

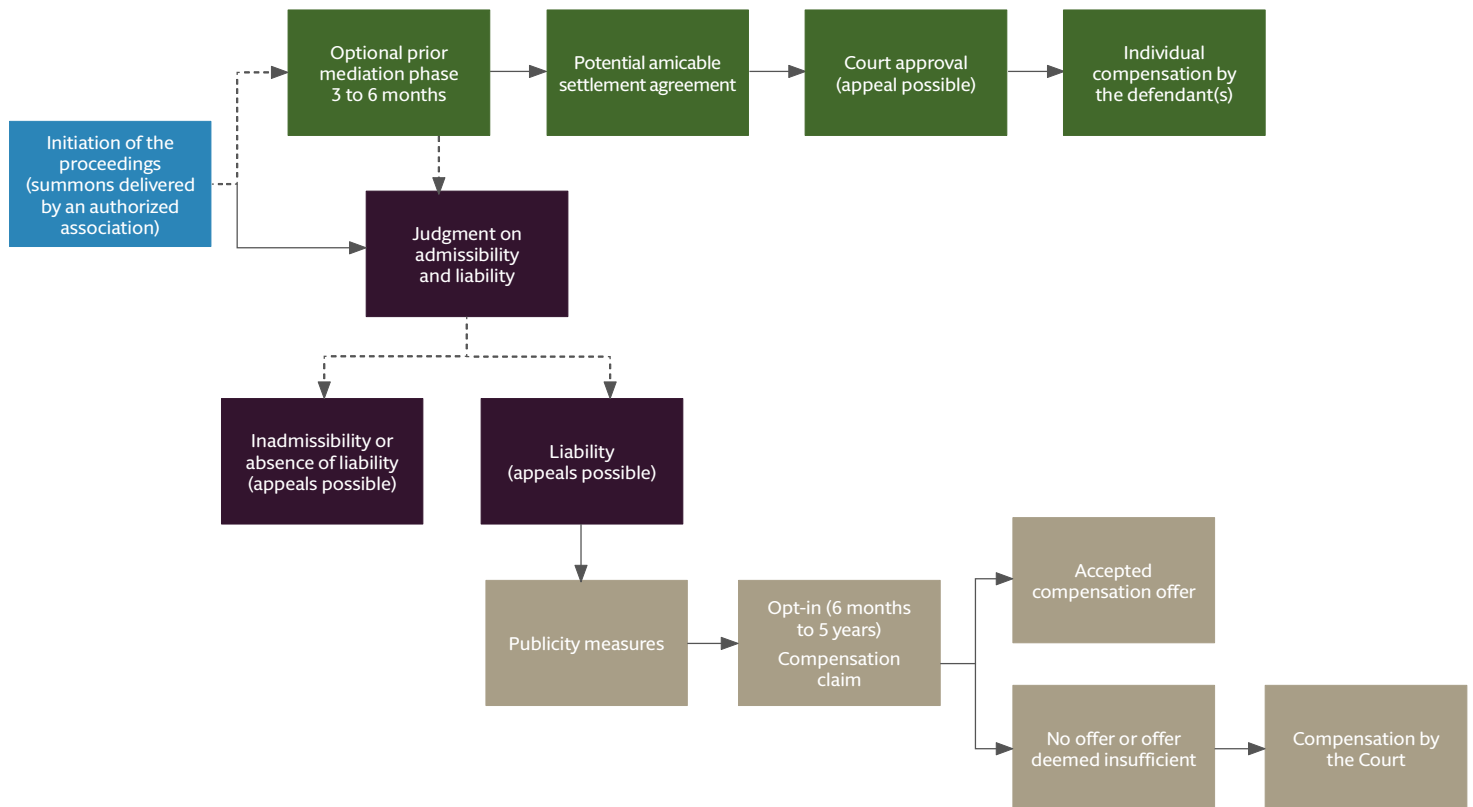


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A long road ahead

Health-related class actions in France

A long and winding procedural road



Article 184 of Law no. 2016-41 of 26 January 2016 on the modernization of the health system introduces class actions in health-related matters under French law.

French class actions for bodily injuries caused by health products and cosmetic products came into force on 1 July 2016.

Within this brochure, we will:

- **Show you the main procedural steps** of class action proceedings
- **Guide you through the main features of these class actions *à la française* with our Q&A:** 15 questions and answers that will provide you with a comprehensive overview of this mechanism
- **Help you anticipate health-related class actions** and not be taken by surprise if an action is launched and the media come knocking at your door.

We would be happy to go through it with you, should you wish to. Please feel free to contact us if you have questions.

The key features of French health-related class actions in 15 questions and answers

1. Who may initiate the action?

Authorized associations representing users of the health system, i.e. more than 480 associations as of June 2016.

2. On behalf of who?

A group of users (starting at two) of the health system placed in an identical or similar position (not defined in the law).

3. For which products?

All products listed in Article L. 5311-1 II of the French Public Health Code, including pharmaceuticals, medical devices and cosmetic products.

4. Against whom?

Manufacturers, suppliers and service providers using a health product (e.g. hospitals, healthcare professionals) as well as their civil liability insurers.

5. On what grounds?

Any breach of legal or contractual obligations by manufacturers, suppliers and service providers, even if the breach has ceased prior to the entry into force of the law. Liability regimes are not affected by the law.

6. For which losses?

Any losses resulting from bodily damage. Compensable bodily damage will be specified in the judgment on liability.

7. What are the major stages ahead?

An optional mediation phase can be decided by the Court with the agreement of the parties.

A liability judgment in which the Court will rule on admissibility and liability, and in case of liability will:

- define the “group”, the criteria and the cut-off date to join the group;
- specify the compensable bodily damage;
- order publicity measures.

Appeals are available against this judgment.

A compensation phase during which users of the health system will ask for compensation out of court based on the judgment.

8. How will scientific and medical questions be decided?

The Court should appoint experts to look into the scientific and medical questions, including an evaluation of the medical records of the users represented by the association, an analysis of the scientific literature on the allegations and the regulatory history of the product, etc.

9. Can the Court seized with the class action order payments?

The Court may award advance payments to the parties at any time subject to different conditions depending on the stage of the proceedings. As per the new law, the Court may also award an advance payment for costs to the association to cover future costs.

10. Can the Court order one party to pay the other's costs?

The only express provision deals with an advance payment to the association (see question 9). For the rest, French Courts' usual approach is to award lump sums for the opposing party's costs, and not compensation of the actual amount of these costs.



11. What is the time allotted to join the group?

The cut-off date to join the group will be determined by the Court in its judgment on liability. This time can range between six months and five years from completion of the publicity measures.

12. Which type of publicity measures can be ordered?

There is no indication in the law as to the types of publicity measures which can be ordered, save for the fact that they shall be “appropriate”. They can be implemented only after the final judgment on liability.

13. How are individual losses compensated?

“Users of the health system” may request compensation from the defendant(s) found liable, either directly or through the association. It is then up to the defendant to examine the compensation claim and make an offer.

14. What happens if the defendant refuses to compensate or if the offer is rejected?

The “user of the health system” may refer his/her individual case to the first-instance Court that ruled on the class action for the Court to order compensation.

15. Are class actions exclusive of other actions?

Class actions will coexist with other types of proceedings: civil cases, out-of-court process of CCIs (Conciliation and Indemnification Committees), criminal cases.

One may not be compensated twice so plaintiffs will have to make a choice between these various options.

Two class actions concerning the same product are possible provided they do not relate to the same facts, breaches or damage.



“Health-related class actions create an additional risk. Trying to handle bodily injuries cases through a collective mechanism before Courts which are not used to it will add complexity. The defense strategy must ideally be anticipated and it must cover both litigation and communication aspects.”

Cécile Derycke



Take steps now. Sleep better later.

Since 1 July 2016, class actions in health-related matters are available to plaintiffs represented by an association. Wherever possible, such actions must be anticipated by: identifying the actors, writing down the story and delivering it in the media and courtrooms, across borders.

Why is anticipation crucial?

Because you won't have much time on the D-day. The media are usually the first battlefield for class actions.

To protect the reputation of the company and start defending the case, the reaction must be **immediate**.

But it must also be **accurate**: you will live for a long time with the facts and arguments initially presented to the media. The best way to ensure you won't have regrets about this is to think about them as much as possible in advance.

How can you get prepared?

Analyze the risks

Start by identifying what the risk level for your company or a certain product is:

- Do you have products (on the French market) that are *crucial* for your business and its future?
- Have you been involved in product liability cases concerning one or several products in France? In other countries, including the USA?

- What does the Internet say about your company and/or the product?
- What do the authorities say about your company and/or the product, especially in France, in Europe and in the USA?
- What are pharmacovigilance data and literature telling you about potential cases to come?

If the risk is high, we suggest that you take all the steps described below. It will make a huge difference if and when the time comes for your company to defend against a class action in France.

If the risk is moderate, you may decide to take just some of these steps.

Of course, don't forget to monitor pending claims, pharmacovigilance data and the literature to identify or fine-tune the risks.

Identify the people

Create a core team within the company: a *small* group of people from management, legal and communication departments who will be activated if a class action is launched.

Identify several spokespeople who will address the various stakeholders (the media, the authorities, the employees, the shareholders...) if an action is launched.

Choose your counsel: lawyers and public relations agency. They will help you anticipate and it will be difficult to make a choice once the crisis is here.

Start to think about private experts who could assist. You may even start working with them already: we would advise that you do this especially if there is a risk that someone else may hire them before you.

“For companies that face litigation in several countries or anticipate such a risk, cross-border coordination is key. The new French class actions will not be an exception to the rule.”

Charles-Henri Caron

Write down the story

With the help of your counsel:

- analyze the science and the regulatory history of the product at risk;
- write down a factsheet on the product (what it is, when and how it was put on the market, what the relevant literature says, etc.)

On that basis, draft key media messages and Q&As.

This part of the work is essential: what you will say to the media will stay in the public and may be used in Court later on.

The key to a solid defense: messages which are strong and simple, accurate and consistent (from the beginning until the end, whatever the context, whatever the country).

Deliver the story

It is always useful to train (again) the spokespeople identified to talk to the media.

Consider making contacts and discussing with: your insurers, the authorities maybe, key opinion leaders, journalists covering health matters...

If an action is launched, you will most likely be talking to all of them again, and to the Courts. This is when consistency will start to really pay off.

How we can help you

Class actions are nothing more but nothing less than a specific kind of mass tort litigation and we have been handling such cases for years.

In Paris, we have the largest litigation team on the market specialising in product liability. Over the years, we have defended cases involving many health products: pharmaceuticals, contraceptive pills, implants, vaccines, dialysers, radiotherapy equipment, blood-derived products, neurovascular devices, etc.

We also have unique, high quality and multi-jurisdictional capabilities in product liability.

We are one team worldwide. If you face or are threatened with actions in various countries, our integrated team will work with you to handle your matters across European jurisdictions and internationally. We will help you to take a global coherent approach and to make sure that this approach is followed everywhere.

Key contacts



Cécile Derycke
Partner, Paris
T +33 1 5367 3854
cecile.derycke@hoganlovells.com



Charles-Henri Caron
Senior Associate, Paris
T +33 1 5367 2282
charles-henri.caron@hoganlovells.com

Heads up:

Class actions remain a hot topic in France. The so-called Bill on the modernization of the 21st century's Justice, which is currently being discussed by the French MPs, provides for a general framework for class actions and streamlines some of the existing class actions, including the health-related ones. This Bill should be adopted over the Summer. We will report on it. For the moment, it notably creates new class actions mechanisms for some discrimination cases, damage to the environment, and data privacy.

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