LIABILITY OF THE PHARMACEUTICAL MANUFACTURER IN PRIVATE LAW ACCORDING TO LAW NO. 7223*

7223 Sayılı Kanunu Uyarınca İlaç Üreticisinin Özel Hukuk Sorumluluğu

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Abstract

This essay explores the development of legal frameworks governing pharmaceutical liability in Turkey, tracing the evolution from historical approaches to contemporary regulations. The paper especially focuses on the Law no. 7223 on Product Safety and Technical Regulations that came into force in 2021 which imposes strict liability on manufacturers through Article 6. The article's official rational states that it was enacted according with the EU Directive No. 85/374. The Directive consists of 19 introductory paragraphs followed by 22 articles exclusively related to the liability of defective products. In contrast, Law No. 7223 regulates product liability through only two articles (Article 6 and 21). As strict liability was long-awaited, even the enactment of those two articles were applauded. Considering the intricate nature and unique dynamics of the pharmaceutical industry, the situation is more complex for pharmaceutical manufacturers who are also liable under these provisions. This article focuses on the conditions of strict liability imposed on all manufacturers, including pharmaceutical manufactures under Law No. 7223, and evaluates these conditions specifically in the context of pharmaceutical manufacturers.

Key Words: pharmaceutical manufacturer's liability, strict liability, tort liability, non-conforming medication, causal link.

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* There is no requirement of Ethics Committee Approval for this study.

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Özet

Çalışmada, Türkiye'de ilaç sorumluluğunu düzenleyen yasal çerçeve, tarihi yaklaşımlar ve çağdaş düzenlemelerle birlikte aktarılmaya çalışılmıştır. Özellikle de, 2021 yılında yürürlüğe giren 7223 sayılı Ürün Güvenliği ve Teknik Düzenlemeler Kanunu'nun 6. maddesi ile üreticilere kusursuz sorumluluk getiren düzenlemeye odaklanılmaktadır. Maddenin resmi gerekçesinde, Avrupa Birliği'nin 85/374 sayılı Direktifi doğrultusunda hazırlandığı belirtilmiştir. Direktif, başlangıç kısmındaki 19 giriş paragrafının ardından sadece ayıplı ürün sorumluluğunu düzenleyen 22 maddeden oluşmaktadır. Buna karşılık, 7223 sayılı Kanun, iki madde (madde 6 ve 21) ile ürün sorumluluğunu düzenlemektedir. Üretilen ürünler dolayısıyla, üreticiye kusursuz sorumluluk getiren bir düzenleme, uzun zamandır beklendiğinden, bu iki maddenin yürürlüğe girmesi bile memnuniyetle karşılanmıştır. Aynı iki hüküm kapsamında sorumlu olan ilaç üreticileri için ise, ilaç sektörünün karışık dinamikleri dikkate alındığında, durum, biraz daha karmaşıktır. Bu makale, 7223 sayılı Kanun'un ilaç üreticilerini de kapsayacak şekilde tüm üreticiler açısından getirilen kusursuz sorumluluğun koşullarına odaklanmakta ve bu koşulları ilaç üreticileri açısından değerlendirmektedir.

Anahtar Kelime: İlaç üreticisinin sorumluluğu, kusursuz sorumluluk, haksız fiil sorumluluğu, uygunsuz ilaç, illiyet bağı.

INTRODUCTION: Historical Development with Comparative Perspective

Pharmaceutical manufacturer's liability varies significantly across jurisdictions, reflecting different legal frameworks, regulatory rules, and judicial practices. The issue has generally been addressed within the framework of general product liability, with only a few countries implementing specific regulations for pharmaceutical manufacturers. For example, in the United States, there are no special Federal Laws for either general product liability or liability for pharmaceuticals. Product liability, in general, is largely governed by judicial precedents and by state laws, though there are common principles such as negligence strict liability and breach of warranty, across jurisdictions of the States[1].

Around Europe, we could say that the final straw occurred around 1960s with medications such as 'thalidomide,' which was used by pregnant women to prevent nausea but caused birth defects, and 'DES,' which was used by pregnant women to prevent miscarriages but led to cancer in babies born[2]. These

[1] Emre Güktekin, *İlaç Üreticisinin Hukuki Sorumluluğu* (Master thesis, Yalova Üniversitesi 2021)71 <https://tez.yok.gov.tr/UlusalTezMerkezi/ > accessed 26 July 2024; Tuba Akçura Karaman, *Üreticinin Ayıplı Ürününün Sebep Olduğu Zararlar Nedeniyle Üçüncü Kişilere Karşı Sorumluluğu* (Vedat Kitapçılık, 2008) 23-29.

[2] Andrew Grubb and Geraint Howells (eds.), *The Law of Product Liability* (1st edn, Lexis Nexis Butterworths 2000) 9; Akçura Karaman (n1) 201; İlyas Sağlam '7223 sayılı Ürün Güvenliği ve Teknik Düzenlemeler Kanunu'na Göre Üreticinin Sorumluluğu' (Phd thesis, Akdeniz

defective products serve as examples and have triggered the implementation of regulations regarding the liability of manufacturers in many countries. Over time, it is recognized that strict liability and special laws are essential components of these frameworks, holding manufacturers accountable for defective products and fostering a safer industry.

European Product Liability Directive (85/374/EEC)[3] establishes a framework for strict liability for defective products, including pharmaceuticals. Under this directive, a manufacturer is liable for damage caused by a defect in their product, regardless of whether there was negligence. The directive covers personal injury and property damage. This strict liability framework ensures that consumers across the EU have consistent protections and that manufacturers are held to high safety standards. The principles of the European Product Liability Directive (85/374/EEC) have been widely adopted and adapted into national laws across EU member states, non-EU European countries such as Turkey and Switzerland, and nations aligning with EU standards. While the exact application of these principles may vary, the overall philosophy of the Directive plays a significant role in shaping national regulations for product liability. Additionally, some countries like Germany and Switzerland have gone beyond the protection provided by the Directive and have implemented specific regulations for pharmaceutical manufacturers[4].

I. TOWARDS STRICT LIABILITY OF MANUFACTURERS IN TURKEY AND THE CURRENT STATE OF PHARMACEUTICAL MANUFACTURES AMONG OTHER MANUFACTURERS

Before the enactment of special laws in Turkey, product liability was primarily subject to general tort and contractual liability principles. Especially in tort cases, it was very difficult for the injured party to prove conditions of liability such as negligence of the manufacturer and the defect in the product. Aware of these challenges, courts began alleviating the burden of proof in many areas in favor of the plaintiff[5].

Üniversitesi 2023) 83 <https://tez.yok.gov.tr/UlusalTezMerkezi/ > accessed 26 July 2024; Duygu Dincioğlu, 'Alman İlaç Kanunu'na Göre İlaç Üreticisinin Hukuki Sorumluluğunun Alman Hukukundaki Diğer Temel Özel Hukuk Sorumluluk Türleri ile Karşılaştırmalı Olarak İncelenmesi' (2024) 58 Türkiye Adalet Akademisi Dergisi 417, 422.

3 Council Directive 85/374/EEC of 7 August 1985 on Product Liability Directive [1985] OJ L210.

4 The German Pharmaceuticals Act (Arzneimittelgesetz, AMG) of 12 January 2005 BGBl. I S 3394 <https://www.gesetze-im-internet.de/englisch_prodhaftg/index.html> accessed 26 July 2024; Switzerland's Federal Act on Product Liability (LRFP) of 18 June1993 RO 1883 3122 <https://www.fedlex.admin.ch/eli/cc/1993/3122_3122_3122/fr> accessed 26 July 2024.

5 See Supreme Court, 4th CC, 1994/6256, 1995/2596, 27.3.1995 <https://www.lexpera.com.tr> accessed 26 July 2024.

The 1990s and 2000s marked a significant shift in Turkish law, with a growing recognition of the need for specialized regulations to address the complex production processes and the consumer protection. This period saw the introduction of laws and regulations that aligned closely with international standards, particularly those of the European Union.

Mainly in the context of significant revisions to the Turkish Code of Obligations (TCO), the Turkish Parliament enacted Law No. 6098, which introduced a general provision on strict liability (Article 71) for all manufacturers and enterprises. This means that the liability is not contingent upon proving negligence or fault but is based on the inherent risks associated with their activities. This reform marks a pivotal shift in how risk and liability are addressed across various industries in Turkey. Pharmaceutical manufacturers could fall under this provision if their activities are deemed to pose significant risks[6].

Additionally, Turkish legislator has also attempted to incorporate the product liability regime accepted by the EU Directive 85/374 into consumer legislation. A provision was added to the clause on the seller's liability for defects in Consumer Protection Law No. 4077, stating that the manufacturer would also be jointly and severally liable along with the seller[7]. Furthermore, Regulation on Liability for Damages Caused by Defective Goods[8] was enacted, closely mirroring the Directive and adopting strict liability for manufacturers in Article 6. However, introducing strict liability through a Regulation faced significant criticism for being legally inappropriate[9]. To date, no court decisions have relied on this regulation's strict liability provision.

Consequently, Turkish legislator addressed product liability towards third parties by adding few provisions to Law no. 7223 on Product Safety and Technical

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6 To this aspect see Serdar Nart, 'Endikasyon Dışı İlaç Tedavisinde Hekimin ve İlaç Üreticisinin Hukuki Sorumluluğu', (2017) 19 Dokuz Eylül Ünivesitesi Hukuk Fakültesi Dergisi, Commemoration to Prof. Dr. Şeref Ertaş, 772; Hakan Hakeri, *İlaç Hukuku*, (2nd edn, Astana yayınları 2018) 173; Gültekin (n1) 24.

7 Law No. 4822 of 6 March 2003 amending the Article 4/3 of Consumer Protection Law No. 4077. This provision has been retained unchanged in the new Consumer Protection Law No. 6502 with Art. 11/2.

8 OG 25137/13.01.2003.

9 See Ayşe Havutçu, *Türk Hukukunda Örtülü Bir Boşluk: Üreticinin Sorumluluğu* (Seçkin 2005) 117 etc.; Damla Özden Çelt, 'Ürün Sorumluluğunda Yaşanan Güncel Gelişme: 7223 Sayılı Ürün Güvenliği ve Teknik Düzenlemeler Kanunu' (2021) 7 (1), Anadolu Üniversitesi Hukuk Fakültesi Dergisi, 75; Gökçe Kurtulan Güner and Yeşim M. Atamer, 'Ürün Güvenliği ve Teknik Düzenlemeler Kanunu ile İmalatçının Sorumluluğu Konusu Türk Hukuku Açısından Çözülmüş müdür?' in Y. M. Atamer and B. Baysal (eds), Ürün Sorumluluğu, Sorumluluk Hukuku Konferansları I, (Oniki levha Yayıncılık 2022), 5; Sağlam (n 2) 43; Akçura Karaman (n 1), 144-147.

Regulations which applies to all products, including pharmaceuticals[10]. As detailed below, Article 6 of Law No. 7223 introduces strict liability for manufacturers. However, the law offers only general provisions, lacking specific regulations for pharmaceutical manufacturer. This approach fails to fully meet the needs of both pharmaceutical manufacturers and consumers, highlighting the ongoing need for specialized regulation.

II. THE SCOPE OF LAW NO. 7223 ON PRODUCT SAFETY AND TECHNICAL REGULATIONS

Law No. 7223 on Product Safety and Technical Regulations[11], establishes a comprehensive framework for product safety in Turkey. It revises existing regulations and introducing new rules to address emerging issues, aligning with contemporary standards. Among its provisions Article 6 is key, establishing strict liability for manufacturers, importers for damages caused by defective products. Before examining the elements of the liability introduced, it is useful to look at what products are covered and who the liable parties are.

A. Definition Of Product: Are Pharmaceuticals Included?

Law No. 7223 broadens product liability provisions to cover a wide range of products. Article 3(s) defines "product" as **"***any substance, preparation, or goods* (*her türlü madde, müstahzar veya eşya*)". The term "müstahzar" (translated as preparation) is often associated with pharmaceuticals in Turkish legislation. For example, in Regulation on the Evaluation of Bioavailability and Bioequivalence of Pharmaceutical Preparations defines "müstahzar" as "*a drug manufactured in a specific pharmaceutical form according to a specific formulation, both in research/development and production dimensions* (Article 4/1)." On the other hand, the Turkish Language Institution (TDK) indicates that "müstahzar" can also refer to any product made ready for use. While the law does not specify which meaning applies, as rightfully accepted in the doctrine[12], the definition in Article 3 (s) covers pharmaceuticals as it includes all types of goods (*eşya*). The term "eşya" used in the definition can even extend to immovable property[13].

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10 Regarding the discussions on the introduction of strict liability through Article 5 of the previously repealed Law No. 4703, which required manufacturers to place safe products on the market, see Havutçu (n9) 117; Çelt (n9) 75; Akçura Karaman (n 1), 144-147.

11 OG 31066/12.03.2020.

12 Çelt (n 9) 90; Sağlam (n 2) 80; Gültekin (n1)55; Atamer and Kurtulan Güner (n9), 553.

13 To this aspect and for further critics see Yeşim Atamer and Gökçe Kurtulan Güner, 'Ürün Güvenliği ve Teknik Düzenlemeler Kanunu ile İmalatçının Sorumluğu Konusu Türk Hukuku Açısından Çözülmüş müdür? (2021)14(70) Anakara Üniversitesi Hukuk Fakültesi Dergisi 543, 553 <https://dergipark.org.tr/tr/pub/auhfd/issue/62472/900613#article_cite> accessed 7 September 2024.

Considering the legislator's aim to align with Directive 85/374, as noted in the article's explanatory notes[14], including pharmaceuticals within the product definition alines with this goal. Article 2 of the Directive defines "product" as all movables, excluding primary agricultural products and game. This includes pharmaceuticals, as confirmed by paragraph 13 of the Directive's explanatory notes[15], which states that the Directive does not prevent the application of the special liability systems for pharmaceuticals in member states. Therefore, claims related to defected pharmaceuticals can be pursued under the Directive or through national special liability systems.

B. Persons liable for the damages

Law No. 7223 states that manufacturers or importers are responsible for the products they place on the market that cause harm (Article 6/1).

A manufacturer is defined in Article 3(g) as the natural or legal person who manufactures the product or has it designed or manufactured and offers it to the market under their own name or trademark. As seen from this provision, not only the person who manufactures the product but also the person who simply places their brand on the product without manufacturing it is considered a manufacturer. This includes the common practice of outsourcing production and selling products under one's own brand. Under this provision, even a company that does not manufacture the product but markets it under its brand is held liable as a manufacturer.

Importers are defined under Article 3(ğ) as the natural or legal person who imports the product and offers it to the market. Given the challenges for injured parties to file lawsuits against foreign manufacturers, importers who bring products into Turkey are also held liable as if they were the manufacturer. This responsibility extends even to the state in the cases where the state is the importer. For example, in the case of COVID-19 vaccines imported by the state, the state could be held liable as the importer[16].

Even though the law does not explicitly state this, it is accepted that liability for damages applies not only to final products but also to those who manufacture or import intermediate products[17]. Excluding importers of intermediate products from liability would undermine the protective purpose of the law. Indeed, an examination of the Turkish Statistical Institute's Foreign Trade Statistics reveals that the largest share of imported goods is intermediate products[18]. The law also

14 <https://www5.tbmm.gov.tr/sirasayi/donem27/yil01/ss173.pdf> accessed 5 September 2024.

15 <https://eur-lex.europa.eu/eli/dir/1985/374/oj> accessed 8 September 2024.

16 Atamer and Kurtulan Güner (n14) 549, footnote 26..

17 To this aspect see Atamer and Kurtulan Güner (n14) 549; Havutçu (n 9) 91.

18 <https://data.tuik.gov.tr/Bulten/Index?p=Dis-Ticaret-Istatistikleri-Ocak-2024-53534> accessed

states that if more than one manufacturer or importer is responsible for the harm, they shall be held jointly and severally liable (Article 6/3). This includes situations where the final product is produced by different manufacturers or imported by different importers, and in our view, it also applies to manufacturers and importers of intermediate products, who will likewise be jointly and severally liable for any harm caused[19]. For instance, if multiple manufacturers are involved in producing a pharmaceutical (e.g., those making intermediate components, packaging, or caps), each would be jointly and severally liable. Joint and several liability can also arise when multiple drugs are used, and interactions between them cause harm[20]. The rules governing joint and several liability are outlined in Articles 61 and 62 of the Turkish Code of Obligations (TCO). The injured party may sue any one or all of the jointly and severally liable parties and can recover the full amount of damages from one of them. In such a case, the party that paid the compensation can seek recourse against the other responsible parties.

If the manufacturer or importer cannot be identified, the distributor is considered secondarily liable (Article 11/3). If the manufacturer, authorized representative, or importer cannot be determined, the distributor must provide their information. Failure to do so within 10 days results in the distributor being held liable for damages as if he was the manufacturer. Article 3(ç) defines "distributor" broadly, including anyone in the supply chain, such as sellers[21]. This regulation aims to prevent the distribution of products whose manufacturer cannot be identified[22].

III. THE CONDITIONS OF THE LIABILITY

Article 6 states that the manufacturer will be liable if the injured party proves the damage suffered and the causal link between the damage and the non-conforming product[23]. The elements of liability can be listed as "existence of a non-conforming product", "damage", and "causal link between the product and the damage". Since the manufacturer's fault is not mentioned, this points to a liability without fault, known as strict liability. Therefore, the legal nature of the liability should be examined before addressing the other elements.

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8 September 2024.

19 To this aspect see Atamer and Kurtulan Güner (n14) 549; Gültekin (n1), s. 82.

20 Gültekin (n1), s. 82.

21 Candan Yasan Tepetaş, *İmalatçının Sorumluluğu ve Uygulanacak Hukuk* (Oniki Levha 2021) 94; Atamer and Kurtulan Güner (n14) 550, footnote 37.

22 Yasan Tepetaş (n 21) 94; Atamer and Kurtulan Güner (n14) 550, footnote 37.

23 Sirmen states that the law does not regulate who bears the burden of proof for the "non-conformity", that there is a gap in this regard, and that this gap could be filled by requiring the suffering party to prove the defect, in parallel with Article 4 of the EU Directive 85/374 (Lale Sirmen, "Ürün Sorumluluğu' in Tufan Öğüz, and K Öz (eds), Sorumluluk Hukuku Sempozyumu Bildiri Kitabı (Filiz Kitapevi, 2022) 63, 77.

A. Legal Nature: Strict liability

Strict liability is an exception to the general rule, which typically requires a law to explicitly state when a person can be liable for damage without fault. Law No. 7223 does not clearly state that it imposes strict liability, leading to potential uncertainty about its legal nature. However, the legislature's intention during the drafting process is crucial. As mentioned earlier, the explanatory notes[24] for Article 6 of the law indicate that the liability provisions were aligned with Directive 85/374/EEC which follows a strict liability regime. In other words, the legislature aimed to adopt the liability regime accepted by the Directive. It is explicitly stated in the second explanatory paragraph of the Directive that strict liability is imposed[25]. Ideally, this concept should have been explicitly mentioned, at least in preamble of the Law No. 7223, to avoid debates in legal doctrine. Nevertheless, based on Article 1 of the Turkish Civil Code, which emphasizes that the essence and wording of the law should align, it can be inferred that Article 6 of Law No. 7223 indeed introduces strict liability, consistent with the legislature's intent and the article's rationale[26].

Furthermore, Article 6/2 of Law No. 7223 specifies that to claim compensation, the injured party only needs to prove the causal link between the defect and the damage. This also indicates that the liability is strict, as the injured party is not required to prove the manufacturer's fault. Strict liability focuses on the cause-and-effect relationship, where the cause of liability is an event specified by law. In this case, Article 6/2 identifies the "defect in the product" as the event triggering liability, meaning the defect must cause the damage. The law emphasizes the connection between the defect and the damage, rather than any fault on the part of the manufacturer. Liability arises simply because the damage was caused by a defective product, not due to any fault conducted by the manufacturer.

B. Non-conforming Product

Law No. 7223 uses the term "non-conforming" rather than the terms "defective" or "unsafe", which are used in the source Directive 85/374/EEC. According to

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24 <https://www5.tbmm.gov.tr/sirasayi/donem27/yil01/ss173.pdf> accessed 5 September 2024.

25 <https://eur-lex.europa.eu/eli/dir/1985/374/oj> accessed 8 September 2024.

26 Atamer and Kurtulan Güner (n14) 560; Sağlam (n 2) 186-188; Tuba Akçura Karaman, '7223 sayılı Ürün Güvenliği ve Teknik Düzenlemeler Kanunu'nun 6. Maddesi ile Düzenlenen Ürün Sorumluluğuna "uygunsuzluk" ve "zarar" Unsurları Açısından Eleştirel Bir Bakış' (2023) 18 (199) Terazi Hukuk Dergisi 78; Kemal Oğuzman and Turgut Öz, *Borçlar Hukuku Genel Hükümler II.* (16th edn, Vedat Kitapçılık 2021) 244; Erhan Kanışlı, 'Ürün Güvenliği ve Teknik Düzenlemeler Kanunu (ÜGTFK) Uyarınca Üreticinin Sorumluluğu', (2020) 78 (3) İstanbul Hukuk Mecmuası 1443; Akın Ünal ve Afir Kalkan, "Türk Hukukunda Ürün Sorumluluğu Üzerine Olan ve Olması Gereken Hukuka Dair Genel Düşünceler" *Türk Adalet Akademisi Dergisi* 39 (2019) 45.

Article 1 of the Directive, the manufacturer is liable for damages caused by a defect in his product and Article 6 of the Directive states that the product is defective when it fails to provide the safety that a person is entitled to expect. The choice to use "non-conformity" in Turkish law, despite it not being mentioned in the source Directive, has been rightfully criticized in Turkish doctrine[27]. As will explained below, the term non-conformity is a broader concept that also includes being unsafe. Even a violation of technical regulations that are not related to human safety can render a product non-conforming. For example, if the technical regulations limits motor power for energy-saving purposes, but manufacturer produces a product with slightly higher power, the product might still be safe but non-compliant. If this more powerful vacuum cleaner damages carpets or flooring, the manufacturer could be held strictly liable under Article 6 of Law No. 7223. In contrast, the , the Directive focuses on holding manufacturers strictly liable only for unsafe products. Therefore, the concept of non-conformity in Law No. 7223 is broader than the concept of unsafe products in the Directive, expanding the scope of strict liability for manufacturers in Turkey.

"Non-conformity" is defined in subparagraph (r) of Article 3, the definitions article of Law No. 7223, as "*the state of a product not conforming to the relevant technical regulation* or *general product safety regulations*." As understood from the definition, a product must be manufactured in accordance with both technical regulations and general product safety regulations. If it violates even one of these, its "conformity" will be in question. Therefore, while the licensing of a pharmaceutical indicates compliance with technical regulations, this alone is not sufficient to ensure that the pharmaceutical is deemed confirming; it must also comply with general product safety legislation.

In Turkey, pharmaceutical manufacturers are required to obtain a marketing license before releasing a drug into the market (Article 5/1, Regulation on the Licensing of Human Medicinal Products, RLHMP[28]). This licensing is granted by the Turkish Medicines and Medical Devices Agency (Türkiye İlaç ve Tıbbi Cihaz Kurumu TİTCK) under the Ministrery of Health to ensure the drug's safety, efficacy, and quality. The procedures followed by TITCK in licensing a medicinal product is outlined in the RLHMP[29]. Therefore, the inspection of

27 Sirmen (n23) 5; Atamer ve Kurtulan Güner (n 16) 563, 564. For further evaluations on the subject see Akçura Karaman (n 3), 90; Sağlam (n 3) 105, 107-109.

28 OG11.12.2021/31686.

29 See Başak Tayşi Bilgili, İlaçların (Beşeri Tıbbi Ürünlerin) Ruhsatlandırılması, Markalarının Oluşturulması, Korunması ve Kısıtlanması, (Galatasaray Üniversitesi Sosyal Bilimler Yüksek Lisans Tezi 2019) 35, 36; Fülurya Yusufoğlu Bilgin and Sıtkı Anlam Altay "İlaç Ruhsatının Askıya Alınmasında Bilimsel Verilere Dayanma Zorunluluğu" in S A Altay and A Ayoğlu and F Yusufoğlu Bilgin (eds), Prof. Ercüment Erdem'e Armağan C.I (Onikilevha 2023) 1480, 1481.

whether a drug is produced in accordance with technical regulations in Turkey, as stated in Art. 3 (r) of the Law No. 7223, is conducted by TİTCK. TİTCK also evaluates complaints, and feedback from patients and healthcare professionals regarding the marketed drugs[30]. These processes are carried out regularly and comprehensively to protect public health and ensure drug safety.

It should be noted that all pharmaceuticals must be licensed, and unlicensed pharmaceuticals are exception[31]. Art. 5 of the RLHMP stipulates that no medicinal product may be placed on the market without a license from TİTCK. An unlicensed pharmaceutical is considered both a violation of the RLHMP and an unsafe product under Art. 5 of the Law no. 7223, leading to liability under Art. 6 of Law No. 7223. Conversely, if a licensed pharmaceutical causes harm, it will be inspected to ensure that it meets all requirements specified in the license and technical specifications. A product failing such an inspection would be deemed non-confirming. Even if the product passes all the inspections and complies with technical regulations, it does not necessarily mean the product is confirming as per the Law no. 7223. The product should also meet the expected safety and risk-free requirements of the General Product Safety Regulation, as explained below.

Compliance with the technical regulations is mandatory but not sufficient. In addition, Article 3(r) of the Law No. 7223 requires that the drug complies with the 'general product safety regulation.' It is not specified in Law No. 7223 what is meant by the 'general product safety regulation.' Upon reviewing the relevant legislation[32], it is understood that the term 'general product safety legislation' refers to the 'General Product Safety Regulation" which was published in the OG in 2021[33]. Article 4(d) of the said Regulation defines safe product as, *"a product that, under normal and reasonably foreseeable conditions, does not pose a risk or poses minimal risk specific to the use of the product, including requirements for its introduction to service, installation, and maintenance where applicable, and that is considered to provide a high level of protection for human health and safety when the following elements are taken into account;..."*

The definition of a safe product provided in Article 4(d) of the Regulation is complex and includes four criteria for evaluating safety. It is unclear how these criteria apply at different stages of product safety evaluation. To clarify, it is helpful to refer to Article 2/1(b) of the EU Directive on General Product Safety No. 2001/95 which is the bases of the Art. 4(d) of the Turkish Regulation[34].

30 Gültekin (n1) 39.

31 Further information on licensing see Tayşi Bilgili (n 29)15.

32 see Article 4g of the Framework Regulation on the Market Surveillance and Inspection of Products, OG 31537/10.07. 2021.

33 General Product Safety Regulation, OG 31420/11.03.2021. Also see Sağlam (n 2) 105.

34 Article 15 of the Regulation explicitly states that the source is EU Directive No. 2001/95.

According to Article 2/1(b) of the Directive 2001/95[35], a product is considered safe if it meets two fundamental criteria. Firstly, the product must either be completely non-hazardous or hazardous to an acceptable degree. This assessment should consider the product's "reasonably foreseeable use", including its lifespan, installation, and maintenance. These conditions, though phrased differently, are similar to those in Article 4(d) of the General Product Safety Regulation. For example, a product must be safe throughout its usage period. If a painkiller is used past its expiration date and causes harm, it is deemed "user error", not an issue of product safety. The 'reasonably foreseeable use' means that the product should be safe for all anticipated and socially accepted uses[36]. Manufacturers must foresee potential hazards and provide adequate warnings. If a product is used in an unforeseeable manner and causes harm, it does not necessarily mean the product is unsafe. For example, if someone overdoses on and suffers harm, the manufacturer is not liable if the usage was not foreseeable. Additionally, a product that causes harm does not automatically means it is unsafe. For example, cancer drugs, despite severe side effects, are considered safe if their long-term benefits outweigh the risks.

The second criteria require the product to provide "a high level of protection for the safety and health of individuals". This involves evaluating several factors, including instructions on usage, maintenance, disposal, and interactions with other products. Thus, if a product is deemed to provide 'a high level of protection for the safety and health of individuals' based on these four criteria and similar criteria, then the product is considered safe.

Moreover, Article 2/1(b) of the Directive no. 2001/95 specifies that the mere possibility of producing a lower risk product does not render a product dangerous. This provision is also reflected in Article 5/3 of the Product Safety Regulation. It clarifies that the presence of safer alternatives or lower-risk products does not automatically classify a product as unsafe. However, this does not imply that manufacturers can produce unsafe products. They are expected to adopt appropriate technology and practice to ensure their products are safe. While manufacturers are not obligated to use the most advanced or expensive technologies, they must implement adequate measures to ensure safety. This principle was affirmed by Turkish Supreme Court in a 1995 decision[37], predating the relevant legislation.

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35 European Directive of 15 January 2002 on general product safety, OJL 11 < https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001L0095> accessed 26 June 2024

36 See also Yvan Markovits, 'La Directive C.E.E. Du 25 Juillet 1985 Sur La Responsabilité Du Fait Des Produits Défectueux', [1990] Revue internationale de droit comparé 210.

37 Supreme Court, 4th CC, 1994/6256, 1995/2596, 27.31995. <https://www.lexpera.com.tr/ictihat/> accessed 26 July 2024.

C. Damage

To claim compensation from the manufacturer under Article 6 of Law No. 7223, the injured party must demonstrate that they have suffered damage caused by a non-conforming product. This damage can effect either individuals or property. Article 6/1 of Law No. 7223 states that the manufacturer or importer is liable for any such damage. Article 6/5 of the Law also specifies that compensation amounts, both material and immaterial, will be calculated according to the Turkish Code of Obligations (TCO).

The reference to the TCO, is intended to guide the calculations amounts, as outlined in Articles 51 and following. Although Law No. 7223 refers only to the TCO's provisions on compensation amounts, the general principles of the TCO can also be used to determine the scope of the damage to individuals or property. Therefore, in the absence of specific regulations in Law No. 7223, the scope of damage and compensation amounts should be determined based on the TCO's general provisions on tort liability (Articles 50-59).

If the injured party cannot fully prove the extent of the damage, the court will determine the amount based on Article 50/II of the TCO. The judge will assess the damage fairly, considering the course of events and the measures taken by the injured party. Additionally, the Law no. 7223 includes provisions for the judge to consider when calculating damages (Article 21/4), which will be reviewed in the section below discussing exemptions.

Article 6/1 of Law No. 7223 allows claims for "damage to individuals and property" without limiting the rights under general provisions[38]. To clarify, Article 6/5 explicitly references the TCO's provisions on non-pecuniary damage.

1. Damage to Individual

Article 6 of Law No. 7223 mentions that, damages suffered by individuals will be compensated; however, it does not clarify what is included in the scope of these damages. To address this gap, it would be appropriate to interpret the reference to the TCO in Article 6/5 of Law No. 7223 broadly, and to resolve the issue according to the provisions of the TCO. This matter is regulated by Articles 53, 54, 55, and 56 of the TCO

Material damage resulting from death and injury is referred to as damage suffered by an individual[39]. TCO provides a dual assessment based on whether the death was caused or not. Accordingly, if a non-conforming product causes the death of an individual, compensation can be sought for funeral expenses;

[38] Erhan Kanışlı, 'Ürün Sorumluluğunda Zarar' in Yeşim Atamer and Başak Baysal (eds.), Ürün Sorumluluğu Sorumluluk Hukuku Konferansları I (Onikilevha Yayıncılık 2022) 178, 184.

[39] Fikret Eren, *Borçlar Hukuku Genel Hükümler* (27th edn, Yetkin Yayınları 2022) N. 1642, 607; Oğuzman and Öz (n25) N. 277; Kanışlı (n 38) 180.

if death does not occur immediately, compensation can be claimed for medical expenses and for material damage arising from the inability to work until death (TCO Art. 53). It should be also noted that, Supreme Court, does not favor the reduction request of the defendant on medical expenses[40]. If a person merely falls ill due to a non-conforming medication, they can claim compensation from the manufacturer and importer for loss of earnings and medical expenses related to the period of illness (TCO Art. 54). Additionally, compensation for loss of earning capacity or the impact on the individual's economic future due to bodily harm can also be compensated[41].

The judge determines the maximum amount of compensation, which should not exceed the damage suffered. The Judge shall determine the scope of compensation, taking into account the requirements of the situation, particularly the severity of the fault (Art. 51/1TCO)[42].

Article 52 of the TCO outlines the circumstances under which the amount of compensation can be reduced. According to this provision, if the injured party has consented to the act causing the damage, contributed to the occurrence or aggravation of the damage, or worsened the situation of the liable party, the judge may reduce the compensation or eliminate it entirely. This is referred to as contributory negligence, where the injured party's actions cause or worsens the damage. If the main cause of the damage is the injured party's fault, this may not just reduce the liability but may also completely eliminate it[43]. As will be explained below[44], if the injured party's fault is deemed the primary cause of the damage, the causal link between the perpetrator's act and the damage is considered to be broken[45]. For example, if A lightly injures B, and B covers the wound with a contaminated cloth, causing an infection that leads to B's death, B's action of using the contaminated cloth breaks the causal link between A's

40 Supreme Court, 4th CC, 604/2504, 30.03.1985: "For the protection of the human legal personality, which includes life and health that one cannot be even waived, the requirement to receive treatment in places and by individuals who are more careful and skilled should not be a reason for a reduction in compensation claims. It is contrary to procedure and law for the court to base treatment expenses on the tariffs of official institutions." <https://www.hukukturk.com/yargitay-kararlari?EsasNo1=1985&EsasNo2=604&KararNo1=1985&KararNo2=2504&Merci=4060> accessed 30 May 2023.

41 Eren (n 39) N. 1635, 606; Oğuzman and Öz (n 25) 100, 101.

42 It is accepted that the injured party can claim compensation for excessive damages by analogy with TCO Art. 122 (Oğuzman and Öz (n 25) N. 264; Rana Nur Sidim, *İlaç Üreticisinin Hukuki Sorumluluğu* (Master thesis, Uludağ Üniversitesi 2023) 72 <https://tez.yok.gov.tr/UlusalTezMerkezi/ > accessed 26 July 2024

43 Oğuzman and Öz (n 25) N. 376, 377..

44 See below "interruption of the causal link" especially context related to fn 75.

45 Oğuzman and Öz (n 25) N. 278, 379.

act and the damage. This principle, set out in Article 52 of the TCO, is further expanded, in Article 21/4 of Law No. 7223, allowing for a broader scope of reductions[46]. The fault of not only the injured party but also any third party under the injured party's responsibility may lead to a reduction or complete elimination of the manufacturer's liability. For example, if a non-conforming drug is prescribed to A to be taken with meals but A's daughter continues to give on an empty stomach, and A subsequently suffers from a stomach ulcer, an investigation might reveal that the drug was non-conforming due to the presence of an unapproved ingredient. However, A's daughter's administration of the drug on an empty stomach increased the risk and triggered the ulcer. In such a case, the judge might reduce or completely eliminate the compensation due to A's daughter's incorrect administration (Article 21/4)

As mentioned Article 51/1 of the TCO states that the judge shall determine the scope of compensation based on the "*requirements of the situation*". The phrase is interpreted to include unforeseen events, extraordinary income of the injured party or harm suffered by the perpetrator[47]. Among these factors, unforeseeable events are particularly significant for pharmaceutical manufacturers. An unforeseen event is one that is independent of the responsible party's actions[48]. For example, if A lightly injures B and B subsequently dies due to an infection contracted in the hospital, the infection would be considered an unforeseen event. Inherent predispositions, such as hemophilia, diabetes, heart disease, or allergies also play a significant role. Although these conditions do not involve any fault or behavior from the injured party, they may necessitate a reduction in compensation based on equity[49]. For instance, a slap to a person with a defect in their skull bones or a slight stab to a hemophiliac might result in severe harm or death. With the perpetrator remains responsible, the court may reduce the compensation to account for the injured party's predisposition.

Norms protecting the right to life generally do not distinguish based on the injured party's inherent predisposition. However, Art. 51/1 of the TCO allows for equitable reduction in compensation. The Supreme Court[50] has supported this view indicating that while inherent predisposition may partially contribute to damage, it justifies a reduction in compensation. This reduction is usually less than the extend of the inherent predisposition's contribution. For example, compensation might be reduced by one-quarter or one-fifth.

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46 See context related to fn 75.

47 Oğuzman and Öz (n25) N. 364 sq.; Eren (n 39) N. 2413.

48 Eren (n 39) N. 2414; Oğuzman and Öz (n25) N. 397..

49 Sidim (n42) 72 ; Eren (n 39) N. 2416.

50 Supreme Court, 4th CC, 6092/8184, 05.11.1984; Supreme Court General Assembly of Civil Law, 481/4-508, 24.06.1964 <https://www.lexpera.com.tr/ictihat/> accessed 26 July 2024.

If the harm suffered by the victim, is caused by the negligent behavior of both the perpetrator and a third party, this situation does not, as a rule, eliminate the perpetrator's liability but rather creates joint liability among the responsible parties. In this case, the perpetrator has the right to recourse against the third party according to the provisions of Articles 61-62 of the TCO. Additionally, the negligent behavior of the third party is also considered among the *requirements of the situation* mentioned in Article 51 of the TCO, that judge shall consider in determining the compensation.

The side effects of medications can vary in severity, and the same medication can cause different harm in different individuals. Additionally, the harm may occur either while the medication is being used or later on. The judge can only decide on the compensation for the harm that has already occurred. However, it is possible to file a lawsuit for harm that occurs after the decision has been made, with the right to claim additional compensation reserved[51]. Furthermore, as regulated in Article 75 of the TCO, if the extent of bodily harm cannot be fully determined at the time of decision-making, the judge may retain the authority to modify the compensation ruling within two years starting from the finalization of the decision.

The amount of compensation for bodily harm is determined based on the date of the judgment. However, while it is considered that the date of the judgment should be taken into account, Supreme Court rulings indicate that the date of the occurrence of the damage is the basis. Interest begins to accrue from the moment the damage occurs. Interest is applied to the amount of damage determined as per the date of the occurrence until the judgment is issued[52].

Additionally, it is necessary to address the issue of compensation for loss of support. Article 53 of the TCO stipulates that the relatives of the deceased may also claim compensation for material damages on the grounds of loss of support. In this context, the relatives of the deceased are also allowed to claim compensation for loss of support from the manufacturer. However, whether compensation for loss of support can be claimed without fault in cases of strict liability is a matter of debate in the doctrine, though it is generally accepted that fault should not be required[53]. Since the Law No. 7223 does not explicitly provide for the possibility of claiming compensation for loss of support from the manufacturer, the discussions we have mentioned under the TCO will also be relevant to product liability.

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51 Eren (n 39) N. 2283, 2284.

52 Eren (n 39) N. 2283, 2284; Oğuzman and Öz (n 25) 88 ; Sidim (n 42) 74.

53 Atamer ve Kurtulan Güner (n 14) 567. The authors have noted that the German product liability law explicitly states that compensation can be claimed without the need to prove fault in this matter.

Article 16 of the Directive No. 85/374, allows member states to set an upper limit on the total compensation that the manufacturer must pay for death and bodily injury caused by the same defect, provided it is not less than 70 million euros[54]. The Law No. 7233 chose not to impose an upper limit in this regard.

2. Non-pecuniary Damage

Article 6/5 of Law No. 7223 stipulates that the amount of material and non-pecuniary compensation shall be determined according to the provisions of the TCO. This implies that non-pecuniary compensation can be claimed from the manufacturer.

Non-pecuniary damage refers to the involuntary reduction in a person's well-being due to violations against their personality [55]. Unlike material damage, non-pecuniary damage does not result in a decrease in assets and cannot be measured in monetary terms. However, in the absence of a better remedy, compensation for this damage is usually determined by awarding a sum of money. Within the framework of the current legislation, Article 58 of TCO is the primary provision that allows for claiming non-pecuniary compensation in cases of infringement of personal rights. TCO Article 58 serves as a general liability rule protecting personal rights, including social and emotional values[56]. On the other hand, TCO Article 56, which is a specific provision, regulates compensation for non-pecuniary damages arising from violations of physical personality values such as the right to life and bodily integrity. If the conditions stipulated in these articles are met, it is possible to claim non-pecuniary compensation from the manufacturer. A relevant Supreme Court decision[57] awarded non-pecuniary compensation to a plaintiff for the distress and depression caused by a heart condition and other side effects resulting from a prescribed medication. The plaintiff, who has been prescribed a muscle relaxant, subsequently developed a heart that forced him to quit his profession as a pilot.

Although TCO provisions do not explicitly mention the element of fault, it is generally accepted that non-pecuniary compensation is based on the principle of fault since it falls within the scope of tort liability[58]. Given that

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54 See Markovits (n 36) 237 N. 379; Catherine Weniger, *La Responsabilité du fait des produits pour les dommages causés à un tiers au sein de la Communauté Européenne* (Librairie Droz 1994) 127, 128.

55 Oğuzman and Öz (n 25) 267 et sq., N. 715; Eren (n 39) N. 2432 et sq.; Henri Deschenaux and Pierre Tercier, *La Responsabilité Civile* (Staempfli 1982) 258.

56 Eren (n 39), N. 2434; Oğuzman and Öz (n 25) 266, 267.

57 Supreme Court, 13th CC, 2017/8553, 2019/7812, 26.6.2019<https://www.lexpera.com.tr/ictihat/> accessed 26 July 2024.

58 As to the claim for non-pecuniary damages being based on the principle of fault: Supreme Court of Appeals 4th CC, 11.7.2002, 2001/12708, 2002/8915 <https://www.kazanci.com.tr> accessed

Law No. 7223 imposes strict liability on manufacturers and importers, the question arises whether it is necessary to prove the fault of the manufacturer or importer for the injured party to claim non-pecuniary compensation under this legislation. Article 6/5 of Law No. 7223 states that the amount of material and non-pecuniary compensation will be determined according to the provisions of the TCO. However, this does not clarify whether the compensation is based on fault. To better understand this, we can refer the source Directive. Article 9/2 of the Directive 85/374 leaves the matter of non-pecuniary compensation to the national laws of the member states, due to its special nature[59]. This approach has been criticized for creating an imbalance in competition among companies in different member states[60]. In our opinion, accepting that the manufacturer is strictly liable also for non-pecuniary damages under Law No. 7223 would serve the protective purpose intended by law.

Since Article 6/5 of Law No. 7223 mentions non-pecuniary damages together with material damages without making a distinction and states that both will be subject to the provisions of the TCO, we believe that non-pecuniary damages can also be claimed without the need to prove fault[61]. Indeed, both the doctrine and the Supreme Court predominantly accept that in cases of strict liability, the responsible person will also be liable for non-pecuniary damages without the need to prove fault, provided that all the conditions required for strict liability are met[62].

3. Damage to Property

Article 6 of Law No. 7223 states that if a product damages property, the manufacturer or importer is obliged to remedy this damage. The damage to

26 July 2024. For further information see Oğuzman and Öz (n 25) 282, 283; Eren (n 39) N. 2483.

59 See also preliminary paragraph 9 of the EU Directive no 85/374. Also see J.S. Christopher Hodges, *Product Liability European Laws and Practice* (Sweet & Maxwell 1993) 56.

60 Markovits (n 36), 238 N. 380. Markovits has stated that in France, those who suffer non-pecuniary damage are protected, and the fault of the harm-doer is not required, whereas in Germany, non-pecuniary damages are not compensated outside of fault liability. As a result of the Directive leaving the application of non-pecuniary damages to national discretion, French manufacturers will be required to pay more non-pecuniary compensation compared to German manufacturers.

61 To this aspect Kanışlı (n 38) 188.

62 Pierre Tercier, *Le nouveau droit de la personalité* (Schulthess, 1984) 266 ; Selahattin Sulhi Tekinay and Sermet Akman and Haluk Burcuoğlu and Atilla Altop. *Tekinay Borçlar Hukuku Genel Hükümler* (Filiz Kitapevi 1993) 688, 689; Atamer ve Kurtulan Güner (n 14) 567; Kanışlı (n38) 1441; Oğuzman ve Öz (n 25) 145, N. 430; Eren (n 39) N. 2483. See Supreme Court General Assembly decision (22.6.1966, 7/7) that neither the employer's nor the employee's fault is a condition for holding the employer liable for non-pecuniary damages under TCO 56. (OG 12360/28.07.1966 <www.resmigazete.gov.tr> accessed 4 January 2023.

property means the loss of value in other possessions caused by the non-conforming product, resulting from the harm or destruction it causes[63]. For example, if a faulty electrical component in a water heater causes a fire, compensation can be claimed from the manufacturer or importer for the harm or destruction to other items in the house. Such a damage would occur rarely in the case of a non-conforming medication to damage. For instance, an excessive amount of acid in the medication might damage the medicine cabinet and other medicines stored alongside it. Thus, such property damage caused by a non-confirming medication also falls within the manufacturer's liability.

It is worth mentioning that price paid for a non-conforming medication do not fall under the manufacturer or importer's liability. The claims for the refund of the amount paid for the product should be made within the scope of the seller's contractual liability[64].

Lastly, it is also useful to note that the EU Directive 85/374 restricts compensation for property damage by both defining the damaged property as a consumer good and setting a minimum limit of 500 euros for the amount of damage (Art 9b). Article 6 of Law No. 7223 does not require the damaged property to be a consumer good or set a minimum limit for the amount of damage[65]. Unlike EU regulations, under Law No. 7223, all damages caused by non-conforming products to any property can be subject to compensation.

D. Causal Link

1. In General

To hold the manufacturer liable, there must be a causal link between the 'damage' and the 'non-conformity'. In fault-base liability, the link is typically between the manufacturer's conduct and the damage. However, under Art 6 of Law no. 7223, the causal link is required specifically required between the non-conforming product and the damage. As examined above, this indicates that the law introduces strict liability.

The burden of proof for the existence of the causal link rests on the injured party (Art. 6/2). For instance, a person whose illness has worsened must prove that was caused by the non-conformity of the medication used, which can be challenging and often requires technical examinations. Various means, such as epidemiological studies, may be used to prove an appropriate causal link. However, the results of such studies alone are not sufficient to definitively

63 Eren (n 39) N. 1643; Kanışlı (n 38) 180.

64 Bilge Öztan, *İmalatçının Sorumluluğu* (Turhan Kitapevi 1982) 22; Gilles Petitpierre. *La Responsabilité du fait des Produits* (Librairie de l'Université Georg 1972) 34, 35.

65 Sirmen (n 23) 79.

establish a causal connection between the damage and the medication's non-conformity. While these studies may reveal the relationship between the disease and the medication, the causal link must be assessed separately.

Article 4 of Directive 85/374 similarly requires the victim to prove the causal link between the product and the damage. This requirement for the plaintiff to prove the causal link has been criticized as an unfairly heavy burden. Acknowledging the difficulty of such proof, the European Commission, in its 1999 publication 'Green Paper'[66], proposed that if the can victim prove both the damage and the defect, it should be presumed that the causal link exists. In line with doctrinal views, we also believe it would be appropriate to extent the same ease to victims seeking compensation from the manufacturer under Law No. 7223[67].

Proving the causal link between the non-conforming product and the damage becomes even more challenging in the presence of multiple causes. Generally, multiple causes can present themselves in three different ways[68].

The first scenario is "common causality". In common causality, none of the causes alone is sufficient to produce the harm result, but when combined, they lead to damage. For instance, if a non-conforming medication becomes even more dangerous and causes a person's death because it was not stored at the required temperature in the warehouse of one of the wholesalers in the distribution chain, this is a case of common causality. In this example, neither the non-conformity in the medication nor the poor storage conditions alone are sufficient to produce a lethal effect, but when these two independent causes come together, they lead to such a result. Similarly, if using a single medication would not have caused any harm, but the use of multiple medications together leads to illness, the concept of common causality among the manufacturers of the medications would apply.

The second scenario is "competing causality", where each cause simultaneously is sufficient to produce the harmful result. Returning to our previous example, this would be the case if both the non-conformity in the medication and the deterioration caused by improper storage were each independently sufficient to produce the lethal result. The causality between these two causes and the damage is in a competing position.

The final scenario is "alternative causality", where only one of the multiple causes has actually produced the harmful result, but it cannot be determined which cause it was. An example of this situation is when there are multiple importers of a non-conforming medication or when the same medication is manufactured

66 COM (1999) 28.7.1999, 396 final, 19 <www.europa.eu.int> accessed 26 June 2024.

67 To this aspect see Gültekin(n 1) 59; Celt (n9) 98; Akçura Karaman (n1) 215.

68 Eren (n 39) N. 1702 et sq.; Oğuzman and Öz (n 25) 56, 57; Akçura Karaman (n 1) 273.

by different producers. In this case, a single medication has caused the damage, and the primary responsible party is the person who produced or imported the product; however, it cannot be determined which manufacturer produced the product or which importer brought it into the country. In cases of "common causality" and "competing causality", all the causes are considered jointly and severally liable[69]. However, in alternative causality, there is essentially only one responsible party, but there is not enough evidence to determine who that is. Consequently, it is accepted that in such cases, no one can be held liable[70].

In the field of pharmaceutical manufacturer liability, the issue of "alternative causality" frequently arises, especially when a medication produced abroad is imported into the country by multiple importers. As mentioned, in cases of alternative causality where the responsible party cannot be identified, it is typically accepted that no one should be held liable. Since exonerating the manufacturer or importers from liability would mean that the victim bears the full extent of the damage, this solution does not seem fair[71]. Therefore, we believe the European Commission's 1999 report proposal, which suggests that if the victim proves that the product is defective and that damage has occurred, the causal link should be presumed, is quite appropriate[72]. In this scenario, each manufacturer can only avoid liability by proving that the product causing the damage was not their own product.

2. Interruption of the Causal Link

Interruption of the causal link occurs when an intervening cause emerges before the initial action has fully realized its effects. This cause pushes the original action to the background and renders it no longer suitable for liability. Interruption causes are classified as force majeure, fault of the victim, or fault

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69 Eren (n 39) N. 1709; Oğuzman and Öz (n 25) 57; Akçura Karaman (n 1) 273; Haluk Tandoğan, *Türk Mes'uliyet Hukuku* (Ajans-Türk Matbaası 1961) 83, 85.

70 Eren (n 39) N. 1714; Oğuzman and Öz (n 25) 57; Tandoğan (n 67) 86; Tekinay and Akman and Burcuoğlu and Altop (n 61) 570. Those authors also argue that when the various causes are not completely independent and form a continuity, all individuals involved should be held jointly liable. A classic example is a fight involving five people where a fatal punch cannot be attributed to a specific person. In such cases, everyone involved is considered jointly liable. This is supported by the 1977 decision of the 4th Civil Chamber of the Supreme Court (19.9.1977, 7150/8449), which states that in cases of alternative causation with an appearance of unity, jointly liable applies under Article 50 of the TCO <https://www.kazanci.com.tr> accessed 26 July 2024.

71 Guillod and Leuba, suggests using a method that considers the market share of the liable parties when determining the existence of the causal link (Oliver Guillod and Audrey Leuba, 'Causalité alternative et responsabilité du fait des produits: un pour tout, tous pour un' (3-4) 2(1994) Revue européenne de droit privé, 455).

72 To this aspect see Gültekin(n 1) 59; Celt (n9) 98; Akçura Karaman (n1) 215.

of a third party[73]. Each situation should be briefly examined.

Force majeure refers to an event that is significantly stronger than an unforeseen circumstance, occurring outside the liable party's control and objectively unavoidable[74]. For example, if a person injured by a non-confirming medication dies from being struck by lightning while being taken to the hospital, this is considered force majeure. Despite the non-confirming medication having caused a serious injury, the person's death due to lightning interrupts the causal link between the non-confirming pharmaceutical and the harm.

Another cause that interrupts the causal link is the fault of the victim, which is also important for the manufacturer's liability. Here, even though the defect in the product could normally cause the damage, the victim's fault in their actions makes the defect secondary and becomes the primary cause of the harm. For example, if a victim consumes a defective medication with the intention of suicide, the manufacturer's responsibility is affected. Even if the medication had met technical specifications, consuming the entire package would still lead to death. Such situations commonly occur when the victim does not follow the medication instructions.

For the victim's fault to interrupt the causal link, it must be significant enough to overshadow the initial cause and become the sole adequate cause of the harm. If the victim's fault only contributes to the damage alongside other causes, as explained above this is referred as contributory negligence[75] and the liable party will not be exempt from liability, but this will be considered in reducing the compensation amount (Art. 52 of TCO)[76]. This is especially relevant for user errors. As a general rule, if the victim's misuse of a non-confirming medication worsens the damage (for example taking overdose), it should only result in a reduction in the compensation amount, not an exemption from liability. However, if the user's fault is the sole adequate cause of the harm, then it can be said to interrupt the causal link. As in the case of swallowing all the pills in the container with the intent to commit suicide. It should also be noted that "fault of the victim" includes not only the victim's actions but also operational risks attributable to the victim and the behavior of the victim's assistants[77]. This

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73 Eren (n 39) N. 1729; Tandoğan (n 67) 79-82; Deschenaux and Tercier (n 54) 62; Franz Werro, 'La responsabilité objective du fait des produits est-elle stricte?' in C. Chappuis ve B. Winiger, Responsabilités objectives, Journée de la responsabilité civile 2002 (Schulthess Editions Romandes 2003) 57.

74 Tandoğan (n 67) 328; Eren (n 39) N. 1730. Eren (N. 1731), states that while force majeure always breaks the causal link, an unforeseen circumstance may not always break the causal link on its own.

75 See above "Damage to Individual" especially the context related to fn. 43.

76 To this aspect see Werro (n 70) 57.

77 Eren (n 39) N. 1748.

issue is clearly addressed in Article 21/4 of Law No. 7223.

Third cause of interruption is the fault of a third party. If the fault of third party is of such a degree that interrupts the causal link between the perpetrator's behavior and the damage, in general it is accepted that, the perpetrator will not be ordered to pay compensation[78]. However, in strict liability cases, the interruption by fault of the third party is not favored, and mostly, the exemption is prevented by law[79]. For example, Swiss aviation law prevents the plane's owner company from exempting liability by claiming that the plane was high jacked by a third party[80]. To that aspect Law No. 7223, Article 21/3 establishes that regardless of the severity of the third party's fault, the manufacturer cannot be exempt from liability. The article states that if the damage arises from both a non-conformity in the product and an act or omission of a third party, it does not reduce the manufacturer's or importer's liability for compensation but allows the manufacturer to seek recourse against the third party. On the other hand, if the fault of third party is the sole cause of the damage and no causality link could be established with the non-corming medication, the manifacturer would not be liable.

IV. EXEMPTIONS FROM LIABILITY

Article 21/2 of Law No. 7223 outlines three specific situations in which a manufacturer can be exempt from liability for compensation. The first is proving that the manufacturer did not introduce the product into the market. The second situation involves proving that the non-conformity in the product is not due to the manufacturing process but rather due to intervention by a distributor, a third party, or the user. The third situation involves proving that the defect in the product arose due to complying with technical regulations or other mandatory technical rules. If any of these three situations are proven, the manufacturer is exempt from liability for compensation as regulated in Article 6 of Law No. 7223 (Article 21/3).

The primary condition for being held liable under the law is that the product must have been placed on the market. The manufacturer cannot be held liable under Law No. 7223 if the product has not been placed on the market. For instance, if an employee of the manufacturer takes and uses the product while still in the factory, the manufacturer would not be held liable in this case. Additionally, if the product has not been placed on the market by the manufacturer but has been stolen from the factory and placed on the market by malicious third parties, the manufacturer can avoid liability by proving this.

78 Eren (n 39) N. 1752, 1753.

79 Werro (n 70) N. 1752.

80 Eren (n 39) N. 1752.

It should be noted that determining when the product was placed on the market is important in terms of the manufacturer's potential to avoid liability. The law only refers to the product being placed on the market and does not mention its commercial use. In this case, the use of the product on patients in hospitals, universities, etc., before it is put up for sale, should also be considered as placing it on the market. Such non-commercial placement on the market, if done by the manufacturer, is sufficient to establish the beginning of liability[81]. Determining the moment when the product was placed on the market lays the groundwork for the manufacturer to avoid liability by proving that the product was not defected when it was released on the market, as explained below, through the second possibility.

Article 21/2b states that if the manufacturer proves that the non-conformity in the product is not due to the manufacturing process but rather due to intervention by a distributor, a third party, or the user. For example, if a properly manufactured medication was not stored in the cold chain by the distributor, this exemption would apply. As mentioned above if the manufacturer can prove that the product was confirming when it was placed on the market, this will also exempt them from liability. In this case, it would be understood that the defect occurred after the product was released. It should be noted that, for this exemption to be valid, the medication must be properly produced. If the medication is also non-conforming when placed in the market, then the manufacturer would not be exempt from liability; the manufacturer would only have the right to seek recourse against the other responsible parties (Art. 21/3 Law No. 7223).

The third exemption regulated in the Law involves proving that the defect in the product arose due to complying with technical regulations or other mandatory technical rules (Article 21/2c). The provision that allows the manufacturer to be exempted from liability by proving that the defect in the product is due to compliance with technical regulations is rightly criticized in the doctrine[82]. Firstly, the technical regulations referred to in Law No. 7223 are minimum standards. Adhering to these minimum standards does not mean that the manufacturer has taken the necessary measures required by science and technology or that the product is safe. The doctrine rightly points out that legal regulations related to products cannot keep pace with scientific advancements and fail to meet the justified safety expectations of consumers.

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81 As to this aspect see Akçura Karaman (n1) 342.

82 As to this aspect see Atamer and Kurtulan Güner (n14) 575; Akçura Karaman (n1) 342; Fulya Erlüle, Avrupa Topluluğu Konsey Yönergesi Çerçevesinde Yapımcının Sorumluluğu (Phd Thesis, Marmara Üniversitesi Sosyal Bilimler Enstitüsü 1992) 170.

V. STATUTE OF LIMITATIONS

Liability in tort is regulated under Article 72 of the TCO with two different statute of limitations as 2 and 10 years. The 2-year period starts from when the victim learns about the damage and the identity of the wrongdoer. For an incurred loss, the maximum period is 10 years from the date of the tortious act (TCO, art. 72). Article 6/6 of the Law no. 7223 sets statute of limitations periods for manufacturers as 3 to 10 years.

The 3-year period begins when the victim learns about the damage and the liable party which is one year longer than the general tort liability (Art. 6/6). Directive 85/374 establishes a similar 3-year period, but starting from when the damage, defect and identity of the responsible party are known, also nothing that mere possibility of knowledge is deemed sufficient. Since Art. 6/6 does not mention possibility of knowledge it must be interpreted as actual knowledge[83]. The absence of explanation in the preamble of the article leaves unclear whether the Turkish legislator's deviation from the Directive was intentional and what the aim might me.

The 10-year period in Article 6/6 of Law No. 7223, while similar to the general tort liability, has different starting points: it begins from the occurrence of the damage whereas general tort liability starts from the tortious act. Directive 85/374 also provides 10-year limitation period, but it starts from the date product is placed on the market. The Turkish law's start date can create uncertainty for manufacturers. The Turkish legislator opting for a longer period to offer broader protection to injured party. Rightful criticism of Article 6/6 focuses on its lack of legal security and difficulties in providing defects over time[84]. Some argues[85] the period should start from the product's market placement. However, we think it's reasonable to start the period from when the damage is discovered, since medication-related harm can appear much later[86]. This approach allows for a 3-year limitations period if the harm and responsible party are identified within 10 years, but holds the pharmaceutical company accountable for long term effects.

A 2019 Supreme Court decision[87] illustrates how Turkish courts may favor the injured party. In this case, a medication prescribed in 2004 led to health issues for the plaintiff. He only filed a claim in 2008, arguing he did not connect his condition to the medication until then. The manufacturer contended that the medication was recalled from the market in 2004 and that the claim should be

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83 Atamer and Kurtulan Güner (n14) 581.

84 Atamer and Kurtulan Güner (n14) 581.

85 Kanışlı (n25) 1453.

86 Sidim (n 42) 89.

87 Supreme Court 13th CC, 2017/8553, 2019/7812, 26.6.2019 <https://www.lexpera.com.tr/ictihat/> accessed 26 July 2024.

barred by the 2-year statute of limitation in Article 72 of the TCO. The court initially, sided with the manufacturer but the Supreme Court overturned this, ruling that the burden of proof was on the manufacturer to show the plaintiff knew of the harm before 2008.

The decision highlights a trend towards easing the burden on plaintiffs, a practice we support given the challenges faced under Law No. 7223.

CONCLUSION

In Turkish law, the liability of pharmaceutical manufacturers for the damages caused by their medications is governed by the same general provisions applicable to all manufacturers under Law No. 7223. This law primarily focuses on administrative inspections and penalties to ensure technical compliance and public health safety, but it lacks specific provisions addressing the unique aspects of pharmaceutical liability. The inclusion of a few articles (Articles 6 and 21) addressing liability for all manufacturers within such a technically oriented law is insufficient to meet the needs of neither manufacturers nor consumers. Given the complex nature of the healthcare sector, it is clear that treating pharmaceutical manufacturers the same as other manufacturers is inadequate. Countries such as Germany, Switzerland and France have implemented specific legislation for this sector, which would be beneficial for public health in Turkey as well. It is clear that these laws will also serve as a reference for legislative developments in Turkey.

Recently, we have sadly followed numerous news reports on the side effects of vaccines and other medications produced and used globally during the COVID-19 pandemic and the lawsuits filed in this regard. It is evident that the strict liability provision introduced in favor of the injured party by Law No. 7223 will not serve its purpose effectively, considering the burden of proof placed on the injured party by the law. According to Law, the plaintiff is obliged to prove the non-conformity of the product and the causal link between the non-conformity and the damage. Determining the non-conformity of the medication means, assessing whether it was produced in accordance with its technical specifications, which is an unfair burden to place on the patient using the medication. It would be more just and realistic to require the pharmaceutical manufacturer to prove that the product was produced according to technical specifications and that it is safe. Additionally, placing the burden of proving the causal link between the non-conformity and the damage on the plaintiff further complicates the compensation claim. Considering that doctors often prescribe multiple medications during an illness, it would be more appropriate to require the manufacturer, rather than the patient, to prove which medication caused the damage. Indeed, the party capable of knowing the side effects of the medication and employing a technical team is not the injured party but the defendant manufacturer.

Finally, it should be noted that although the law aimed to impose strict liability on manufactures, this strict liability is considerably weakened by various defenses available them. Especially, Article 21/2c which allows manufacturers to avoid liability by showing that the product's non-conformity resulted from compliance with technical regulations, has been rightly criticized. This is because legal and technical regulations often lag behind scientific advances and may not fully address the safety expectations of consumers.

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