

Summary of the Danish Act on the Right to Complain and Receive Compensation within the Health Service

(Consolidated Act of 28 august 2017, No. 1022, as last amended by the Act of 25 April 2018, No. 314)

Compensation for pharmaceutical injuries *Area of application*

Section 38: Compensation is paid to patients who sustain an injury due to the characteristics of pharmaceutical drugs used during an examination, treatment, etc., (pharmaceutical injuries) in accordance with the rules set out in this Chapter. This also applies to the survivors of such patients.

Clause 2: Individuals who take part in clinical trials with drugs (scientific health studies), that is not part of the diagnosis or treatment of the individual's disease or illness, are considered equal to patients. This also applies to patients from whom tissue and other biological material is taken.

Section 39: Compensation is only paid if the pharmaceutical drug is commercially dispensed in Denmark for consumption or clinical trials with pharmaceutical drugs. The drug shall be dispensed through a pharmacy, hospital, doctor, dentist or approved non-pharmacy sales outlet for over the counter pharmaceutical drugs in accordance with the Danish Medicines Act.

Section 40: By a pharmaceutical drug it is meant a product that is presented as a suitable agent to treat or prevent human diseases/illnesses or one that can be used or administered to humans to either restore, change or affect physiological functions with a pharmacological, immunological or metabolic effect or to set a medical diagnosis.

Section 41: A pharmaceutical injury caused by a prescription drug is only compensated if the drug was prescribed for the injured party.

Section 42: A pharmaceutical injury is not considered a disease or other injury:

- 1) caused by the drug not having the intended effect on the patient concerned; or
- 2) one that is caused by a mistake or negligence in connection with the prescription or dispensing of the drug to the patient.

Section 43: A pharmaceutical injury that is caused by the side effects of a pharmaceutical drug is only compensated if the nature or scope of the side effects affect the injured party in a way that is in all fairness acceptable. The provision includes both known and unknown side effects, as well as those that are expected and unexpected.

Clause 2: When making a decision in relation to Clause 1, emphasis should be placed on the following:

- 1) The nature and severity of the disease/illness for which the treatment was intended.
- 2) The injured party's state of health.

- 3) The scope of the injury; and
- 4) Other possibilities for taking into account the risk of injury.

Section 44: Compensation is only paid if the injury was most probably caused by taking or using the pharmaceutical drug.

Compensation sum

Section 46: Compensation and damages are determined in accordance with the provisions of the Danish Liability for Damages Act, cf. however this Chapter.

Clause 2: Compensation is paid after DKK 7,300 has been deducted from the main sum of compensation or damages.

Clause 5: The amount determined in Clause 2 is adjusted on 1 January each year by 2.0 per cent with the adjustment rate for the applicable financial year added, cf. the Danish Rate Adjustment Percentage Act.

Case processing

Section 55: The Minister for Health (the Patient Compensation Association by authorisation) processes, discloses and passes decisions on cases in accordance with this Chapter.

Clause 5: The State pays the determined sum immediately the complaint deadline, stated in Section 58 b, Clause 2, first sentence, expires. However, this does not apply if the decision is appealed.

Patient Compensation Appeals Board

Section 58 b: The decisions passed in accordance with Sections 33 and 55 can be appealed before the Patient Compensation Appeals Board, which will pass the final administrative decision. The Appeals Board can reaffirm, repeal or change the decision.

Clause 2: Complaints to the Patient Compensation Appeals Board must be submitted within one month after the complainant is informed of the decision. The complaint has a suspensive effect.

Clause 3: The Patient Compensation Appeals Board can ignore breach of the complaint deadline if there is special reason to do so.

Section 58 d: Decisions passed by the Patient Compensation Appeals Board can be brought before a court of law, which can reaffirm, revoke or change a decision.

Clause 2: The decision must be brought to a court of law within six months after the decision has been announced.

Statute of limitation

Section 60: Compensation claims under Clause 4 must be reported to the Minister of Health, or entity the Minister authorises to carry out tasks in accordance with this Chapter, within three years after the person entitled to compensation has been notified or should have been notified of the injury.

Clause 2: However, the statute of limitation for compensation claims in accordance with this Chapter will be effectuated within 10 years after the date on which the pharmaceutical drug was dispensed to the injured party.

Section 60 b: Should a binding decision be passed regarding recognition of an injury that falls under Chapter 3 or 4, or measurement of compensation for such an injury, a limitation deadline of three years from the decision date will be applied to claim compensation for the injury.

Clause 2: However, if the person entitled to compensation was unaware of the compensation claim, the limitation deadline under Clause 1 will apply from the date on which the person was notified or should have been notified of the claim.

Clause 3: The statute of limitation is effectuated within 10 years after the said decision in Clause 1, but within 30 years after the date on which the injury was sustained or the pharmaceutical drug was dispensed to the injured party.