

PHARMACEUTICAL LIABILITY FOR UNEXPECTED ADVERSE DRUG REACTIONS: A COMPARATIVE STUDY OF SLOVENIAN AND GERMAN LAW

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NATAŠA SAMEC BERGHAUS,¹ NINA BRNDUŠIČ²

¹ University of Maribor, Faculty of Law, Maribor, Slovenia

natasa.samecberghaus@um.si

² Higher Court of the Republic of Slovenia, Maribor, Slovenia

nina.brndusic@gmail.com

CORRESPONDING AUTHOR

natasa.samecberghaus@um.si

Abstract Medicinal products are vital to healthcare, yet their use entails unavoidable risks, especially unexpected adverse drug reactions. This article examines how Slovenian and German law allocate civil liability for such harm and what implications arise for injured persons. It argues that Slovenia's framework is normatively sound but fragmented, with evidentiary support for claimants underdeveloped, whereas Germany's is more coherent and claimant-oriented. Both rely on strict liability and continuous pharmacovigilance but diverge in evidentiary and institutional design. Using a doctrinal-comparative method, the article analyses Slovenian and German statutes in light of Product Liability Directive (EU) 2024/2853. It finds that Slovenian law lacks key safeguards, including an express, sector-specific presumption of causation and a statutory right of access to safety data, and imposes no insurance duty. German law offers clearer rules, procedural support, and mandatory financial coverage. The Directive's innovations point toward a more claimant-friendly model, offering Slovenia an opportunity for reform.

Keywords

pharmacovigilance,
pharmaceutical liability,
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tort law,
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1 Introduction and Methodology

The pharmaceutical industry develops, manufactures, and markets medicinal products, which require strict regulation due to their impact on human life and a clear legal framework, typically through marketing-authorisation regimes and patent protection (Drofenik & Kerč, 2020, pp. 24-25). Because medicines are *sui generis* goods, regulation must balance industry interests with patients' rights. Liability may arise before or after market entry, including labelling, storage, pharmacovigilance, and use (Možina & Brvar, 2017, pp. 143-145), potentially involving multiple actors.

Users may sustain harm from adverse drug reactions (ADRs), and may seek legal redress, particularly when a manufacturer has withheld relevant information. Under point 51 of Article 6 of the Slovene Medicinal Products Act (Zakon o zdravilih, hereinafter: ZZdr-2),¹ an ADR is defined as any harmful and unintended response of a patient to a medicinal product for human use. An unexpected adverse reaction refers to any such reaction not listed in the Summary of Product Characteristics (SmPC); in other words, its seriousness, nature or outcome is inconsistent with the SmPC. A distinction is also drawn between adverse reactions and side effects - the latter encompassing undesirable, but either harmful or non-harmful effects resulting from the properties of the medicine when used at the correct dose (Možina, 2006, pp. 312-313). In some literature, however, the two terms are treated as interchangeable (see Due, 2023, p. 16).

Due to the inherent nature of medicinal products, harm may still occur to users despite safety measures such as regulatory oversight and adverse-reaction monitoring. Such harm may result from defective products, for example contaminated batches, manufacturing irregularities, or formulation errors, as well as from unexpected adverse reactions caused by inadequate pre-market testing, withheld information by manufacturers or pharmaceutical companies, or insufficient post-marketing research (Dangerous Drugs Leading to Products Liability Lawsuits, 2024). The development and monitoring of medicines is a multi-stage process, requiring continuous oversight both during trials and after market entry. Affected individuals may seek compensation under civil liability, raising questions of who

¹ Zakon o zdravilih (Medicinal Products Act), Official Gazette of the Republic of Slovenia, Nos. 17/14, 66/19, 102/24 – ZZKZ, 24/25 and 27/25 – corr.

bears responsibility and what must be proven. This article argues that Slovenia's framework, though normatively in place, remains fragmented and procedurally incomplete, whereas Germany's system is more coherent and claimant-oriented, as analysed through doctrinal comparison within the evolving EU context.

General tort liability in Slovenian law is set out in the Obligations Code (Obligacijski zakonik, hereinafter: OZ).² Article 10 of the OZ encapsulates the *neminem laedere* principle - the duty not to cause harm. Once wrongfulness, compensable damage, and causation are established, fault is presumed. By contrast, under strict liability no proof of fault is required (see further: Samec Berghaus, Bitrakov & Drnovšek, 2024, pp. 43-46). Within the Slovenian legal order, two acts are particularly relevant: the ZZdr-2 and the Consumer Protection Act (Zakon o varstvu potrošnikov, hereinafter: ZVPot-1),³ each of which contains specific liability provisions. Under the maxim *lex specialis derogat legi generali*, claims should be brought under the more specific statute, with the OZ applying subsidiarily to fill any lacunae. Accordingly, it is essential to determine which statute constitutes the *lex specialis*. Although ZZdr-2 and ZVPot-1 both regulate liability - albeit not as comprehensively as the OZ - they do so in diametrically opposed ways; the ensuing competition between statutes generates legal uncertainty and unpredictability. From this perspective, a precise delineation of the applicable regime is essential to ensure legal certainty.

At the core of these issues lies the product-liability regime for manufacturers of medicinal products, which in Slovenian law operates at the intersection of general tort rules and sector-specific statutes. The provisions of ZZdr-2, ZVPot-1, and the OZ frequently overlap or are construed divergently, generating legal uncertainty and disadvantaging injured parties.

This article adopts a doctrinal-comparative methodology to examine civil liability for harm caused by unexpected adverse drug reactions in Slovenian law and to compare it with the German legal framework. The doctrinal part of the analysis interprets the relevant EU, Slovenian and German provisions by using textual, systematic and teleological methods, with particular attention to the relationship between general

² Obligacijski zakonik (Obligations Code), Official Gazette of the Republic of Slovenia, No. 83/01 (with subsequent amendments: 97/07 – UPB, 64/16 – odl. US; 20/18 – OROZ631).

³ Zakon o varstvu potrošnikov (Consumer Protection Act), Official Gazette of the Republic of Slovenia, No. 130/22.

product liability rules and sector-specific pharmaceutical liability regimes. The comparative part follows a functional approach: it does not seek to measure litigation outcomes empirically, which would be difficult given the scarcity of Slovenian case law in this field, but instead compares how the two legal systems address the same practical problem, namely the injured patient's ability to obtain compensation for harm caused by medicines.

The comparison is guided by five analytical criteria that are particularly relevant in pharmaceutical injury cases: the clarity of the applicable liability regime, the allocation of the burden of proof, especially with regard to causation, the claimant's access to safety-related information, the relevance of limitation periods for latent health damage, and the existence of financial safeguards such as liability insurance. Germany is selected as the comparator not as an ideal model, but because the German Medicinal Products Act (*Arzneimittelgesetz*, hereinafter: AMG)⁴ contains several instruments that are either absent from or less clearly developed in Slovenian law, including a specific pharmaceutical liability regime, a statutory presumption of causation, a right of access to information and mandatory financial coverage.

The article addresses three research questions. First, which rules govern civil liability for harm caused by unexpected adverse drug reactions in Slovenian law? Secondly, how does the Slovenian framework differ from the German model of pharmaceutical liability under the AMG? Thirdly, can the new EU product liability framework, especially its rules on disclosure of evidence and rebuttable presumptions, offer guidance for strengthening claimant protection in Slovenia?

The article first outlines the EU-level framework governing manufacturers' liability, including the implications of Directive (EU) 2024/2853 (hereinafter: Directive 2024/2853).⁵ It then turns to Slovenian law, mapping the relevant rules on the liability of manufacturers and marketing authorisation holders, causation, defences and liability insurance. The following section addresses German law, with particular attention to pharmaceutical-company liability under the Medicines Act, the presumption of causation, the right to information and financial coverage. The

⁴ *Arzneimittelgesetz* (Medicinal Products Act). *Bundesgesetzblatt I*, p. 3394; last amended by Art. 2 of the Act of 23 October 2024 (*Bundesgesetzblatt I*, p. 324). Consolidated version consulted on 3 November 2025.

⁵ Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC, OJ L 2024/2853.

article then provides a comparative discussion of the Slovenian, German and EU approaches, before concluding with the main findings and reform implications for Slovenian law.

2 EU-Level Framework for Liability in the Context of Medicinal Products

Given the structural imbalance between individual claimants and manufacturers in most product-related harm cases, the European Union introduced a regime of strict liability for defective products in Council Directive 85/374/EEC (hereinafter: Directive 85/374)⁶. This Directive laid down essential rules for individuals injured by defective products, providing a harmonised legal framework that did not require proof of fault.

In 2024, Directive 85/374 was repealed and replaced by Directive 2024/2853. Member States must transpose it by 9 December 2026, pursuant to Article 22(1). One of the core innovations is the explicit inclusion of software - including AI-enabled systems and connected digital services - as standalone products falling within the scope of product liability. This reflects the increasing role of software in determining the safety and functionality of modern products. The revised Directive also introduces important evidentiary reforms, including mechanisms for presumptions of defectiveness and causation, as well as the right of claimants to request disclosure of relevant evidence, thereby alleviating the burden of proof in favour of the injured party (see more Li & Faure, 2024, pp. 166-167). Article 9(1) of Directive 2024/2853 provides that in a product liability lawsuit, if the claimant presents facts and evidence making the claim plausible, “the defendant is required to disclose relevant evidence that is at the defendant’s disposal” upon the court’s order. This marks a change from the old 1985 Directive 85/374, which had no such disclosure mechanism, often leaving victims struggling to obtain technical evidence held by manufacturers. The revised law thus gives courts a tool to force manufacturers to share internal documents or data relevant to the alleged defect, helping claimants access proof that would otherwise be out of reach. If a defendant fails to comply with a court’s evidence disclosure order, the Directive 2024/2853

⁶ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210.

presumes the product was defective. Article 10(2)(a) establishes that “the defectiveness of the product shall be presumed” if “the defendant fails to disclose relevant evidence pursuant to Article 9(1)”. In other words, when a manufacturer withholds evidence that the court ordered it to produce, one of the statutory conditions for presuming a product defect is met. This presumption is rebuttable - the manufacturer can still offer proof to contest defectiveness - but unless rebutted it spares the claimant from having to affirmatively prove the defect. Notably, the Directive 2024/2853 includes other triggers for a defect presumption (such as the product’s non-compliance with safety regulations or an obvious malfunction). However, failure to disclose evidence is a key new trigger, directly aimed at discouraging defendants from hiding information. As Li & Faure (2024) observe, the revised Directive “sets up the conditions to presume the defectiveness of the product” when evidence is withheld. These innovations greatly strengthen the claimant’s hand: they either gain the evidence needed to prove their case, or benefit from a legal presumption of defect that the defendant must overcome. This eases the victim’s path to compensation by reducing the obstacles in proving a defective product caused their damage.

Directive 85/374 already recognised that Member States may adopt or retain special liability regimes for certain sectors - most notably pharmaceuticals. According to Recital 13, “in so far as effective protection of consumers in the sector of pharmaceutical products is already attained in a Member State under a special liability system, claims based on this system should similarly remain possible”. The new Directive 2024/2853 preserves this flexibility. Recital (10) affirms that “the right to make [pharmaceutical-related] claims should remain unaffected by this Directive”, provided they do not undermine the objectives of the harmonised regime. In addition, Recital (11) clarifies that national compensation schemes (e.g., social security, insurance funds) remain outside the scope of the Directive, explicitly mentioning non-defective pharmaceuticals as an example.

The distinction between the general product liability regime and the special framework applicable to pharmaceuticals has also been examined by the Court of Justice of the European Union, which emphasised that medicinal products occupy

a special status due to their therapeutic purpose, setting them apart from ordinary consumer goods.⁷

Because Directive 85/374 already allowed Member States to retain pre-existing special liability schemes - for pharmaceutical products - the EU regime set up a harmonised strict-liability framework for defective products while leaving room for special regimes to continue operating (Recital 13; see also Recitals 10–11 of Directive 2024/2853). Within that space, Member States may enact or maintain sector-specific rules for medicinal products; this article focuses on Slovenia and Germany.

Germany provides a dedicated pharmaceutical liability regime under the AMG. The AMG establishes a special strict-liability scheme (*Arzneimittelhaftung*) for harm caused by medicinal products and, inter alia, contains a presumption of causation under specified conditions (e.g., Section 84(2) of the AMG). This yields a more granular level of claimant protection than the Slovenian ZZdr-2, which does not regulate civil liability in comparable detail and therefore requires subsidiary recourse to the OZ.

Like Slovenia, the German legislature transposed Directive 85/374 by a separate Product Liability Act (*Produkthaftungsgesetz*, hereinafter: *ProdHaftG*).⁸ Section 15 *ProdHaftG* expressly excludes the application of the *ProdHaftG* to human medicinal products governed by the AMG; liability under other provisions (i.e., the AMG regime) remains unaffected. With the upcoming implementation of Directive 2024/2853, the German legislature plans to replace the *ProdHaftG* with a new *ProdHaftG-E*, in which the current 15th section will become Section 21, maintaining the same content (*Bundesministerium der Justiz und für Verbraucherschutz*, 2025). No changes are necessary in pharmaceutical liability law: liability under the AMG remains the primary regulation (*lex specialis*) and already meets the standards established by the new EU product liability framework. The new EU product liability rules will govern other medical products, digital health applications, and digital

⁷ See Judgement of the Court of Justice of 22 December 2022, *Case C-530/20, EUROPTIEKA SLA*, ECLI:EU:C:2022:1014; see also Judgement of the Court of Justice of 19 May 2009, *Joined Cases C-171/07 and C-172/07, Apothekerkammer des Saarlandes and Others v. Saarland and Ministerium für Justiz, Gesundheit und Soziales*, ECLI:EU:C:2009:316, para. 31.

⁸ *Produkthaftungsgesetz* (Product Liability Act). *Bundesgesetzblatt I*, p. 2198; last amended by Article 5 of the Act of 17 July 2017 (*Bundesgesetzblatt I*, p. 2421). Consolidated version consulted on 3 November 2025.

software in the medical sector. By contrast, Slovenia's Consumer Protection Act (ZVPot-1) implements the general product liability regime but - unlike German law - does not carve out pharmaceuticals from its scope; still, in light of the EU *acquis* (Directive 85/374, Recital 13; Directive 2024/2853, Recitals 10–11), claims under more claimant-friendly national rules outside the product-liability regime remain possible, which in Slovenia points to the OZ as *lex generalis* (see also Samec Berghaus, 2025).

This EU-level backdrop frames the national analysis that follows. The next chapter examines, in turn, the applicability and interplay of ZZdr-2, ZVPot-1 and the OZ in Slovenia, with particular attention to allocation of risk, causation standards, defences, limitation periods, and the availability of liability insurance.

3 Liability under the Relevant Rules of Slovenian Law

3.1 Delineation of Regimes

In the Slovenian legal system, two sector-specific statutes are relevant to liability for harm caused by medicinal products: ZZdr-2 and ZVPot-1. Since both instruments regulate liability, the threshold question is whether medicinal products can be treated as goods within the meaning of ZVPot-1 for the purpose of determining the applicable regime. Any assessment must consider that medicines constitute a special category of goods, subject to specific rules on quality, safety and efficacy (ZZdr-2). In a broad sense, medicines may be subsumed under the concept of goods in ZVPot-1; however, as emphasised in the EU framework, both Directive 85/374 and the new Directive 2024/2853 were adopted on the understanding that they do not displace Member-State rules in certain sectors, one of which is medicinal products for human use. The practical consequence is this: where a field is specifically regulated (here, the pharmaceutical sector in Slovenia), general consumer-law provisions must yield to the sector-specific rules insofar as the latter would otherwise be encroached upon. In Slovenia, the field of medicines is primarily regulated by ZZdr-2.

From the foregoing - and from the fact that ZZdr-2 itself implements EU legislation (see Article 2 of the ZZdr-2) - it follows that ZVPot-1 does not apply to matters that fall, by virtue of EU-driven sector regulation, within the scope of ZZdr-2.

This conclusion is reinforced by general principles of interpretation. Having regard to legislative purpose, it is apparent that ZZdr-2 - particularly its liability provision - was enacted to protect injured parties where medicines, as a distinct class of products, cause harm, and it does so by regulating more strictly and in greater detail the liability of specific actors, namely manufacturers and/or MAHs in the Republic of Slovenia. As will be shown below, Paragraph 4 of Article 27 of the ZZdr-2 imposes liability even where “the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered.” By contrast, Article 64 of the ZVPot-1 provides the development-risk defence, allowing the manufacturer to avoid liability if it proves that, given the then current state of scientific and technical knowledge, the defect could not have been discovered. The legislative design is thus evident: ZZdr-2 affords stronger claimant protection, tailored to the specific risks associated with medicines. Consequently, ZZdr-2 is the more claimant-friendly regime in this field, consistent with the protection of the weaker party. The two statutes regulate liability in diametrically opposed ways: ZZdr-2 tightens the scope for exculpation, thereby enhancing legal certainty for injured parties. For this reason, ZVPot-1 does not govern liability for harm caused by medicines. This does not mean that ZVPot-1 is irrelevant in the broader consumer-protection context; for example, it remains pertinent to marketing and distribution practices for medicines.

When determining liability, the doctrine of manufacturer’s liability under Article 155 of the OZ is likewise unavoidable. That provision contemplates two heads of liability: (i) cases where the thing itself is defective, thereby increasing the risk of harm, and (ii) cases where the thing has dangerous properties. Primary protection for injured parties in the pharmaceutical context, however, is provided by Article 27 of the ZZdr-2, which - under the maxim *lex specialis derogat legi generali* - functions as the special regime *vis-à-vis* the OZ. The provisions of the OZ therefore apply subsidiarily, i.e., to issues not regulated by ZZdr-2. One such issue concerns causation - its standard, proof and presumptions - which will be addressed in what follows.

3.2 Medicinal Product as a “Dangerous Thing” or a “Defective Thing”?

When analysing liability for harm caused using medicinal products, Slovenian law requires a distinction between the concepts of a dangerous thing and a defective thing, as these are distinct institutions that may entail different consequences.

Medicinal products cannot be assessed as “dangerous things” in the same way as other products. Strict liability for medicinal products arises from special statutory provisions (ZZdr-2) that take into account their complexity, unpredictability, and the health status of users. The traditional criteria for dangerous things: high probability of harm and risks unmanageable even with utmost care, do not directly apply. A defective thing, by contrast, is one that fails to provide the level of safety a user is entitled to expect, including adequate instructions, warnings, and consideration of reasonably foreseeable uses. In practice, medicinal products may (depending on the facts and user conduct) be characterised as defective things, dangerous things, or a combination of both. Liability largely depends on whether users are adequately informed, as properly provided warnings and instructions generally protect manufacturers from claims for inherent risks. These rules highlight that medicinal products require a distinct assessment from ordinary products, where inherent dangers are treated differently (see more: Jadek Pensa et al., 2003, pp. 850-851; see also: Samec Berghaus, Bitrakov & Drnovšek, 2024, pp. 109-111).

3.3 The ZZdr-2 Regime

3.3.1 Liability of the marketing-authorisation holder (MAH)

Liability in the field of pharmacovigilance is governed by Article 27 of the ZZdr-2. Article 27(1) provides that “the marketing-authorisation holder for a medicinal product in the Republic of Slovenia is responsible for the development of the product and its placing on the market in accordance with the marketing authorisation, and for any damage that may arise in connection therewith, including damage resulting from inadequate quality of the medicinal product, for which the manufacturer is responsible.” The MAH need not be the manufacturer but must have a contractual arrangement with the manufacturer ensuring compliance of production with the authorisation and quality requirements (Article 27(2) of the

ZZdr-2). Where a manufacturing defect occurs, the MAH is liable to the injured party and may subsequently pursue recourse against the manufacturer.

ZZdr-2 does not speak in terms of “defectiveness” or of medicines as “dangerous things”; rather, it refers to inadequate quality (a quality defect). A quality defect is defined as any deviation from the data set out in the marketing authorisation that affects the safety or efficacy of the product (Rules on the Recall of Medicinal Products (Pravilnik o odpoklicu zdravil),⁹ Article 2). Examples include contamination, incorrect composition, damaged packaging, inconsistent instructions for use, or manufacture without authorisation (Slak, Planinšek, Miklič, & Frangež, 2019). The content and currency of the instructions for use are the responsibility of the MAH, while the manufacturer is responsible for their physical inclusion in the packaging and for proper labelling - i.e., the preparation of the finished product. The injured party may claim damages exclusively against the MAH, who bears ultimate liability.

3.3.2 Liability of the manufacturer

Although the MAH is the primary liable person, the manufacturer’s duties must be specified. Article 27(3) - (5) of the ZZdr-2 stipulates that the manufacturer is responsible not only for production as such, but also for quality control, packaging, and labelling of the medicinal product. The manufacturer is also directly liable for damage caused by falsified medicines where it is established that it removed or covered the safety features on the product and replaced them with new ones on a falsified medicinal product.

3.3.3 Causation

Causation links the harmful event to the damage and is a core element of liability in damages. Article 27 of the ZZdr-2 does not lay down rules on causation; consequently, the OZ, as *lex generalis*, applies subsidiarily. Given that liability for medicinal products is strict (objective), a rebuttable presumption of causation arises once the injured party establishes a connection between the damage and the

⁹ Pravilnik o odpoklicu zdravil (Regulation on the recall of medicinal products), Official Gazette of the Republic of Slovenia, Nos. 105/08 and 17/14 – ZZdr-2.

medicinal product, i.e., the anchor facts that trigger the presumption. It suffices for the claimant to prove this factual basis; in other words, the damage must in fact occur in connection with the use of the medicine.

By way of example, in cases involving substandard-quality medicines (quality defects), the presumption may be supported where the claimant points to adverse effects listed in the package leaflet – for instance, the leaflet warns of potential cardiac disorders, and such a disorder develops within a relevant period after administration. In that scenario the risk is already signalled in the instructions and can serve as the basis for the presumption. For unexpected adverse reactions not disclosed to users, establishing causation is harder, especially where multiple medicines are taken simultaneously (polypharmacy) or where the adverse effect appears only after some time has elapsed from the start of treatment.

For situations of this kind, EU case law allows courts to find a causal link based on serious, specific and consistent indicia, even in the absence of scientific evidence establishing causation. It is for the courts – within their margin of appraisal – to assess whether the facts relied on (e.g., the temporal proximity between vaccination and the onset of the disease, and the absence of prior medical history relating to that disease) amount to serious, specific and consistent presumptions sufficient to establish defect and the causal link, notwithstanding the lack of medical proof. The Court of Justice clarified that the claimant is not required to adduce precise and irrefutable proof of the defect and causation; rather, it is for the national court to determine, because of such indicia, whether a defect exists and whether that finding corresponds to the actual circumstances of the case. However, the indicia must be sufficiently serious, specific and consistent such that a defect in the product is the most plausible explanation for the damage, in which case the causal link may reasonably be treated as proven.¹⁰ This does not preclude courts from assessing the manufacturer's liability on other evidence as well.

¹⁰ Judgement of the Court of Justice of 21 June 2017, C-621/15, *N. W. v Sanofi Pasteur MSD SNC*, ECLI:EU:C:2017:484, paras 28 and 37.

3.3.4 Possibility of Exculpation

As noted, Article 27 of the ZZdr-2 introduces strict (objective) liability of the manufacturer and/or the MAH for medicinal products. This affords stronger protection to injured persons: under a purely fault-based regime it would be nearly impossible for many claimants to obtain compensation. They would not only have to establish the usual elements - where fault is presumed only once the first three are shown - but manufacturers/MAHs could also more easily exonerate themselves simply by proving that they exercised due care. A strict-liability regime is therefore justified not only because it alleviates the claimant's evidentiary position, but also on grounds of public-health protection: the credible threat of liability deters negligent or careless behaviour by pharmaceutical companies.

Whereas fault (negligence or intent, coupled with tort capacity) is the cornerstone of subjective liability, strict liability attaches irrespective of fault. This does not mean "liability without any fault in fact", but that fault is not a constituent element of this type of liability. The crucial difference lies in the grounds of exoneration (exculpation), which the defendant must prove. These are events or conduct that exclude liability - negative conditions of liability. Unlike in fault-based liability, where the injurer seeks to show no fault (e.g., no tort capacity or due care), under strict tort (non-contractual) liability the defendant must prove that the harm was caused by an event or conduct outside the defendant's sphere of control, i.e., not reasonably foreseeable and not preventable (Plavšak et al., 2003).

Compared with the general rules, Article 27 of the ZZdr-2 further tightens the room for exculpation. Paragraph 4 provides that the manufacturer remains liable for damage caused by inadequate quality of a medicinal product even if it proves that, at the time the product was placed on the market, the global state of scientific and technical knowledge was not such as to enable the defect to be discovered. In other words, for medicinal products the law adopts a stricter stance: compensation is due even where the defect was scientifically undetectable at the time of marketing. This again reflects the overlap between inadequate quality because of a dangerous property or a defect in a medicine. It bears repeating that not all medicines can be labelled dangerous or defective; the classification is fact-sensitive in every case.

From this provision follows a duty of ongoing pharmacovigilance. It entails the active monitoring of scientific findings and technical advances and the continuous reassessment of the benefit–risk balance, followed by appropriate measures: market withdrawal where the balance becomes unfavourable (risks outweigh benefits), or updates to the instructions for use, packaging and warnings, including variations to the marketing authorisation. A manufacturer therefore cannot rely solely on the argument that, at the time of marketing, certain properties or effects could not be detected.

In this respect, ZZdr-2 establishes a stricter liability regime than ZVPot-1, which - as noted - contains in Article 64(5) the opposite rule, i.e. the development-risk defence, allowing the manufacturer to avoid liability where “the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered (e.g., by known methods and analyses).” At this juncture, it may again be concluded that – for reasons of public-health protection and effective compensation – medicinal products should not be treated as generic ‘goods’ under ZVPot-1, but as a specific category of products requiring a special, stricter approach.

3.3.5 Exception from liability

Article 27(6) of the ZZdr-2 provides an exception under which the MAH, the manufacturer, health-care providers and health-care professionals are not liable for damage arising from the use of a medicinal product that is not in accordance with the marketing authorisation or that has no marketing authorisation, where such use is ordered by the JAZMP (Javna agencija Republike Slovenije za zdravila in medicinske pripomočke - Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) or by the competent ministry in extraordinary circumstances (e.g., epidemics, chemical accidents, nuclear disasters).

This exception is grounded in the public-interest rationale: it enables rapid intervention in crises. At the same time, it raises ethical concerns about the protection of injured persons, particularly in jurisdictions without compensation mechanisms (e.g., dedicated compensation funds).

3.3.6 Limitation of Damages Claims

A particular feature of harm associated with medicinal products is that it may manifest immediately or only after many years – for example, where a link between a medicine and a disease is discovered later. Article 352 of the OZ governs the limitation of damages claims and provides a three-year subjective period and a five-year objective period. In Slovenia, the objective limitation period is significantly shorter – only five years. By contrast, in Germany, the objective limitation period for similar claims is 30 years (see Section 4.6 below). The difference between the commencement of the subjective and objective period is that the latter runs from the occurrence of damage, whereas the former begins when the claimant learns (or could have learned) of that fact. In practice, this means that damages claim becomes time-barred five years after the damage occurs, regardless of when the claimant gained knowledge of the damage or the tortfeasor (Article 352(2) of the OZ).¹¹ No longer limitation period is provided for damage affecting fundamental values such as life or health. However, where the harm constitutes a criminal offence, the injured party may rely on the longer limitation period for criminal prosecution (Article 353(1) of the OZ), provided that the offence has been established.

3.4 Manufacturer's Liability Under the OZ

In addition to the special liability regime in Article 27 of the ZZdr-2, Article 155 of the OZ lays down the general manufacturer's liability. Paragraph 1 governs liability for damage caused by a defect in the product, whereas paragraph 2 concerns liability for damage arising from dangerous properties of a thing. The provision rests on the idea that the manufacturer must assume certain risks inherent in industrial production and, where a defect is established, liability is strict. The possibility that the manufacturer knew of the defect is not excluded; nonetheless, the injured party may still pursue compensation under the strict-liability rule (Grilc in Plavšak et al., 2003, pp. 894–895).

¹¹ See also Judgement of the Higher Court in Ljubljana of 27 August 2014, *II Cp 954/2014*, ECLI:SI:VSLJ:2014:II.CP.954.2014.1.

This provision also illustrates the interplay between defect and dangerous property. Although Article 155 is situated in the chapter on the liability of the manufacturer of a defective thing, Slovenian courts have at times drawn parallels between the two notions for the purposes of Article 155 of the OZ. In the Coca-Cola bottle explosion case¹², the lower courts relied on both concepts on the same facts - product defect and dangerous property – whereas the Supreme Court clarified the distinction: paragraph 1 addresses product defects, while paragraph 2 concerns dangerous properties inherent in the nature of the product (as with poisons or explosives), in which case the manufacturer must adopt additional precautions to prevent harm. Unlike paragraph 1, which establishes strict liability for defective products, paragraph 2 sets out fault-based liability for dangerous properties (not defects) where the manufacturer has not done everything reasonably required – by warnings, safe packaging or other appropriate measures, to prevent foreseeable harm. On this basis the manufacturer cannot be expected to anticipate every careless or improper use by a consumer (e.g., a user who, without reason, ignores clear instructions), nor to provide a separate warning for each such eventuality. For instance, it suffices that the instructions for heating milk state that the milk must be stirred while heating; there is no need to add an explicit warning that failure to do so may, in very rare cases, lead to overheating, spillage and consequent burns or other damage.¹³ It should be emphasised that instructions for medicinal products differ fundamentally from the brief usage notes found on milk cartons or beverage bottles: they are an integral, legally required component of the product, intended to ensure safe and effective use by patients and healthcare professionals. Transposed to the instructions for use of medicinal products, inadequate instructions will amount to a defect within the meaning of Article 155(1) of the OZ, because a medicinal product, as marketed, consists of the active substance (in various dosage forms such as tablets or drops), the packaging (e.g., glass or plastic), and the instructions for use (package leaflet). A defect in any of these components is a product defect.

¹² Judgement of the Supreme Court of the Republic of Slovenia of 22 October 1998, *II Ips 416/97*, ECLI:SI:VSRS:1998:II.IPS.416.97.

¹³ See Judgement of the Higher Court in Ljubljana of 13 November 2013, *I Cp 1145/2013*, ECLI:SI:VSLJ:2013:I.CP.1145.2013 and Order of the Supreme Court of the Republic of Slovenia of 15 May 2014, *II DöR 1/2014*, ECLI:SI:VSRS:2014:II.DOR.1.2014.

3.5 Taking Out Liability Insurance

Slovenian law expressly requires compulsory liability insurance for activities that involve an elevated risk of damage to third parties. Accordingly, for damage arising in the performance of their professional activity, physicians, attorneys, notaries, healthcare institutions and other comparable entities must take out compulsory insurance. No such obligation is prescribed for manufacturers of medicinal products and holders of a marketing authorization for a medicinal product. However, under the second paragraph of Article 77 of the Medicinal Products Act (ZZdr-2), a physician or veterinarian who, at a healthcare or veterinary services provider, prescribes and uses a non-routinely prepared advanced therapy medicinal product must insure their liability for any damage that may be caused to the patient or animal, for a sum insured of at least EUR 100,000.

4 Liability Under the Relevant Rules of German Law

The thalidomide tragedy of the 1960s - resulting in severe birth defects - was a watershed for German legislation, prompting reforms that introduced a stricter liability system (1976) and, later, a presumption of causation (2002) (Deutsch & Lippert, 2010, pp. 2-4).

4.1 The AMG (Arzneimittelgesetz) Regime

German law addresses liability for harm caused by medicinal products through two tracks: (i) the general, fault-based regime under the German Civil Code (Bürgerliches Gesetzbuch, hereinafter: BGB),¹⁴ and (ii) a special strict-liability regime for medicinal products under Section 84 of the AMG.

For the avoidance of doubt, general tortious producer liability under Sections 823 et seq. BGB is not displaced by the AMG. Pursuant to Section 91 of the AMG, such claims may be pursued in parallel with liability under Section 84 of the AMG. However, unlike the special AMG regime, liability under Section 823 of the BGB remains fault-based and requires proof of an intentional or negligent breach of a

¹⁴ Bürgerliches Gesetzbuch (German Civil Code). Bundesgesetzblatt I, pp. 42, 2909; last amended by Art. 1 of the Act of 17 July 2025 (Bundesgesetzblatt I, No. 163/2025). Consolidated version consulted on 3 November 2025.

duty of care, as well as causation. In pharmaceutical cases this makes the BGB route considerably more demanding in evidentiary terms and, in practice, usually secondary to the strict-liability regime under the AMG.

The ProdHaftG, which transposes the same EU directive as the Slovene ZVPot-1 (Directive 85/374), does not apply to damages caused by medicinal products authorised under the AMG (Section 15 of the ProdHaftG). In contrast, the ProdHaftG covers damage arising from unauthorised medicinal products and medical devices (Seifert, Landolt & Fritze, 2024). Compared with Slovenia - where doubts about the applicability of ZVPot-1 to medicine-related harm must be dispelled by general principles (protection of the weaker party and *lex specialis derogat legi generali*) - Germany's delineation is clearer. By analogy, in Slovenia ZZdr-2 should be the primary regime for medicinal products, while ZVPot-1 governs other products, such as medical devices or food supplements.

4.2 Liability of the Pharmaceutical Undertaking

The question of who bears civil liability in Germany is answered by Section 84(1) of the AMG, which attributes liability to the pharmaceutical undertaking (pharmazeutischer Unternehmer) whose medicinal product, placed on the market, causes the death of, or serious bodily injury or harm to the health of, a consumer. The provision sets out two alternative bases of liability, imposing an obligation to compensate where:

- the medicinal product, when used as intended or in the usual manner, produces harmful effects exceeding the level regarded as acceptable according to the current state of medical science, or
- the damage is caused because the labelling, professional information (Fachinformation), or instructions for use (Gebrauchsinformation) do not conform to the current state of medical science.

This rule recognises that medicinal products are goods of a special nature, whose adverse effects can never be fully eliminated. Liability arises only where the medicine produces effects which, despite proper use, exceed the permissible threshold defined by contemporary medical knowledge. The provision is rooted in the prohibition of 'questionable' (bedenkliche) medicines under Section 5 of the AMG, which defines

such products as those for which, according to the current state of scientific knowledge, there is a well-founded suspicion that in intended use they have harmful effects exceeding what is justifiable considering medical science. The acceptable level of risk is determined through a benefit-risk assessment, requiring that the therapeutic benefits of the product substantially outweigh its risks. Some adverse effects are therefore regarded as tolerable, if they do not outweigh the benefits. The benefit-risk ratio necessarily varies with each individual product; in the case of life-threatening diseases, even serious adverse effects may remain acceptable (Deutsch & Lippert, 2010, p. 133). In the literature, it has also been argued that a claimant who experiences adverse reactions cannot claim compensation where the medicine has fulfilled its therapeutic purpose and no alternative treatment was available (Stauch, 2011).

The first point of Section 84(1) of the AMG establishes strict (no-fault) liability of the pharmaceutical undertaking for damage caused by the harmful effects of a medicinal product used as intended or correctly, where such effects exceed the level acceptable according to medical science. ‘Intended use’ includes the instructions for use, professional information, and advertising, and may reflect the manufacturer’s tacit acceptance of certain uses of the product in practice (Deutsch & Spickhoff, 2014, pp. 1174–1176).

A particular issue arises with off-label use, defined at the EU level as “situations where a medicinal product is intentionally used for a medical purpose not in accordance with the terms of the marketing authorisation” (European Medicines Agency [EMA], 2024). In European practice, off-label use is generally seen as an exceptional departure from the authorised SmPC-based system, justified by specific patient needs, and primarily falling under the physician’s professional responsibility rather than the manufacturer’s (Diaz Hernandez, Roslin, & Mansnerus, 2024, pp. 138-139).

This creates an interplay of responsibility: the physician assumes an increased duty of care and an expanded duty to inform the patient, while the manufacturer is generally liable only for authorised uses or for off-label uses that have become widely accepted medical practice. Isolated or occasional off-label use does not, as a rule, establish manufacturer liability. German jurisprudence further clarifies that, prior to any tacit acceptance of off-label use by the manufacturer, responsibility lies

predominantly with the physician, who retains therapeutic freedom. Prescribing outside the marketing authorisation does not automatically deviate from medical standards if sufficient scientific evidence or clinical experience supports the use. In such cases, the physician must justify the choice of therapy by the specific circumstances of the patient's condition and apply an increased level of caution, monitoring, and informed consent. Conversely, failure to prescribe an evidence-supported off-label treatment may itself amount to negligent treatment (Lenk & Duttge, 2014, pp. 542-543).

The state of medical science is, however, a dynamic concept, continuously developing and being refined. Therefore, manufacturer liability may also arise when a product is used in a manner not expressly indicated in the marketing authorisation, but which has since become accepted and reasonably foreseeable due to scientific and clinical progress (Arif & Benecke, 2020, p. 62).

Liability under Section 84(1) no. 1 of the AMG therefore stems from the ongoing duty of pharmaceutical companies to investigate and monitor their products to always maintain the proper benefit – risk balance. In general terms, a company is liable where the risk proves disproportionate to the product's therapeutic efficacy. German courts, however, differ as to the relevant temporal point for assessing this balance - whether it should be measured at the time the product was first placed on the market, or later, for instance at the time of injury or at the final oral hearing. In most decisions, the courts have held that knowledge acquired up to the final oral hearing should be retrospectively imputed to the time of marketing. This means that current information about the product's risks is treated as if it had been known from the outset of its commercialisation (Landgericht Kempten, 2024, paras 77–81). Pursuant to Section 84 of the AMG, the pharmaceutical undertaking is therefore liable for design defects, manufacturing defects, and defects in warning or information.

The significance of information duties is underscored by Section 84(1) no. 2 of the AMG, which imposes liability for damage resulting where labelling, professional information, or instructions for use fail to correspond to the current state of medical science. The objective is to ensure that users can recognise contraindications and risks. The pharmaceutical undertaking is responsible for providing clear and up-to-

date instructions, and for continuous post-marketing surveillance of the medicinal product (pharmacovigilance).

From the foregoing, both doctrine and case law confirm that, on an *argumentum a contrario* basis, Section 84 of the AMG implies that where a medicinal product causes adverse effects explicitly listed in the package leaflet (and, by analogy, in the Summary of Product Characteristics), the pharmaceutical undertaking will generally not be liable for the resulting harm, since these effects are foreseen and accepted as part of the possible consequences of treatment. However, case law recognises an exception: if, after the product has been placed on the market, it becomes apparent that such adverse effects occur more frequently or more severely than initially anticipated, a renewed safety assessment is required. Failure to act accordingly - such as not updating the instructions for use or risk information to reflect new data (e.g., frequency rates or newly identified adverse effects) - may give rise to liability of the pharmaceutical undertaking (Landgericht Kempten, 2024, para. 76). In practice, the benefit-risk evaluation, even for adverse effects already described in the instructions for use, will generally be assessed at the time of trial. It may thus transpire that a risk or adverse effect, though once considered acceptable and duly disclosed, is no longer acceptable considering the current state of medical science and therefore constitutes a basis for liability.

Liability thus attaches to the pharmaceutical undertaking, defined in Section 4(18) of the AMG as including both the marketing-authorisation holder or registrant and any person marketing the product under their own name. Under Section 9 of the AMG, the decisive factor is whose name appears on the product. Where several persons fall within this definition, they are jointly and severally liable pursuant to Section 93 of the AMG. Theoretically, pharmaceutical undertakings could attempt to avoid liability by marketing products not requiring marketing authorisation without using their own name, thereby falling outside the AMG's scope. Nevertheless, they remain liable under the general civil-law regime of the BGB. Section 823 BGB provides that any person who intentionally or negligently unlawfully infringes another's life, body, health, freedom, property or other right is obliged to compensate the resulting damage. Under this provision, any participant in the process of developing a medicinal product may, in principle, be held liable (Magnus, 2018).

4.3 Possibility of Exculpation

Under Section 84(3) of the AMG, the pharmaceutical undertaking is not liable if, considering the circumstances, it can be inferred that the harmful effects of the medicinal product did not originate from the sphere of development or production. Manufacturing defects may occur not only at the stage of developing the medicinal product but also subsequently, where the information or data relating to the product are incomplete or erroneous (Deutsch & Lippert, 2010, p. 788). Because injured persons are not involved in the development process and have no access to the internal stages of pharmaceutical research and production, proving such facts is particularly difficult. For this reason, the AMG grants a special right of access to information and disclosure in Section 84a, which is presented in Section 4.5.

4.4 Presumption of Causation

To facilitate proof by the injured party, Section 84(2) of the AMG establishes a presumption of causation between the medicinal product and the damage. Where, in the circumstances of the individual case, the medicine can cause the type of harm suffered, it is presumed to have caused it. The product's potential to cause harm is assessed case-by-case, considering the composition and dosage of the medicine, the manner and duration of its prescribed use, the temporal proximity between administration and injury, the nature of the harm, and the patient's health condition at the time of treatment.

The injured party must demonstrate that damage occurred and that it can be linked to the use of the medicinal product; once this is established, causation is presumed. This constitutes a rebuttable presumption (*praesumptio iuris tantum*). The pharmaceutical undertaking may rebut it by proving the existence of another plausible cause that could have produced the damage.

German case law further clarifies the scope of this presumption. The Regional Court of Kempten emphasised that liability under Section 84 of the AMG requires twofold causation: (1) the injury must originate from the use of the medicinal product, and (2) it must also stem from deficient information about the product. The causal link between the defective information and the injury can be affirmed only where it is virtually certain that the harm would have been avoided had proper information

been provided. In that case, the claimant's statement that she would not have agreed to vaccination if she had been aware of other possible side effects was deemed insufficient, since she had previously stated that she was vaccinated to protect vulnerable persons in her environment. The court further clarified that the acceptability of harmful effects is to be determined through a benefit–risk assessment, encompassing all users of the medicine rather than the individual claimant, evaluating whether the balance of efficacy and risk remains positive for the intended patient population.¹⁵

Similarly, the Regional Court of Waldshut-Tiengen upheld the presumption of causation, since the medicine was capable of causing thrombosis and a temporal connection existed between use and harm. The product contained an active ingredient known to increase the risk of thrombosis, establishing a link between the injury and the medicine's known risk profile. The temporal proximity was also relevant, as the damage occurred after several months of use. However, the presumption was rebutted, the defendant having demonstrated other probable causes (a venous anomaly and multiple long-haul flights). The court stressed that an increased risk alone is insufficient; both the general capacity of the product to cause harm and specific causation in the individual case must be established. It thus excluded liability under the AMG, leaving open the possibility of a claim under general tort law (Section 823 of the BGB) - though none succeeded, as the causal link remained unproven, which is a prerequisite for any liability.¹⁶

From these cases it follows that causation is determined in two stages. First, the court assesses whether the circumstances justify establishing a causal link between the medicine and the injury - namely, whether the harm could plausibly result from a known risk of the product. If so, this suffices to trigger the presumption. Only thereafter does the analysis turn to the individual claimant, examining personal circumstances such as pre-existing conditions. At this stage, the burden of proof shifts to the defendant, i.e., the pharmaceutical undertaking (Deutsch & Lippert, 2010, p. 788). Courts also consider the time interval between administration and manifestation of the damage, which must be proportionate and medically plausible.¹⁷

¹⁵ Judgement of the Regional Court of Kempten of 8 August 2024, 31 O 957/23.

¹⁶ Judgement of the Regional Court of Waldshut-Tiengen of 20 December 2018, 1 O 73/12, ECLI:DE:LGWALDS:2018:1220.1O73.12.00.

¹⁷ See Judgement of the Federal Court of Justice of 16 March 2010, VI ZR 64/09, and Judgement of the Federal Court of Justice of 1 July 2008, VI ZR 287/07.

To further ease the evidentiary burden, German courts additionally accept *prima facie* evidence (*Anscheinsbeweis*) in establishing the causal connection.

In addition to liability for medicinal products under Section 84 of the AMG, fault-based producer liability under Sections 823 et seq. BGB also comes into play; this follows expressly from Section 91 of the AMG (Deutsch & Lippert, 2010, p. 805). As a rule, German law does not provide a general reversal of the burden of proof for fault: beyond unlawfulness, damage, and causation, the injured party must also prove the tortfeasor's negligence (Westermann, Grunewald, & Maier-Reimer, 2023, p. 4130) - a requirement that makes proof significantly more onerous than under the special AMG regime. However, because of evidential difficulties in complex manufacturing processes, German case law has developed a special rule within fault-based producer liability: once the claimant proves that the product was defective and that this defect caused the harm, there is a presumption of a breach of due care by the producer (Westermann et al., 2023, p. 4155). The burden of proof as to diligent conduct then shifts to the producer (Deutsch & Lippert, 2010, p. 805).

While the ProdHaftG (strict liability) excludes concurrence with Section 84 of the AMG (Section 15 of the ProdHaftG), fault-based producer liability under the BGB may run in parallel. Article 13 of Directive 85/374 (now repealed) stated that the Directive "shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified." In practice, fault-based producer liability has been extensively developed in the pharmaceutical field (Deutsch & Lippert, 2010, p. 805). As noted above, where medicinal products fall outside the AMG, the pharmaceutical undertaking may still incur strict liability under the ProdHaftG.

4.5 Right of Access to Information

The presumption of causation is triggered where the medicine can cause the harm in question based on known risks reflected in the instructions for use. Where the harmful effect is unknown and therefore not listed, the presumption does not arise, making proof more difficult for the claimant. In such cases, Section 84a of the AMG provides a right of access to information, enabling the injured party to request from the manufacturer data on the product's effects and interactions as well as reports of

alleged cases or suspicions of adverse reactions. This right is qualified: disclosure may be refused where it would breach confidentiality or jeopardise overriding company interests (e.g., trade secrets, prospective patents). The same applies to regulatory authorities, which may decline to transmit confidential information. By reference to Sections 259-261 of the BGB, the framework also permits the manufacturer to provide a declaration in lieu of oath as to the truthfulness and completeness of the information rendered.

To invoke the right, the claimant must show a plausible causal connection and that the requested information is material to the specific case. The Federal Court of Justice underscored that a claimant is not required *ex ante* to prove correct use of the product where doing so would require specialist knowledge; the purpose of Section 84a is precisely to open access to the evidence needed to substantiate damages claim.¹⁸ It is therefore an important procedural instrument that mitigates proof difficulties in cases involving previously unknown adverse effects.

The overarching aim is to rebalance procedural asymmetries between claimant and manufacturer, the latter possessing the development, composition and safety data for the product. The right strengthens the claimant's evidentiary position and complements the limits of proof in cases of unknown adverse effects. The claimant must be placed in a position to obtain the facts necessary to articulate a *prima facie* case capable of triggering the presumption of causation under Section 84(2) of the AMG. Any substantive counterarguments by the defendant (e.g., competing expert opinions) are not pertinent at the information-disclosure stage; they are to be addressed only in the subsequent damages' proceedings.¹⁹

As to limitation, the exercise of this right is constrained by the general subjective three-year period under Section 195 of the BGB, which begins when the claimant learns of the circumstances that justify the presumption that the harm was caused by use of the medicine. In addition, an absolute ten-year period applies under Section 199 of the BGB. Thus, a request under Section 84a AMG is time-barred after ten years, irrespective of knowledge (Deutsch & Lippert, 2010, pp. 794-797). These

¹⁸ Judgement of the Federal Court of Justice of 12 May 2015, *VI ZR 328/11*.

¹⁹ *Ibidem*.

general limitation rules apply subsidiarily, because the AMG contains no specific limitation provisions for the information claim.

4.6 Limitation of Damages Claims

As noted in the previous chapter, limitation of damages claims under the AMG is governed subsidiarily by the provisions of the BGB. According to Section 195 of the BGB, the regular limitation period is three years, commencing at the end of the calendar year in which the claimant became aware (or ought to have become aware) of the damage, of the relevant circumstances, and of the liable person. This so-called “Ultimo-Verjährung” rule benefits claimants by effectively extending the limitation period until the end of the year in which knowledge of the damage is acquired²⁰ (Westermann et al., 2023, p. 676). In Slovenian law, such a deferred commencement applies only to household claims with a one-year limitation period, pursuant to Article 355(2) of the OZ.

Section 199 of the BGB additionally provides an absolute limitation period (Verjährungshöchstfrist) for damages claims. Irrespective of Section 195 BGB, any claim for injury to life, body, health or liberty becomes time-barred thirty years after the tortious act or other harmful event.²¹ This means that the subjective three-year period cannot run indefinitely: even if the claimant has not yet become aware of the damage in full, the claim extinguishes upon expiry of the 30-year maximum period.

4.7 Obligation to Obtain Liability Insurance

Section 94 of the AMG stipulates that every pharmaceutical undertaking must provide financial coverage for compensation of damage resulting from the use of medicinal products for human use, either by means of liability insurance with an authorised insurance company or through a compensation or guarantee commitment issued by a credit institution.

The minimum insurance coverage must correspond to the amounts specified in Section 88 of the AMG. That provision establishes maximum compensation limits:

²⁰ See Judgement of the Federal Court of Justice of 12 May 2009, *VI ZR 294/08*.

²¹ See Judgement of the Federal Court of Justice of 25 July 2017, *VI ZR 433/16*, ECLI:DE:BGH:2017:250717UVIZR433.16.0.

in cases of death or personal injury to an individual, the ceiling is EUR 600,000 as a lump-sum payment or an annual annuity of up to EUR 36,000. Where compensation is owed to multiple individuals harmed by the same medicinal product, the overall ceiling is EUR 120 million as a lump-sum payment or an annual annuity of up to EUR 7.2 million. If the total compensation payable exceeds this amount and must be distributed among several injured parties, the individual sums are reduced proportionally (Section 88 of the AMG).

Any agreements limiting or excluding payment are void. A person who intentionally places on the market a medicinal product intended for human use without valid liability insurance or a guarantee or indemnification obligation in accordance with Section 94 of the AMG, or after such coverage has ceased to exist, commits a criminal offence (Section 96, no. 19 of the AMG). If the act is committed negligently, it constitutes an administrative offence (Section 97(1) and (3) of the AMG).

5 Discussion: Comparative Assessment and Implications for Slovenian Law

The comparison shows that the difference between Slovenian and German law does not lie in the abstract acceptance of strict liability. Both systems recognise that medicinal products create risks that cannot be fully controlled by ordinary fault-based liability and that patient protection requires special attention to information asymmetry, scientific uncertainty and post-marketing surveillance. The decisive divergence lies in how each legal system translates these concerns into operational legal rules.

Slovenian law has an important claimant-protective foundation. Article 27 of the ZZdr-2 establishes strict liability in the pharmaceutical context and is stricter than the general product liability regime insofar as it does not allow the development-risk defence in the same way as ZVPot-1. The central role of the marketing-authorisation holder may also be seen as beneficial for injured persons, since it identifies a responsible actor connected to the placing of the medicine on the market. These are significant advantages and show that Slovenian law is not normatively indifferent to pharmaceutical injury. Its weakness lies elsewhere: the regime is not sufficiently self-contained. Key elements, especially causation, evidentiary support and limitation, must be reconstructed through the OZ and general principles. This creates

uncertainty in precisely those cases in which claimants face the greatest practical difficulties, namely where harm appears after a delay, where medical causation is complex, or where relevant pharmacovigilance data are controlled by the manufacturer or MAH.

German law offers a more structured model. The AMG clearly functions as the *lex specialis* for medicinal-product injury, while the general Product Liability Act is excluded for claims falling within the AMG. This prevents the kind of regime collision that remains problematic in Slovenian law. More importantly, the AMG combines substantive strict liability with procedural and evidentiary tools: the presumption of causation under Section 84(2), the information claim under Section 84a, and mandatory financial coverage under Section 94. These mechanisms do not guarantee success for every claimant, nor do they remove the need to prove a legally relevant causal connection. They do, however, reduce the structural disadvantage of injured persons by recognising that the manufacturer is usually in a better position to know, collect and disclose safety-related data.

At the same time, the German model should not be idealised. Its presumption of causation operates within defined limits and may be rebutted where alternative causes are established. The information claim is also qualified by confidentiality and trade-secret considerations. In addition, fault-based producer liability under Sections 823 *et seq.* of the BGB remains available in parallel but is considerably harder to enforce, since the injured party must prove fault and causation. The German regime is therefore more claimant-oriented in its design, but not claimant-friendly in an unlimited sense. Its value as a comparator lies in its institutional coherence rather than in an assumption that claimants always prevail.

Directive 2024/2853 points in a similar direction by introducing disclosure of evidence and rebuttable presumptions of defectiveness and causation. These mechanisms are particularly relevant for complex products and scientifically demanding claims. Nevertheless, the Directive cannot by itself resolve all difficulties in pharmaceutical liability. First, it preserves space for special national liability regimes in the pharmaceutical sector. Secondly, its product-defect logic does not always map neatly onto unexpected adverse drug reactions, where the medicine may be authorised, correctly manufactured and accompanied by appropriate information, yet still produce serious harm in individual cases. The Directive is therefore best

understood as a source of procedural inspiration rather than as a complete solution for pharmaceutical injury.

For Slovenia, the comparative analysis suggests that reform should not merely transpose the Directive mechanically. A more coherent approach would be to clarify expressly the priority of ZZdr-2 for harm caused by medicinal products, introduce a sector-specific presumption of causation modelled cautiously on Section 84(2) of the AMG, and create a statutory right of access to pharmacovigilance and safety data, subject to proportionate safeguards for confidential information. The objective limitation period should also be reconsidered for latent bodily and health injuries, and compulsory liability insurance or equivalent financial coverage for MAHs/manufacturers should be introduced. Such reforms would not copy the German system wholesale, but would adapt its most relevant claimant-protective elements to the Slovenian legal context.

6 Conclusions

This article examined civil liability for harm caused by unexpected adverse drug reactions in Slovenian and German law. It has shown that Slovenian law contains a claimant-protective basis in Article 27 of the ZZdr-2, but that the regime remains insufficiently precise in its practical operation. The relationship between ZZdr-2, ZVPot-1 and the OZ is not fully clear, causation is not regulated through a sector-specific presumption, claimants have no express statutory right of access to safety data, and there is no mandatory liability insurance for MAHs or manufacturers. These gaps are especially important in pharmaceutical cases, where harm may appear only after a delay and where relevant information is usually held by the pharmaceutical undertaking.

German law provides a useful comparator because it regulates pharmaceutical liability through a clearer special regime under the AMG. The AMG excludes the general product liability regime for medicinal products falling within its scope, while preserving other claims, including fault-based producer liability under the BGB. Its main claimant-protective features are the presumption of causation, the right of access to information and mandatory financial coverage. These mechanisms do not

remove all evidentiary problems, but they create a more coherent framework for addressing them.

Directive 2024/2853 strengthens the broader EU product liability framework through disclosure rules and rebuttable presumptions. For Slovenia, its implementation should be treated not only as a formal transposition exercise, but as an opportunity to improve pharmaceutical liability more systematically. The most important reforms would be: express clarification of ZZdr-2 as the primary regime for medicine-related harm, a statutory presumption of causation adapted to unexpected adverse drug reactions, access to relevant pharmacovigilance and safety data, longer or more appropriate limitation rules for latent health damage, and compulsory financial cover.

The central conclusion is therefore not that Slovenia lacks liability rules, but that its rules are fragmented and procedurally underdeveloped. Given that life and health are at stake, a claimant-friendly and predictable framework is a constitutional desideratum. A more coherent pharmaceutical liability regime would enhance legal certainty, improve the claimant's real access to compensation and align Slovenian law more closely with the protective direction of both German law and the new EU product liability framework.

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Povzetek v slovenskem jeziku

Zdravila so ključnega pomena za zdravstveno varstvo, vendar njihova uporaba prinaša neizogibna tveganja, zlasti nepričakovane neželene učinke zdravil. Članek preučuje, kako slovenska in nemška zakonodaja urejata civilno odgovornost za takšno škodo in kakšne posledice lahko ima to za oškodovance. Članek zagovarja, da je slovenski pravni okvir normativno ustrezen, a razdrobljen, pri čemer je dokazna podpora za tožnike premalo razvita, medtem ko je nemški okvir bolj koherenten in usmerjen v tožnike. Oba sistema temeljita na objektivni odgovornosti in stalni farmakovigilanci, vendar se razlikujeta v dokazni ureditvi in institucionalni zasnovi. S pomočjo doktrinarno-primerjalne metode članek analizira slovenske in nemške zakone v luči Direktive o odgovornosti za izdelke (EU) 2024/2853. Ugotavlja, da slovenski zakonodaji primanjkuje ključnih zaščitnih ukrepov, vključno z izrecno, sektorju specifično domnevo o vzročni zvezi in zakonsko pravico do dostopa do podatkov o varnosti zdravil, ter da ni predpisano obvezno zavarovanje. Nemška zakonodaja ponuja jasnejša pravila, postopkovno podporo in obvezno finančno kritje. Novosti direktive kažejo v smeri modela, ki je prijaznejši do tožnikov, kar Sloveniji ponuja priložnost za reformo.