18 June 2021

INFORMATION ON PREMIUM CALCULATION

The costs of the Drug Liability Association's (DLA) product liability insurance are allocated between the members of the Association in proportion with their drug turnover (Article 9 of the DLA Articles of Association).

On 15 May 2019, the DLA's Board of Directors resolved to change the basis for the calculation of premium with effect from 2020 onwards, to be calculated on the basis of the price actually achieved upon the sale of drugs from the manufacturer to the manufacturer's customer, i.e. the purchase price paid by the wholesaler or other party to whom the manufacturer sells drugs, after the deduction of any discounts.

Formerly, until and including 2019, the premium was calculated on the basis of drug turnover measured at the pharmacy purchase price (AIP) level.

The basis for calculation of premium to the DLA is now the same as for calculation of supplier tax to the Norwegian Medicines Agency (NoMA). Turnover shall be reported to the DLA after the end of each year, and not quarterly as to NoMA. The deadline for reporting annual turnover is the end of January, and the deadline for submitting auditor's certificate is the end of February, of the following year. Turnover may be reported to the DLA by sending a copy of the NoMA form to the DLA. The specification shall be sent by e-mail to unedv@bahr.no. Auditor's certificates shall be sent to the Drug Liability Association, P.O. Box 1524 Vika, 0117 Oslo.

If one does not wish to use the same form for the DLA as for NoMA, the turnover specification to the DLA may be submitted in another practicable format.

Premium shall also be paid in respect of certain drugs that are exempted from supplier tax. This applies to vaccines for the Norwegian Institute of Public Health, disinfectants, radiopharmaceuticals for the Institute for Energy Technology and drugs exempted from registration. If one chooses to use the same form for the DLA as for NoMA, turnover of such drugs shall be reported separately to the DLA.

The DLA acknowledges that information on each manufacturer's own drug turnover constitute trade secrets. The DLA undertakes to only use such information in connection with the calculation of premiums. Such information will also not be disclosed to the members of the DLA Board of Directors.

If no turnover specification or auditor's certificate is submitted as mentioned above, the turnover-based premium shall be calculated on the basis of the approved pharmacy purchase price (AIP) of the drugs sold.

Detailed provisions on the calculation and payment of premium will be found in the attached «Supplementary Provisions on the Calculation and Payment of Premium» as at 15 May 2019.

This information and the attachment are available in Norwegian and English on the DLA website; www.laf.no.

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SUPPLEMENTARY PROVISIONS ON THE CALCULATION AND PAYMENT OF PREMIUM

Adopted by the Board of Directors of the Drug Liability Association on 15 May 2019 pursuant to Article 9, second paragraph, of its Articles of Association

Section 1 Payment obligation upon the production and sale of drugs

For drugs produced in Norway, the premium shall be paid by the manufacturer.

For drugs produced abroad, the premium shall be paid by the manufacturer, or alternatively by a representative in Norway, or by the importer of the relevant drug or by the wholesaler selling the drug, unless the manufacturer is a member of the Drug Liability Association and does itself pay the premium.

Manufacturers and importers of drug ingredients and semi-finished drugs, as well as wholesalers selling these, are not obliged to pay premium in respect of such goods. The premium shall in such cases be paid by the end manufacturer or the importer of the end product, or by the wholesaler selling the end product.

Section 2 Payment obligation upon clinical trials

For clinical trials, the sponsor is obliged to ensure payment of premium, cf. Section 1-5 s), cf. Section 2-4, of Regulations of 30 October 2009 No. 1321 relating to Clinical Trials on Medicinal Products for Human Use (the Clinical Trial Regulations).

If premium has been paid in respect of a clinical trial, the sponsor, the principal investigator and the investigator are considered members of the Drug Liability Association to the extent compatible with Article 3 of the DLA Articles of Association.

Section 3 Payment obligation discharged by others

Premium shall only be paid once per relevant quantity of drugs sold, or per trial subject in the same trial. If several parties are at the outset obliged to pay premium in respect of the same quantity of drugs or the same trial subject in a specific trial, payment by one of these parties will discharge the payment obligations of the other parties.

Upon a change of sales channel for the drug, the premium is calculated on the basis of who was representative/importer/wholesaler for the drug as at 31 December of the year preceding the payment year.

Section 4 Turnover-based premium

The basis for calculation of turnover-based premium is the price actually achieved upon the sale of drugs from the manufacturer to the manufacturer's customer, i.e. the purchase price paid by the wholesaler or other party to whom the manufacturer sells drugs, after the deduction of any discounts. Value Added Tax shall not be included in the calculation basis.

For drugs that are used without having been sold, the premium shall be calculated on the basis of the price assumed to be achievable upon a sale to a customer that is independent of the manufacturer.

The calculation basis for the payment year is the drug turnover in the calendar year preceding the payment year. For purposes of establishing the calculation basis, the drug is allocated to the calendar year in which it was sold by the manufacturer. If the party did not sell any drug in the calendar year preceding the payment year, the minimum premium stipulated at any given time shall be paid.

Calculation of turnover-based premium pursuant to the first and second paragraphs is conditional upon the Association receiving a specification of annual turnover no later than the end of January, with an auditor's certificate by the end of February, of the following year. If the manufacturer has not previously been a member of the Association, the turnover specification shall be submitted prior to membership registration.

If no turnover specification or auditor's certificate is submitted as mentioned, the turnover-based premium shall be calculated on the basis of the approved pharmacy purchase price (AIP) of the drugs sold.

Section 5 Premium for clinical trials

For clinical trials, premium shall be paid on the basis of the number of trial subjects. For trials with fewer than 51 trial subjects, the minimum premium stipulated at any given time shall be paid. However, if the trial involves more than 50 trial subjects, a supplement of NOK 100 per trial subject shall be paid in respect of trial subject no. 51 onwards.

One member may be responsible for several trials. The supplement of NOK 100 per trial subject only applies when the member is responsible for trials involving more than 50 trial subjects in total.

If a drug manufacturer is sponsor, cf. Section 1-5 s) of the Clinical Trial Regulations, and the manufacturer pays turnover-based premium, the trial is automatically covered through the turnover-based premium.

If the clinical trial is conducted under the auspices of a manufacturer that does not pay turnover-based premium, the premium shall be NOK 100 per trial subject. The minimum premium shall be NOK 2,500 per calendar year and covers up to 25 trial subjects in the relevant calendar year, irrespective of the number of trials.

For clinical trials involving more than 5,000 trial subjects over the course of one calendar year (large-scale trials), a special premium shall be agreed. This applies to trials conducted both in collaboration with, and independently of, the manufacturer or a representative thereof.

Premium for clinical trials shall be paid every calendar year of the trial on the basis of the number of trial subjects involved in the trial in the relevant year.

Section 6 Payment of premium – Due date

The parties obliged to pay premium are themselves responsible for calculating and paying the correct premium.

The turnover-based premium shall be paid in one instalment falling due on 15 February each year. The Association may extend the said deadline upon request or at its own initiative. Upon the start-up of new business operations, the minimum premium shall fall due on the start-up date.

Special premium for clinical trials shall fall due for payment prior to commencement of the trial in respect of the trial subjects registered as participants in the calendar year in which the trial is commenced. The premium shall thereafter fall due for payment on 15 February of each of the subsequent calendar years of the trial.

Section 7 On-account premium payment

If the calculation basis is not known as at the payment date, the member shall make an on-account payment based on the expected calculation basis, with subsequent additional payment or repayment taking place as soon as the final calculation basis is known.

Section 8 Payment specification

Any payment to the Association must be accompanied by specification of the calendar year(s) to which the payment pertains, as well as, if applicable, whether it is an on-account payment. The name of the member shall also be specified. The name of the principal investigator shall be specified as far as payments relating to clinical trials are concerned.

Section 9 Resignation

If a member does not renew its membership by paying premium by the deadline stipulated in Section 6, second paragraph, above, such member shall be deemed to have resigned its membership with effect from 1 January of that year. If the premium is paid later, the membership is deemed to have been retroactively reinstated. However, such subsequent payment of premium shall have no effect in relation to any injuries established prior to the date of such payment.

If a member expressly resigns its membership of the Association, such membership is deemed to have been discontinued with effect from the date on which the notice of resignation is received by the Association.

Section 10 Effective date – Revocation of earlier guidelines

These provisions shall enter into effect on 1 January 2020. The "Supplementary Provisions on the Calculation and Payment of Premium" adopted by the Board of Directgors on 30 November 2015 shall be revoked with effect from the same date.

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