GDV German Insurance Association

Comment

of the German Insurance Association (GDV)
ID-number 6437280268-55

on the Revision of EU Pharmaceutical Regulation of the European Commission

Executive Summary

According to Article 177 (7) of the proposed Regulation, the scope of Article 76 (1) Clinical Trials Regulation (CTR) shall be extended to **any damage caused to third persons or the environment**. In the attached position paper dated 18 September 2023 GDV has already explained in detail why this regulation is not necessary but **endangers the insurability** of clinical trials to a high degree. **GDV therefore strongly recommends that the current version of Article 76 (1) CTR should remain as it is and not be amended as suggested in Article 177 (7) of the proposal.**

Fallback: If despite all serious concerns Article 76 (1) CTR is to be extended as suggested in Article 177 (7) of the proposal to third-party and environmental damage, it would be essential to define and clarify some terms and details in Article 177(7).

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Introduction

Pursuant to the current version of Article 76 (1) of Clinical Trials Regulation (EU) No 536/2014 (CTR), Member States shall ensure that systems for compensation for any damage suffered by a **subject** resulting from participation in a clinical trial are in place in the form of insurance, a guarantee, or a similar arrangement that is appropriate to the nature and the extent of the risk.

According to Article 177 (7) of the proposed Regulation, Article 76 (1) CTR shall be extended to also include the obligation to provide compensation for **any damage caused to third persons** or **the environment** during the trial. **This extension jeopardises the insurability of clinical trials in Europe.**

Insurers' concerns about the extension of Article 76 CTR in a nutshell

For the following reasons the proposed amendment of Article 76 CTR is not necessary and carries the risk that clinical research can no longer be insured and is therefore no longer possible in Europe:

1. The terms "damage to third parties" and in particular "damage to the environment" can be very broadly interpreted. There is no specification or limitation. **Without specification, however, the risk cannot be calculated by the insurer.**

2. Without a specification and restriction of the term "any damage to third persons and the environment", **considerable problems in the approval process would be inevitable**. After all, how is the competent authority or ethics committee supposed to check whether the insurance, particularly with regard to damage to the environment, "corresponds to the nature and extent of the risk" in accordance with Article 76 CTR? Even if the terms were to be defined more precisely, it would remain questionable how the necessary specialist knowledge would be maintained by the authorities responsible for the approval.

3. An extension of Article 76 CTR to **any damage caused to third persons** or **the environment** during the trial would not only be highly problematic but also **unnecessary, as the insurance of third-party and environmental damage is already offered on a voluntary basis.** For example in Germany damage to third persons or the environment is already covered on a voluntary basis by taking out commercial third-party liability insurance. The market penetration of commercial third-party liability insurance is very high.

4. **There is no obligation to provide cover or take out insurance for environmental risks,** either at European or national level. We are not aware of any cases in which a clinical trial has resulted in damage to the environment

or harm to third parties. Many activities pose a much higher risk to the environment than clinical trials**. It is therefore incomprehensible why compulsory insurance should be introduced for clinical trials in particular.**

5. **Prevention of damage** is in every respect the preferable method compared to securing compensation through compulsory insurance. Insurance does not prevent damage. Instead of introducing compulsory insurance, the third-party and environmental risk should also be examined in the approval process of a clinical trial. At the national level, comparable legal requirements already exist that include environmental protection as a prerequisite for clinical trials (see for example Section 40a of the German Medicines Act).

For a more detailed explanation see GDVs position paper dated 18 September 2023 (**Attachment**).

Proposal of the German Insurers

German insurers recommend the following:

1. Since Article 177 (7) of the proposal endangers the insurability of clinical trials, the current version of Article 76 (1) CTR has to remain as it is and should not be extended as suggested in Article 177 (7). Accordingly Art. 177 (7) of the proposal should be deleted, since it is not only highly problematic but also unnecessary, as the insurance of third-party and environmental damage is already offered on a voluntary basis.

2. Fallback Position:

   a) If despite all serious concerns Article 76 (1) CTR is extended as suggested in Article 117 (7) of the proposal it is **essential** that the wording of Article 76 (1) CTR makes clear that a Member State also complies with Article 76 if the compensation system is built on three different insurance policies:

      - one clinical trial policy only to protect the **patient**,
      - one policy in which **third party damage** (other than the patient) caused to third persons during such a clinical trial as part of a general liabibility,
      - one policy in which damage caused to the **environment** during such a clinical trial as part of an environmental policy.

      This has to apply, as well when the **three policies have different policy holders**.

b) Finally it is essential

- **that the authority, who is responsible for the approval of the insurance cover (in Germany the Ethics Committee) has to approve the clinical trials policy only.** This is due to the reason that there might most probably not be the necessary and very special knowledge to judge the environmental risks of the study and the appropriateness of the insurance cover in different insurance contracts from different policyholders.
- **that the term ‘any damage to the environment’ is clearly defined on basis of the EU Environmental Liability Directive 2004/35/EC (ELD).** Otherwise no insurance cover could be provided for this. Insurance cover can only be provided for environmental damage under the ELD. **Cover for "any” damage to the environment is currently not available.**

Berlin, 27 August 2024

GDV Gesamtverband der Versicherer

ATTACHMENT

Position Paper

of the German Insurance Association (GDV)
Lobby register No R000774

on the EU Commission's Proposal - COM(2023) 193 final of 26 April 2023

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Executive Summary

German insurers are grateful for the opportunity to comment on the EU Commission's proposals on reforming the EU pharmaceutical legislation. German insurers fully support the objectives of the reform, in particular the objective to establish an attractive and innovation-friendly legal framework for research, development, and production of medicinal products in Europe. According to Article 177 (7) of the proposed Regulation, the scope of Article 76 (1) Clinical Trials Regulation (CTR) shall be extended to damage caused to third persons or the environment. This position paper will set out why, in the view of German insurers, this amendment is **unnecessary** and **highly problematic** and why it would **significantly increase the cost** of clinical studies. Making research even more difficult and giving rise to additional, unnecessary costs, however, should be prevented if the EU Commission is serious about the above-mentioned objective of establishing an attractive and innovation-friendly legal framework for research, development, and production of medicinal products.

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Introduction

Pursuant to Article 76 (1) CTR, Member States shall ensure that systems for compensation for any damage suffered by a **subject** resulting from participation in a clinical trial are in place in the form of insurance, a guarantee, or a similar arrangement that is appropriate to the nature and the extent of the risk.

According to Article 177 (7) of the proposed Regulation, Article 76 (1) CTR shall be amended to also include the obligation to provide compensation for **any damage caused to third persons** or **the environment** during the trial.

Position of German insurers

The proposed extension of compulsory financial security to also cover damage to third persons or the environment is unnecessary and indeed highly problematic for the following reasons:

1. **There is no need for legal regulation since damage to third persons or the environment are covered on a voluntary basis by taking out commercial third-party liability insurance[1].**

Commercial liability insurance covers the legal liability of policyholders arising from performing their business or professional activities. Insurance cover is provided if the policyholder is made liable by a **third party** to pay compensation for personal injury, property damage or financial loss resulting therefrom. According to the non-binding model terms and conditions of the GDV, the cover also includes civil liability arising out of activities that have an impact on the environment (**environmental liability insurance**) as well as the cost of measures to remedy damage to the environment as a common good pursuant to the German Environmental Damage Act (**environmental damage insurance**). The Environmental Damage Act *(Umweltschadensgesetz)* transposes the EU Environmental Liability Directive (2004/35/EC) into German law. Insurance cover is provided on the conditions and within the limitations of coverage as stipulated in the insurance contract and the terms and conditions of the insurance policy.

The market penetration of commercial liability insurance is very high in Germany: it can be assumed that almost every German business has taken out commercial liability insurance.

2. **It is incomprehensible why compulsory financial security to cover environmental damage and damage to third persons should be introduced for clinical studies with medicinal products of all things.**

We would like to point out that compulsory financial security requirements with regard to environmental risks, in particular, do not exist, either at European or the national level.

[1] also commercial liability insurance

This also applies to genetic engineering, in particular. For many years, pursuant to Section 36 of the German Genetic Engineering Act *(Gentechnikgesetz, GenTG)*, the federal government has had the power to require persons who run certain genetic engineering facilities or release genetically modified organisms to take out insurance cover for damage caused by properties of an organism that are the result of genetic engineering. This power, however, has not been exercised so far. **It is not clear why clinical studies, in particular, would have a special exposure to environmental damage,** which might require compulsory financial security.

Mandatory coverage of damage to **third persons**, as envisaged by the proposal, is not justified either in relation to already authorised medicinal products (authorised products are much more widely spread, which means that the risk of damage to third persons is higher too). Also, in relation to other activities in the medical sector, we believe that such an extension of compulsory financial security would not be appropriate.

3. **The terms “damage to third persons” and “damage to the environment” may be interpreted very broadly. There is no specification or limitation at all.**

If indeed, despite all the concerns raised, compulsory financial security will be introduced without specifying the term “damage to the environment”, it is very likely that **no appropriate insurance cover can be provided for clinical research**, due to the fact that there are no insurance products available which cover all damage to the environment. The widespread environmental damage insurance is in line with the scope of liability pursuant to the Environmental Damage Act. According to the statutory provisions stated therein, the liability is limited to certain significant environmental damages. If the plan to implement mandatory financial security for environmental damages will not be abandoned, the term would have to be specified accordingly. **The planned extension of compulsory financial security for clinical trials to "damage to the environment" could mean that clinical research could no longer be covered by insurance and thus no longer be possible.**

Specifying the term “damage to the environment” would also be inevitable regarding the verification of the financial security **within the scope of the authorisation procedure**. But even if the term is specified, it is very likely that the verification of the existence of financial security that is appropriate to the risk would result in considerably **more bureaucracy as well as in increased efforts in terms of time and funds** on the part of the authorising authority, ethics commissions, researchers, and insurers in the authorisation procedure or in the procedure before the ethics commissions.

4. A functioning system of protection against damages on a voluntary basis is superior to a mandatory system of protection.

If a legal obligation to provide for financial security is introduced, it must be considered that a **general minimum standard** will be stipulated with regard to the requirements on insurance cover, which will ensure adequate compensation for the **majority of claims**[2]. Given that the risks related to a study vary significantly depending on the study, having a general minimum standard would inevitably mean accepting the risk of inappropriate (too high or too low) requirements on insurance cover.

(Liability) insurance taken out on a voluntary basis enables policyholders and insurers to agree on **insurance cover that is appropriate to the respective risk involved**. And they make use of this possibility. **Particularly high-risk exposures** can thus also be covered in a way that is **proportionate to the risk**.

Examples include damage caused by genetic engineering.

- Many commercial liability insurances exclude the risks arising from the application of genetic engineering since the risk is difficult to assess for the insurer.

- Most clinical studies do not involve such risks Therefore, inclusion of risks arising from the application of genetic engineering in the mandatory financial guarantee would not be necessary for most claims.

- However, where there is a risk from the application of genetic engineering, those responsible have a personal interest in minimizing the risks by taking preventive measures and, on that basis, finding an insurance solution with their liability insurer. Ultimately, the licensing process could ensure that preventive measures are taken, and residual risk is covered on a case-by-case basis, if necessary.

5. Extending the German clinical trials insurance to damage to third persons and damage to the environment would contradict the basic concept of the clinical trials insurance.

Currently, Article 76 CTR serves only to cover persons who volunteer to take part in studies to support science and research and agree to use unauthorised medicinal products and accept the risk of a potential health damage. Based on this concept, the German clinical trials insurance is designed in such a way that compensation for damages caused by the study will even be paid when no-one is liable for the damage. This specific feature of the German solution cannot be applied to third

[2] For more information on this concept see Hedderich, Studien zum Privatrecht, volume 11 (2011), Pflichtversicherung, p. 303; see also Brand in Münchener Kommentar zum VVG, volume 2 (2011), preliminary note to Sections 113 - 124, para. 5 - 7 (only available in German). It basically says that the mandatory minimum sum to be agreed upon shall reflect the risk potential and be calculated so as to provide adequate compensation for the majority of claims. At the same time, however, the provision stipulated in constitutional law which says that no unnecessary burdens shall be imposed on persons subject to mandatory insurance calls for some restrictions. Hence, with regard to mandatory insurance, different levels of minimum amounts of coverage might have to be established, which make sure that activities that are below the average risk do not have to be insured disproportionately high. Furthermore, the amounts of coverage must not be calculated so as to cover every situation or every case no matter how realistic it might be. It has to be tolerated that in exceptional cases the largest differences between actual damage and insurance benefits might not obtain full coverage.[1]

persons or the environment. The risk of third persons or the environment to be damaged by the study is not comparable to the risk of the subjects directly involved in the study.

If the clinical trials insurance must include damage to third persons or the environment, it is very likely that the already **small number of clinical trials insurers will become even smaller.**

The German concept of clinical trials insurance would reach its limits. The existing insurance concept, which provides compensation to the subject regardless of liability and the right of direct action against the insurer, representing an insurance of a sui generis nature (between accident and liability insurance), only works for a known group of people (here: subjects participating in the study).

In addition, the inclusion of damage to third persons or the environment into clinical trials insurance could even result in disadvantages for the subjects, as the sum insured could be exhausted by damage to the environment or third persons at the expense of the subjects. Extending Article 76 CTR to damage to third persons and environmental damage in the clinical trials insurance would thus be **contrary to the system**. (The only exception refers to the unborn child of a female insured person who had already been conceived before the clinical trial was conducted. The unborn child is covered by clinical trials insurance pursuant to the GDV's non-binding model terms and conditions.)

Damage to third persons and environmental damage are covered by **voluntary liability insurance that is taken out in addition** to the clinical trials insurance (see above 1). This has been common practice in Germany for many years. If, despite the concerns raised, mandatory financial security is to be extended to damage to third persons and environmental damage, there should be the **possibility to cover these damages through a separate form of cover**. This is crucial, as the inclusion of new risks into mandatory financial security should by no means come at the expense of the subjects.

6. Liability requires a causal connection between the cause of damage and the actual damage.

Pursuant to Article 177 (7) of the proposed Regulation, Article 76 (1) CTR shall be amended to ensure that systems for compensation for damage "caused to third persons or the environment during such trial" are in place.

A coincidence in time between the cause of damage and the actual damage alone is not sufficient to establish any liability. Indeed, it is necessary that it can be assumed or proven by respective evidence that the damage is attributable to a particular cause. This requirement is not adequately reflected in the current wording "caused […] during such [clinical] trial".

Berlin, September 18, 2023