

## PERSONAL INFORMATION

Herve Le Louet

## WORK EXPERIENCE

September 2013–Present

**Professor of clinical Pharmacology**

University Paris-Est Creteil (UPEC) (France)

February 2013–Present

**Head of the Pharmacovigilance and Risk Management Coordination of the Ile of France (region of 12 millions inhabitants)**

Assistance publique – Hôpitaux of Paris (AP-HP) (France)

Since 2000: Head of the Pharmacovigilance and Risk management Department, University Hospital Henri Mondor (Creteil)

July 2012–Present

**Co-opted Member of the PRAC,coopted by the European Commission**

European Medicines Agency (United Kingdom)

January 2010–Present

**Co-chair of the Pharmacoepidemiology unit of the Assistance Publique Hopitaux of Paris**

Assistance publique – Hôpitaux of Paris (AP-HP) (France)

January 1999–August 2000

**Advisor of the French Minister for Health and Social Security, responsible of the drug policy**

French government (France)

advisor responsible for drug policy.

February 1996–January 1999

**Regulator, deputy director of the Pharmacovigilance department. Research in Pharmacogenomics and mitochondria. Lecturer at Paris 12 University.**

University Creteil Hospital Henri Mondor (France)

March 1995–February 1996

**Regulator**

French Medicines Agency (France)

Responsible of blood derivated products, Pharmacovigilance unit. Participation to the Pharmacovigilance Working Party and CHMP.

April 1993–March 1995

**Investigator for clinical trials in a service society, course in Pharmacoepidemiology**

MEDPHAREX (France)

## EDUCATION AND TRAINING

- **MD:Thesis in specialization in Hepatology and Gastroenterology**

University paris XI and university of Franche comté (France)

Hepatology

- **PhD: Clinical Pharmacology, Pharmacogenetics. Paris XII University**

University Paris 12 (France)

Drug Metabolism

February 1994–February 1994

### Courses: Pharmacoepidemiology, principle and application

University Bordeaux 2 (France)

## ADDITIONAL INFORMATION

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### Expertise

Post marketing safety surveillance:

Since 2011:

Member of the working group 9 of the Council for International Organisation of Medical Sciences on risk minimization (CIOMS group 9: risk minimization)

Since 2007:

Invited member of the Eudravigilance Expert Working Group (EMA)

Member of the European Network of Centers for Pharmacovigilance and Pharmacoepidemiology, ENCePP Project (EMA)

Since 2003:

Collaborator of the RegiSCAR group: European Registry of Severe Cutaneous Adverse Reactions to drugs (included in the ENCePP project).

Since 1996:

Collection, assessment and registration of adverse drug reactions, National and European Pharmacovigilance reports; drug information to health professionals.

Expert of the French Pharmacovigilance Commission: assessment reports for AFSSAPS and EMA on Liver toxicity and Pharmacogenetics

1995-1996:

Implementation and supervision of the National organisation of Pharmacovigilance for blood products.

- At the European level: promotion of the new paediatric regulation during the French EU presidency (2000).

- At the national level: implementation of the new drugs reimbursement rules (1999-2000); organisation of the Pharmacovigilance for blood products (1995-1996).

- At the regional level: management of the project about the reorganisation of the Pharmacovigilance of clinical trials at the AP-HP (2005-2006); creation and management of the regional Pharmacovigilance department in Henri Mondor hospital (2000-2001), implementation of drug risk management in APHP.

Risk management:

- Chairman of the first committee about drug risk management in Paris university hospitals (2002-2007).

- Conception and Development of a system about medical errors for health professionals (2006-ongoing).

- Management of European Risk Management Plans for the AFSSAPS (2005-ongoing).

Crisis management:

- Drugs alerts for the APHP (eg: European drug withdrawals, erythropoietin and erythroblastopenia, pregnancy and antiretroviral use) (2001-ongoing).

- Public health crisis, such sun eclipse (1999-2000).

- Blood derived products and risk of Creutzfeldt Jacob disease (1995-1996).

Risk communication:

- Collaboration to the national program for consumers' reports conducted by AFSSAPS: pilot study with consumers associations (2007), (submitted for publication).

- Since 2007, collaboration in the field of risk communication and transparency with the King's Centre for Risk Management, University of London (optimization of risk communication in hospitals).

Phase I-III drug development, signal detection and risk management:

AP-HP represents the first clinical trial site in Europe. Its main activity of biomedical and clinical research is driven by the Department of Clinical Research and Development (DRCD) and from 2005

to 2011 a strong partnership between DRCD and the Pharmacovigilance department of Mondor hospital was organised, combining the competence of Pharmacovigilance professionals and tools in order to comply with the new regulations. The specific tools are MedDRA dictionary, software tool for management and declaration of Individual Case Safety Reports (ES1-SafetyManager®), software tool for secure exchange of data on Internet (NetIXServer®).

This partnership allowed a better signal detection and an overall view of drug risk management resulting from biomedical researches.

#### Publications

- 1- Lelouet H, Morin M, Trenque T, Bidault I, Castot A, Alexandre JM.  
[Evaluation of declarations of severe adverse effects from the publication of the decree dated 13 March 1995 about the organisation of pharmacovigilance].  
Therapie. 1996 Sep-Oct;51(5):555-6. French. PMID: 9138393.
- 2- Albengres E, Le Louet H, Tillement JP.  
Immunosuppressive drugs and pregnancy: experimental and clinical data.  
Transplant Proc. 1997 Aug;29(5):2461-6. Review. PMID: 9270811.
- 3- Albengres E, Le Louet H, Tillement JP.  
Systemic antifungal agents. Drug interactions of clinical significance.  
Drug Saf. 1998 Feb;18(2):83-97. Review. PMID: 9512916.
- 4- Le Louet H, Ruivart M, Bierling P, Duche JC, Godeau B.  
Lack of relevance of the acetylator status on dapsone response in chronic autoimmune thrombocytopenic purpura.  
Am J Hematol. 1999 Dec;62(4):251-2. PMID: 10589083.
- 5- Morin C, Zini R, Simon N, Charbonnier P, Tillement JP, Le Louet H.  
Low glucocorticoid concentrations decrease oxidative phosphorylation of isolated rat brain mitochondria: an additional effect of dexamethasone.  
Fundam Clin Pharmacol. 2000 Sep-Oct;14(5):493-500. PMID: 11129090.
- 6- Bechtel YC, Lelouet H, Brientini MP, David-Laroche M, Miguet JP, Paintaud G, Bechtel PR.  
Caffeine metabolism differences in acute hepatitis of viral and drug origin.  
Therapie. 2000 Sep-Oct;55(5):619-27. PMID: 11201977.
- 7- Bechtel YC, Haffen E, Lelouet H, Brientini MP, Paintaud G, Miguet JP, Bechtel PR.  
Relationship between the severity of alcoholic liver cirrhosis and the metabolism of caffeine in 226 patients.  
Int J Clin Pharmacol Ther. 2000 Oct;38(10):467-75. PMID: 11073287.
- 8- Lelouet H, Bechtel YC, Paintaud G, Brientini MP, Miguet JP, Bechtel PR.  
Caffeine metabolism in a group of 67 patients with primary biliary cirrhosis.  
Int J Clin Pharmacol Ther. 2001 Jan;39(1):25-32. PMID: 11204934.
- 9- Albengres E, Le Louet H, d'Athis P, Tillement JP.  
S15176 and S16950 interaction with Cyclosporin A antiproliferative effect on cultured human lymphocytes. Fundam Clin Pharmacol. 2001 Feb;15(1):41-6. PubMed PMID: 11468012.
- 10- Bechtel YC, Lelouet H, Hrusovsky S, Brientini, Manton G, Paintaud G, Miguet JP, Bechtel PR.  
Caffeine metabolism before and after liver transplantation.  
Int J Clin Pharmacol Ther. 2001 Feb;39(2):53-60. PMID: 11270802.
- 11- Bordet R, Gautier S, Le Louet H, Dupuis B, Caron J.  
Analysis of the direct cost of adverse drug reactions in hospitalised patients.  
Eur J Clin Pharmacol. 2001 Mar;56(12):935-41. PMID: 11317484.
- 12- Bechtel YC, Bechtel PR, Lelouet H, Choisy H, Dy NR.  
[The acetylator polymorphism in a Khmer population: clinical consequences].  
Therapie. 2001 Jul-Aug;56(4):409-13. French. PMID: 11677864.
- 13- Elimadi A, Sapena R, Settaf A, Le Louet H, Tillement J, Morin D.

- Attenuation of liver normothermic ischemia–reperfusion injury by preservation of mitochondrial functions with S-15176, a potent trimetazidine derivative.  
Biochem Pharmacol. 2001 Aug 15;62(4):509-16. PMID: 11448461.
- 14- Hamdan M, Urien S, Le Louet H, Tillement JP, Morin D.  
Inhibition of mitochondrial carnitine palmitoyltransferase-1 by a trimetazidine derivative.  
Pharmacol Res. 2001 Aug;44(2):99-104. PMID: 11516258.
- 15- Murr D, Bocquet H, Lelouet H, Fischer RM, Revuz J, Cosnes A.  
[Adverse cutaneous reaction to celecoxib: 6 cases].  
Ann Dermatol Venereol. 2003 May;130(5):519-21. French. PMID: 12843828.
- 16- Szafir D, Lelouet H, Imbs JL.  
Prevention of drug-induced risks.  
Therapie. 2003 May-Jun;58(3):221-7. English, French. PMID: 14655317.
- 17- Lonjou C, Thomas L, Borot N, Ledger N, de Toma C, LeLouet H, Graf E, Schumacher M, Hovnanian A, Mockenhaupt M, Roujeau JC; RegiSCAR Group.  
A marker for Stevens-Johnson syndrome ...: ethnicity matters.  
Pharmacogenomics J. 2006 Jul-Aug;6(4):265-8. Epub 2006 Jan 17. PMID: 16415921.
- 18- Le Louet H, Loupi E, Haramburu F; Round Table No 3, Giens XXII.  
Which pharmacovigilance for vaccines?  
Therapie. 2007 May-Jun;62(3):241-7. Epub 2007 Sep 6. Review. English, French. PMID: 17803893.
- 19- Le Louet H, Thomas L, Babai S.  
DRESS: is oxcarbazepine safer than carbamazepine? An analysis of the French Pharmacovigilance database.  
Eur J Neurol. 2008 May;15(5):e43. Epub 2008 Mar 18. PMID: 18355308.
- 20- Nasrallah-Irles D, Castot A, Thomas L, Babai S, Delorme B, Le-Louet H.  
[Adverse drug reactions: a pilot study on patient reporting through patient associations].  
Therapie. 2008 Sep-Oct;63(5):385-92. Epub 2009 Jan 21. French. PMID: 19154708.
- 21- Esteve E, Beau-Salinas F, Esteve L, Lemacon JM, Autret-Leca E, Le Louet H, Hocine R, Wolkenstein P, Plaquet JL.  
[Melanoma during latanoprost therapy: three cases].  
Ann Dermatol Venereol. 2009 Jan;136(1):60-1. Epub 2008 Nov 28. French. PMID: 19171236.
- 22- Sassolas B, Haddad C, Mockenhaupt M, Dunant A, Liss Y, Bork K, Hausteiner UF, Vieluf D, Roujeau JC, Le Louet H.  
ALDEN, an algorithm for assessment of drug causality in Stevens-Johnson Syndrome and toxic epidermal necrolysis: comparison with case-control analysis.  
Clin Pharmacol Ther. 2010 Jul;88(1):60-8. Epub 2010 Apr 7. PMID: 20375998.
- 23- Babai S, Auriche P, Le-Louet H.  
Comparison of adverse drug reactions with donepezil versus memantine: analysis of the French Pharmacovigilance Database.  
Therapie. 2010 May-Jun;65(3):255-9. Epub 2010 Aug 11. PMID: 20699079.
- 24- Medkour F, Babai S, Chanteloup E, Buffard V, Delchier JC, Le-Louet H.  
Development of diffuse psoriasis with alopecia during treatment of Crohn's disease with infliximab.  
Gastroenterol Clin Biol. 2010 Feb;34(2):140-1. Epub 2010 Feb 6. PMID: 20138448.
- 25- Thomas L, Cordonnier-Jourdin C, Benhamou-Jantelet G, Divine C, Le Louet H.  
Medication errors management process in hospital: a 6-month pilot study.  
Fundam Clin Pharmacol. 2011 Dec;25(6):768-75. doi: 10.1111/j.1472-8206.2010.00907.x. Epub 2011 Jan 7. PMID: 21210845.
- 26- Faillie JL, Babai S, Crépin S, Bres V, Laroche ML, Le Louet H, Petit P, Montastruc JL, Hillaire-Buys D; French Pharmacovigilance Centers Network.  
Pancreatitis associated with the use of GLP-1 analogs and DPP-4 inhibitors: a case/non-case study from the French Pharmacovigilance Database. Acta Diabetol. 2014;51(3):491-7. doi: 10.1007/s00592-

013-0544-0. Epub 2013 Dec 19. PubMed PMID: 24352344.

27- Aljadhey H, Mahmoud MA, Alshammari TM, Al-Dhaeefi M, Le Louet H, Perez-Gutthann S, Pitts PJ. A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia. *Saudi Med J.* 2015 Sep;36(9):1097-102. doi: 10.15537/smj.2015.9.12125. PubMed PMID: 26318468; PubMed Central PMCID:PMC4613635.

28- Alshammari TM, Al-Kathiri WH, Le Louet H, Aljadhey HS. Completeness of adverse drug reactions reports of the Saudi adverse event reporting system. *Saudi Med J.* 2015 Jul;36(7):821-8. doi: 10.15537/smj.2015.7.11751. PubMed PMID: 26108586;

PubMed Central PMCID: PMC4503901.

29- Leguay Z, Bourneau-Martin D, Pellier I, Le Louet H, Drablier G, Lagarce L, Lainé-Cessac P. Successful Treatment with Etoposide Base after an Acute Hypersensitivity Reaction to Etoposide Phosphate. *Pediatr Blood Cancer.* 2015 Oct 15. doi: 10.1002/pbc.25797. [Epub ahead of print] PubMed PMID: 26468691.

30- Thomas L, Canoui-Poitine F, Gottenberg JE, Economu-Dubosc A, Medkour F, Chevalier X, Bastuji-Garin S, Le Louët H, Farrenq V, Claudepierre P. Incidence of new-onset and flare of preexisting psoriasis during rituximab therapy for rheumatoid arthritis: data from the French AIR registry. *J Rheumatol.* 2012 May;39(5):893-8. doi: 10.3899/jrheum.111347. Epub 2012 Apr 15. PubMed PMID: 22505694.

## Projects

### Memberships

- President of the Internal Society of Pharmacovigilance (ISOP)
- Vice president of the Council for International Organisation of Medical Sciences (CIOMS/WHO).
- Member of the European Association for the Study of the Liver
- 2009-2012 chairman of the education and training programs of the ISOP
- Since 2003, Member of the Drug Information Association (DIA)
- Since 2007 member of the International society of Pharmacoepidemiology.

### Other Relevant Information

- 2004-2009: Co-coordinator of the drug risk management module, Master of clinical Pharmacology and Public Health, jointly delivered by Paris VI.
- Since 1996: Pharmacokinetic, Pharmacogenetic, Pharmacovigilance, Medical School, Paris XII University.