Programme of the European Union.

DR. SABINE WALSER
Administrative Officer, Council of Europe

Dr. Sabine WALSER is a pharmacist and holds a doctoral degree in pharmacology and master degrees in toxicology and public health. Since 2002, she works for the Council of Europe, an international political organisation. In her capacity as administrator she coordinates programmes of activities carried out by Member States focused on public health-oriented policy-making in the fields of public health risk management and prevention from counterfeit medicines and similar crimes, patient-centred pharmaceutical care, the classification of medicines into prescription and OTC medicines, carried out by expert bodies and overseen by senior officials. Within the above mentioned programmes, the Council of Europe activities against counterfeiting of medicines and similar crimes were launched in 2003 by the former Ad Hoc group on counterfeit medicines. As co-secretary of the concerned bodies, she facilitated the transfer of public health expertise to the drafting of the future Council of Europe Medicrime Convention, an international treaty in the criminal law field. Since 2008, she works for the European Directorate for the Quality of Medicines and Healthcare (EDQM, Council of Europe) and is inter alia contributing to programmes aiming at assisting Member States with the practical implementation of national and international legislation also through networking, intelligence building and training. Since 2007, more than 320 officials from health and law enforcement sectors from more than 45 countries, including certain countries in Africa (Morocco, Angola, Cape Verde, Mozambique, RD Congo, Congo-Brazzaville, Zambia) and South-America, have been enrolled in training programmes on how to combat counterfeit medicines and to protect public health set up within the above-mentioned programmes of activities.

From 1991 to 2001, she held different positions in the pharmaceutical industry, from 1995 to 2001 as Regulatory Affairs Manager Austria and Eastern and Central Europe for a globally operating, research-based pharmaceutical company.
MR. BEJON KUMAR MISHRA
Founder Director, Partnership for Safe Medicines (PSM) India

Mr. Bejon Kumar Misra, is both an entrepreneur and an international consumer policy expert. The broad interest of Mr. Misra is reflected by the honors he was awarded in recent years: he won the ‘World No-Tobacco Day 2013 Award’ for South-East Asia of the WHO, obtained the status of ‘Rural Innovator on Improving Access to Safe Drinking Water’ from the National bank for Agricultural and Rural Development, was given the ‘Bramashah Award’ for service to consumers by the Confederation of All India Traders and in 2014 served on a 4 member expert committee commissioned by Government of India, Ministry of Health & Family Welfare, to advice on measures to regulate the relationship between Diagnostics Centres and Pharmaceutical Companies on the one hand and Medical Practitioners and Hospitals on the other.

Mr. Misra obtained a degree in Business Management with a major in marketing from Banaras Hindu University (BHU) in 1971. His University awarded him a ‘Distinguished Alumni Award’ in 2012. Mr. Misra started his career in 1971 as a Marketing Executive at TATA steel in Kolkata and subsequently established his own company in the Travel Industry and Leasing Business in Jamshedpur, which he wound-up and shifted to Delhi from 1994 to work full-time in social development and as a Consumer Policy Expert Internationally. Mr. Misra became seriously involved in the Indian Consumer Movement in 1983 when he created the Consumer Guidance Society of Jamshedpur. This was the start of a more than 32 year long career in consumer advocacy. Mr. Misra is among many other things a former chairman of the Consumer Coordination Council (CCC), a national coalition of 70 leading consumer organizations in India. Around 1998, Mr. Misra started a third parallel career as a consumer policy expert. He worked as a short term consultant for at least 9 international organizations and NGOs like the UNDP and WHO and Gain & EPOS. At the same time he has also been a member of the Food Safety & Standards Authority of India from 2008-2013 and at the moment is Chairman & Managing Director of a rural hospital project in Uttar Pradesh. This short biography can do no justice to all the activities Mr. Misra has been involved in and is still involved in at the moment. His contribution in the Partnership for Safe Medicines (PSM) India Initiative from 2010 to tackle the issue of fake medicines and Patient Safety has been globally recognised by various Governments and industry associations. His present mission is to enable Indian Citizens to ACCESS Quality Healthcare and initiate Universal Health Coverage in India and other developing countries.