Clinical research on drugs in France and in Quebec

A Guérin[1], C Tanguay[1], D Lebel[1], O Bourdon[2], J-F Bussières[1]

1. Département de pharmacie et Unité de Recherche en Pratique Pharmaceutique, Centre Hospitalier Universitaire Sainte-Justine. Montréal 2. Département de pharmacie, Hôpital Robert Debré, APHP. Paris

Objectives

To identify differences between France and Quebec (Canada)

- in clinical research organization
- in pharmacy practice

Methods

- A literature review was performed in order to describe the organization of clinical research and the role of pharmacists in clinical research for both countries
- Differences were identified by a panel consisting of one French pharmacy intern, one French hospital pharmacist, one Quebec research assistant and two Quebec hospital pharmacists

Results

Table 1. Differences in the regulatory framework and the organization of clinical research

Areas	Differences
Normative framework	France: international, European and French normative framework Quebec: international, Canadian and Quebec normative framework
Competent authority	France: Agence nationale de sécurité du médicament et des produtis de santé (ANSM) Quebec: Santé Canada
Authorization process	France: an authorization is required for Phase I, II, III and IV clinical trials Quebec: an authorization is required for Phase I, II, III clinical trials . Required for Phase IV, clinical trials if the drug is used for a new indication
Deadline for authorization	France: 60 days Quebec: 30 days
Database	France: an EudraCT application is required by the ANSM before applying for a clinical trial authorization Quebec: application on a database of the WHO or on Clinicaltrials.gov is encouraged by Santé Canada, but not mandatory
Institutional Review Board (IRB)	France: Comité de Protection des Personnes (CPP) Quebec: Comité d'éthique de la Recherche (CER)
Term of office of IRB members	France: 3 years Quebec: 4 years
Appointment of IRB members	France: appointment by the prefect of the region Quebec: recommendation of the Chairman of the Board of Directors of the establishment to the Ministry of Health and Social Services
Number of IRB	France: 40 CPP Quebec: 220 CER (155 establishments)
Scope of the IRB	France: the CPP decision has a national value Quebec: the CER decision has value for its own institution. However, a local CER can endorse the opinion of the CER of another institution
Composition of the IRB	France: 14 members, including a hospital pharmacist Quebec: Minimum of five members. The majority of members must be Canadian or permanent resident. There must be men and women. The presence of a pharmacist is not mandatory.
Consent for minors	France: given by the two holders of parental authority Quebec: given by one holder of parental authority
Interruption of a clinical trial	France: the principal investigator informs the sponsor and participants. The sponsor informs the CPP and the ANSM Quebec: the principal investigator informs the CER, the sponsor and the granting agencies
Archives	France: 15 years (Medicinal products derived from human blood: 40 years) Quebec: 25 years

Table 2. Differences in pharmacy practice

Areas	Differences
Training	France: diplôme d'études spécialisées (DES) (specialized diploma study) Quebec: professional Master degree
Authorization to produce experimental drugs	France: this optional activity must be approved by the ANSM. It is possible to be the production coordinator for several sites Quebec: this optional activity to be confirmed within the protocol
Fixing pharmaceutical tariffs	France: presence of a national reference adopted by Les entreprises du médicament (LEEM) Quebec: absence of provincial framework
Softwares for the computerization of pharmacy services	France: use of commercial dedicated software Quebec: dedicated commercial software are not used, but some centers are using local databases
Sterile medical devices and medicinal products derived from human blood	France: management of sterile medical devices and medicinal products derived from human blood clinical trials Quebec: these products are not managed by pharmacists
Code of conducts of pharmacists	France: no mention of clinical research on drugs in the July 2009 edition of the pharmacists code of conduct Quebec: chapter VI contains seven articles devoted to the obligations of the pharmacist in clinical research (since 2008)
Provision of pharmaceutical care	France: inpatients : dispensation and patient counselling outpatents : little presence of the pharmacist in clinical services Quebec: inpatients : dispensation and patient counselling outpatients : decentralized pharmaceutical care offered in the majority of clinical services
Pharmacist as principal investigator	France: the pharmacist cannot be a principal investigator Quebec: the pharmacist can be a principal investigator, but the qualified researcher must be a doctor

Discussion / Conclusion

- Clinical research in France and in Quebec is similar on many aspects, but 22 main differences were identified
- Pharmacists have a role to play in the evolution of clinical research
- Comparisons between countries help identify best practices and may contribute to practice improvement

Poster presented at the 18th congress of the EAHP—March 13-15 2013, Paris, France
OHP - 015

Contact: jf.bussieres@ssss.gouv.qc.ca **Conflict of interest**: none
Funding: Réseau mère-enfant de la Francophonie