Pietro Erba

PERSONAL INFORMATION

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Nationality: Italian

WORK EXPERIENCE

from July 2016 - to present

Office of the Director General (Technical Secretariat of the Director General) External Relations Area

AIFA (Agenzia Italiana del Farmaco – Italian Medicines Agency), Via del Tritone 181, 00187- Rome
http://www.agenziafarmaco.gov.it/

- Managing technical, scientific and regulatory international activities;
- Participation and support to international projects and working groups;
- Supervision of two human resources on rationales for missions and other international items;
- Member of the Italian delegation at the Head Medicines Agencies and ICMRA (International Coalition of Medicines Regulatory Agencies) (from Jul. 2013 and Sep. 2014 respectively);

- Member of SCOPE WP7 (Strengthening Collaboration for Operating Pharmacovigilance in Europe – Work Package 7 – Quality Management Systems).
- AIFA contact point for project IMI Call 10 – Topic 7 Enhanced Patients' Voice in Medicines Life Cycle since Dec 2016.

External Relations

from Oct. 2015 - to 30 June 2016

Pharmacovigilance Inspector

AIFA (Agenzia Italiana del Farmaco – Italian Medicines Agency), Via del Tritone 181, 00187- Rome
http://www.agenziafarmaco.gov.it/

- Inspector Junior candidate for Pharmacovigilance inspections in the GCP and Pharmacovigilance Inspectorate of AIFA;
- Responsible for Quality Assurance GCP and GVP Inspectorate from May 2016;
- Member of the Italian delegation at the Head Medicines Agencies and ICMRA (International Coalition of Medicines Regulatory Agencies) (from Jul. 2013 and Sep. 2014 respectively);
- Member of SCOPE WP7 (Strengthening Collaboration for Operating Pharmacovigilance in Europe – Work Package 7 – Quality Management Systems).

GVP Inspections

from Dec. 2011 - to Sep. 2015

Pharmacovigilance Assessor Senior

AIFA (Agenzia Italiana del Farmaco – Italian Medicines Agency), Via del Tritone 181, 00187- Rome
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- Member of the Italian delegation at the Head Medicines Agencies and EMA Management Board meetings (from July 2013);
- Appointed Vice-Responsible of Pharmacovigilance Quality System of the PhVOffice (from 29 March 2013);
- Member of SCOPE WP7 (Strengthening Collaboration for Operating Pharmacovigilance in Europe – Work Package 7 – Quality Management Systems);
- Responsible for Training of the Pharmacovigilance Office;
- Monitoring National Adverse Drug Reactions (ADRs) and literature;
- Assessment of Periodic Safety Update reports (PSURs) and Risk Management Plans;
- Evaluation of Core Safety Profiles to support renewals of dossiers; Update of Product Information
- Collaboration with other European Agencies and EMA ;
- Writing/Editing/Translation of Safety Communication.

Post-marketing drug safety

from Feb. 2009 - to Nov. 2011

Regulatory Compliance Specialist

Actavis Italy S.p.A., Nerviano Plant. Nerviano (MI). Actavis is a worldwide generic manufacturer, the Group has more than 10,000 employees operating in over 40 countries. Nerviano Plant manufactures sterile products (Aseptically prepared/Terminally sterilised. Lyophilisates/small liquide volume) and Non-sterile Products (capsules) both for ownbrand and third parties (Pfizer Inc.).

- Regulatory Compliance from May 2010 to Nov. 2011:
  Person in charge for US products: new Dossiers and DMF type V editing

- Regulatory Compliance from Feb. 2009 to Nov. 2011:
  Drafting of documents for product transfer and all other variations type I or II;
  Active member of transfer groups for transfer and implementation of development products;
  Checking and updating CTD volume 3;
  Releasing of specifications of API, excipients and FP;
  Site Master File;
  Interacting with people inside the plant for regulatory issue about the products assigned.

Quality operations

from Jan. 2007- to Jan. 2009

Clinical trial manager and off-label manager

University Hospital for treatment and clinical research.Fondazione IRCCS Policlinico Ospedale Maggiore, Mangiagalli e Regina Elena. Via F. Sforza 35, Milan.

- Clinical trial manager: in charge of non-medical issues: dossier evaluation, relations between Sponsor/CRO and investigators;
- Off-label manager: drug literature research, consultant for the physicians, buyer;
- Pharmacovigilance manager: communication with AIFA pharmacovigilance Dpt and with regional pharmacovigilance institute, NSIS user, managing contact between physicians and Companies, Dpt.'s trainer for Pharmacovigilance.

Clinical trials

from Oct. 2005 - to Dec. 2006

Manager of the laboratory staff

University Hospital for treatment and clinical research.Fondazione IRCCS Policlinico Ospedale Maggiore, Mangiagalli e Regina Elena. Via F. Sforza 35, Milan.

- In charge of the lab: GLP, training technicians;
- Output: parenteral nutrition's and citotoxics, galenicals compounding.

Hospital compounding pharmacy

from Jan. 2003- to Sep. 2005

Clinical trials and off-label therapy assistant

University Hospital for treatment and clinical research.Fondazione IRCCS Policlinico Ospedale Maggiore, Mangiagalli e Regina Elena. Via F. Sforza 35, Milan.

- CT pharmacist assistant: Dossier evaluation, managing relations between sponsor and investigator;
- Off-label assistant: drug literature research;
- Pharmacovigilance assistant: using NSIS, contact relations between physicians and companies.

Clinical research

from Dec. 2003- to Jan. 2009

Clinical Research Associate (as internal for Policlinico Hospital)

University Hospital for treatment and clinical research.Fondazione IRCCS Policlinico Ospedale Maggiore, Mangiagalli e Regina Elena. Via F. Sforza 35, Milan.

- From May 2007 to Jan 2009
  Monitor for the study PROFIL C (Pphylaxis of fungal invasive infection in leukemia). Drug Accountability Record, GCP, ICH Quality Assurance.
  Clinical organization: G. Rossi (Ematology, Spedali Civili, Brescia).

- From Dec 2003 to Dec 2006

Monitor for the study PREPEC (Relapses hepatocarcinome prevention in patients with cronic hepatic disease). Drug Accountability Record, GCP Quality Assurance.
Clinical organization: M. Strazzabosco (U.O. Gastroenterology, Ospedali Riuniti di Bergamo), M. Colombo (Hepatology dpt., Policlinico, Università di Milano).

CT monitoring

EDUCATION AND TRAINING

from Feb. 2009- to Dec. 2010

Regulatory Affairs expert

ISCED 6

Master level II of Regulatory Affairs "Carlo Benzi" University of Pavia (two years course)

- Regulatory affairs (EU – Italian legislation, GMP, EMA-FDA-AIFA rules, Pharmacoeconomy, Clinical trials)Thesis: "EMA vs FDA - Development of the section 32P."

from Jun. 23rd - to Jul. 5th 2008

Beginner of biostatistics

Summer school on Modern Methods in Biostatistics and Epidemiology)

- Biostatistic I (Prof. M. Pagano) + Epidemiology (Prof. D. Trichopoulos);
- Harward School of Public Health, Boston, USA ."

from Feb. 2003 - to Jul. 2005

Hospital pharmacist

ISCED 6

Specialist school in Hospital Pharmacist – University of Milan, Italy

- Legislation, Pharmacology and tossicology, Biometry, Pharmacovigilance;
- Thesis: "Patented drugs, Off-label therapy, investigational Medicinal Products: three ways to treat the patient". Final mark 70/70.

December 2002

Pharmacist

ISCED 5

Qualifying examination – University of Milan, Italy;
Degree of Pharmacy – Univarsity of Milan, final mark 94/110

ADDITIONAL INFORMATION

Publications

- "The individual feedback letter provided by AIFA to reporters of suspected adverse drug reaction (ADRs)"
  13th ISoP Annual Meeting 'New Landscapes for Pharmacovigilance'; Italy, Pisa 1-4 Oct. 2013.
- "Eye disorders: A New potential signal of Strontium Ranelate? An Analisys of Italian Pharmacovigilance Database".
  36th Annual Meeting of Representatives of the National Centres Participating in the WHO Programme for International Drug Monitoring; 25-28 Sep. 2013, Rome.
- "Bisphosphonate-Associated Cardiac Adverse Reactions: Reports from the Italian Database of spontaneous Reporting of Adverse Drug Reactions"
  12th ISoP Annual Meeting 'New Landscapes for Pharmacovigilance'; Cancun, Mexico 30 Oct.–2 Nov. 2012.
- "Signal Detection in the Italian Spontaneous Reporting System"
  12th ISoP Annual Meeting 'New Landscapes for Pharmacovigilance' Cancun, Mexico 30 Oct.r–2 Nov. 2012.
- "Home total parenteral nutrition: products quality assurance and Continuity of care from hospital to home". ISS XIII National Seminary: Evaluation of drug safety (2005).
- "Good manufactoring practice: the experience of Ospedale Maggiore of Milan"
  Bollettino Sifo: Vol. 50 N° 2 (2004).
- "Off-label prescription: the experience of Ospedale Maggiore of Milan"
  Giornale Italiano di Farmacia Clinica: Vol. 18 N° 4 (2004).

Presentations

- Moderator at the 36th Annual Meeting of Representatives of the National Centres Participating in the WHO Programme for International Drug Monitoring;Sep. 2013, Rome.
- "The Italian national system of pharmacovigilance", 20 Nov. 2015, Belgrade, Serbia
- "The Scope project", 19 Nov. 2015, Belgrade Serbia.
- "Benefit/Risk ratio in pharmacovigilance", 17 Apr. 2013, AIFA, Rome.
- "Pharmacovigilance Quality System in AIFA", Farmindustria Seminar, 13 Sep. 2012, Rome.

Projects

- SCOPE Joint Action, run from 2013 until 2016
  The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to the EU legislative requirements. Italian member of the Work Package 7 on Quality Management Systems.
- CHRODIS Joint action from Sept 2016 until Mar 2017
  JA-CHRODIS has been designed to exploit the potential to reduce the burden of chronic disease by making better use of the knowledge within EU Member States on effective and efficient ways to prevent and manage cardiovascular disease, stroke and diabetes type-2.
- IMI Call 10 – Topic 7 Enhanced Patients' Voice in Medicines Life Cycle
  The goal of this topic is to provide a framework and guidance for all stakeholders on the best ways to meaningfully engage patients at different stages of the medicines lifecycle.

Nominees

- Pharmacovigilance Office Quality System Vice manager; 29 Mar 2013.
- Member of a public selection committee; April 2014
- GCP and GVP Inspection Office Quality System manager; 28 Apr 2013.

Seminars

- XXV National Congress GIQAR (Italian group of quality assurance in regulatory), 18-20 May 2016, Parma, Italy;
- Presenter at TAIEX Workshop on the Implementation of EU Pharmacovigilance Legislation on 19-20 Nov. 2015 Belgrade, Serbia;
- The Inspector Working Group workshop, 11-13 Nov. 2013, EMA, London.

Honours and awards

- Commendation letter from Prof. Luca Pani (Director General, AIFA) for HMA/MB delegate assistant job from 2013 to date. 13 Apr. 2015.
- Commendation letter from Prof. Luca Pani (Director General, AIFA) for the contribution in the organization of the HMA (Heads of Medicines Agencies) Presidency meetings during the Italian Presidency, II semester 2014. 3 Feb. 2015.

Memberships

Pharmacist register since Jan 2003.

Courses

- English Course, level C.1.1 with Trinity School, 2016 at Italian Medicines Agency.
- English Course, Level C1.2 with Easy Life, 2014 at Italian Medicines Agency.
- French Official Delf level B1 achieved in June 2010 (Final score by Centre Culturelle Francaise: 89.5/100).
- French Official Delf level A2 achieved in Feb 2009 (Final score by Centre Culturelle Francaise: 86/100);

Certifications

Car and motorcycle licences.
Swimming coach accreditation, pool lifeguard licence.