**LEGEMIDDELANSVARSFORENINGEN**
(THE DRUG LIABILITY ASSOCIATION)
2 January 2024

# LIABILITY INSURANCE IN CONNECTION WITH CLINICAL TRIALS OF DRUGS

## 1 About the Drug Insurance

The Product Liability Act of 23 December 1988, Chapter 3, contains special rules concerning liability in the case of injuries caused by drugs. Pursuant to these rules, the manufacturers and importers of drugs and persons conducting clinical trials of drugs are obliged to take out a special insurance, the Drug Insurance. Such insurance will, under the more detailed rules of this Act, indemnify any injured persons on a no-fault basis, that is, regardless of culpability.

The Product Liability Act presupposes that the manufacturers and importers of drugs and persons conducting trials of drugs will carry such insurance through membership of the Drug Liability Association. The obligation to join this Association is formulated as follows in the Product Liability Act, section 3-4, subsections 1 and 2:

> "*A producer of a drug is obliged through membership of the Drug Liability Association ... to be insured against drug liability according to the present Chapter. The same applies to a drug importer if the producer does not have such insurance. ...*
>
> *Anyone engaged in carrying out tests on humans as a stage in development of drugs is obliged to have such insurance as is mentioned in the first paragraph if neither the producer nor the importer of the drugs has such insurance as also covers the test.*"

The task of the Drug Liability Association is to ensure that such Drug Insurance is taken out and kept in effect as prescribed. Claims for compensation arising from drug injuries are submitted to and considered by, on behalf of Norsk Legemiddelforsikring AS, Norsk Pasientskadeerstatning (Norwegian System of Compensation for Injuries to Patients), P.O. Box 232 Skøyen, 0213 Oslo, Norway, telephone +47 22 99 45 00.

Failure to register as a member of the Association when obliged to do so, entails unlimited personal liability for any claim for compensation in connection with the trial. Membership of the Association thus provides protection against personal liability.

## 2 Membership and premium payment

### 2.1 Clinical trials organised by a manufacturer

If the trial is organised by a manufacturer, it is presupposed that the manufacturer registers as a member. The trial is considered organised by the manufacturer if the manufacturer signs and sends the application to the Norwegian Medicines Agency, cf the Regulations relating to clinical trials on medicinal products for human use of 30 October 2009 no. 1321 (“Regulation on Clinical Trials”).

The following applies in respect of premium payment to the Association: If the manufacturer holds a marketing authorisation for one or several proprietary medicinal products in Norway, and the manufacturer is a member of the Association, the trial is considered to be covered by the manufacturer's turnover-based premium payment to the Association. This is the case regardless of whether the manufacturer holds marketing authorisation for the study product of the clinical trial in question or not. In such cases it is not necessary to notify the Association of the trial, which will automatically be covered. If the manufacturer does not hold a marketing authorisation for any proprietary medical products in Norway, the manufacturer shall register as a member of the Association and pay a separate premium payment of NOK 100 for each trial subject from and including trial subject no. 1. The

minimum premium payment per calendar year is NOK 2.500 and covers 25 trial subjects in a calendar year, regardless of how many trials there are conducted. For clinical trials with more than 5,000 trial subjects per calendar year, the premium payment will be fixed according to special agreement.

2.2 Clinical trials that are not organised by a manufacturer

If the trial is not organised by a manufacturer, the responsible medical doctor or dentist shall register as a separate member of the Association. Responsible medical doctor or dentist means the medical doctor or dentist who is in charge of the study, and who signs the application to the Norwegian Medicines Agency pursuant to the Regulation on Clinical Trials, section 2-1.

The following applies in respect of premium payment to the Association: For the responsible medical doctor or dentist there is a minimum fee of NOK 2.500 per calendar year. This amount covers up to 50 trial subjects per calendar year regardless of the number of trials. If, in the course of one calendar year, the member in question conducts trials involving more than 50 trial subjects, an additional NOK 100 shall be paid for each trial subject from and including trial subject no. 51. For clinical trials with more than 5,000 trial subjects per calendar year, the premium payment will be fixed according to special agreement.

The responsible medical doctor or dentist must ensure that the payment covers the correct number of trial subjects. If the number of trial subjects has not been decided ahead of the trial, an agreement can be made with the Association to pay an instalment with a subsequent settlement of the account.

If circumstances require, it is the duty of the responsible medical doctor or dentist to ensure that the manufacturer is a member of the Association.

## 3 Registering as a member

The simplest way to register as a member is by e-mailing to the Association: unedv@bahr.no**.** We will then take contact by e-mail regarding further details concerning the clinical trial and invoicing. After the invoice is settled, the Association will forward a membership confirmation.

The membership is valid for one calendar year, and must be renewed each year as long as the obligation for insurance prevails

## 4 Miscellaneous

Membership of the Association does not exempt the members from their obligation to give notification of clinical trials to the regional committees for medical research ethics and to the Norwegian Medicines Agency. The Drug Liability Association presupposes that all trials will be notified pursuant to the rules in force.

Questions concerning membership of the Association or fees/premium payments should be directed to:

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