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Client Alert Commentary

Latham & Watkins Litigation & Trial Practice

March 3, 2016 | Number 1939

5 Questions About France's New Health-related Class Action Law

The number of eligible associations and the law's broad scope could portend a significant number of health-related class actions.

A new law, referred to as Loi Santé No. 2016-41 and enacted on 26 January 2016, contains provisions enlarging the scope of class action litigation in France to include health-related claims. Such provisions will enter into force after the French government publishes an implementing decree, expected by 1 July 2016 at the latest.

Loi Santé follows Law No. 2014-344 called, Loi Hamon (enacted on 17 March 2014 and entered into force on 1 October 2014), that allowed for the first class actions, though limited to consumer and competition violations (please see Latham's *Client Alerts*: Introduction of Class Actions in France: A Growing Threat to Professionals; Class Actions enter into force in France as of 1st October 2014).

1. What is the scope of class actions under Loi Santé?

Concerned products

Loi Santé applies to health-related products and cosmetic-related products. Article L. 5311-1 II of the Public Health Code provides a non-exhaustive list:

- Medicines including insecticides, acaricides and anti-parasite treatments for human beings, compounds, narcotic drugs or poisonous substance used in medicine, essential oils and plants
- Raw materials for pharmaceutical purposes
- Birth control
- Biomaterials and medical devices
- Labile blood products
- Organs, tissues, cells or any products from humans beings or animals
- Breast milk
- Contact lenses cleansing products
- Cosmetics
- Disinfection processes and devices for premises and vehicles
- Micro-organisms and toxins
- Tattoo products
- Software which is not medical device, but is used by medical laboratories for control of medical exams and for the validation, interpretation, communication and storage of results

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- Devices without strictly medical purposes used in medical laboratories in order to realize medical biology exams
- Software used to assist with prescribing and dispensing pharmaceuticals

Concerned breaches

A class action can be brought before French courts when a producer or supplier of a health-related product or of a cosmetic-related product or a provider using such products allegedly fails to comply with the applicable statutory or contractual duties (future Article L. 1143-1 of the Public Health Code). Breaches may occur before the entry into force of the law.

Concerned harms

Harms resulting from physical injuries may be indemnified (future Article L. 1143-1 of the Public Health Code).

2. Who are the actors of such class actions?

Claimants

Only accredited associations representing health system users are entitled to bring a class action before a court. The representing associations can be either regionally or nationally representative. Therefore, 486 associations are authorized to bring such claims (345 regionally representative associations and 141 nationally representative associations) whereas only 15 associations of consumers are entitled to represent consumers.

Defendants

Class actions can be brought before French courts against producers or suppliers of a health-related product covered in the list above or against providers using one of those products. The defendant can be a natural or a juridical person.

Claimants can also bring a claim directly against the insurance of the allegedly liable professional.

3. Which courts have jurisdiction to hear a class action case?

Civil courts and administrative courts have jurisdiction to hear a class action case. In principle, civil courts have jurisdiction when defendant is a private entity whereas administrative courts have jurisdiction when defendant is a state-owned entity.

4. What are the main steps of the proceedings?

A first ruling on liability

A first ruling will:

- Assess whether the conditions required to bring a class action are met
- Rule on the liability of the professional
- Determine the group of health-system users entitled to compensation or set forth criteria for group inclusion
- Determine what harms resulting from physical injuries may be indemnified

Measures to inform health-system users of a class action

The judge will determine the appropriate measures to inform health system users, *i.e.* news,press release, website, mail or emails, etc.

Those measures may only be performed once the first ruling on liability is final, *i.e.* may no longer be challenged before an appellate jurisdiction or the Supreme Court.

The defendant, who has been recognized liable, bears the cost of those measures.

An opt-in phase

Inclusion in the group is based on an "opt-in" system, *i.e.* health system users must consent to their inclusion. In the first ruling, the court will determine the time period during which consumers can opt-in to the class after the publication of this ruling, *i.e*. no less than six months and no more than five years. This extended period is based on the fact that harms resulting from physical injuries can appear a long time after the alleged causal event occurred.

An individual liquidation of the assessed losses

The health-system user has a choice between asking for compensation directly to the professional or granting a mandate to the accredited association to act on the individual's behalf.

Pursuant to the new law, when a professional held liable refuses to amicably allocate damages to a user, the user (or the association on the user's behalf) must seek relief individually before the court which rendered the first ruling on liability.

5. Is there an alternative to court proceedings?

The new law provides for a detailed mediation process. In parallel with the proceedings described above, and even if the court has not yet ruled on liability, the parties can pursue a mediation in order to reach an agreement establishing the basis for an amicable compensation..

Pursuant to the new law, the agreement must contain at least:

- Individual expertise modalities
- Allocation of costs
- Conditions under which settlements can be individually offered to concerned users
- The time period to seek relief
- Follow-up measures
- Appropriate measures to inform consumers of the agreement

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