

THE CIVIL LIABILITY OF ENTITIES CONDUCTING MEDICAL ACTIVITIES FOR DAMAGES CAUSED BY MEDICINAL PRODUCTS AND MEDICAL DEVICES UNDER POLISH LAW

AGNIESZKA RABIEGA-PRZYŁĘCKA

Faculty of Law and Administration, University of Łódź

Abstract: Polish regulations provide a variety of mechanisms of liability for damages caused by medicinal products and medical devices, including a fundamentally significant mechanism – civil liability. Such a liability may be assumed by different categories of entities, including their producers, trading entities or entities conducting medicinal activities and using medicinal products, medical devices under the subject's activities. The civil liability regime of entities conducting medicinal activities is conditional upon the formal and legal status of the entity conducting medicinal activities and the relationship binding them with a patient on the basis of tortious and contractual principles. Statutory obligations to apply such liability regimes may frequently prevent (or even inhibit) the rectification of damage caused by medicinal products and medical devices, which gives rise to proposals to modify the general principles of liability and seeks solutions to provide an optimal system of compensation for such damages.

Keywords: Civil liability, medicinal product, medical devices, medical damages

Despite the dynamic steps forward in the field of medical science and the development of new, safer treatment and diagnostic methods, the treatment process related to the application of the medicinal products and medical devices entails certain risks. Aside from the desired effect (completed treatment or prevention of an illness), the effects of the application of a particular medicinal product or a medical device may also involve the occurrence of adverse reactions, unfavorable for an individual. Therefore, the legislators have provided a plethora of legal instruments to guarantee the safe use of medicinal products and medical devices and to prevent, or mitigate, the effects of damage caused by medicinal products and medical devices. As stated by law, the negative consequences of a failure to provide the safe use of medicinal products and medical devices may be identified as liability. Liability involves the potential to instigate assessments and legal instruments against a defined entity. It also involved drawing negative consequences for an each (as set forth by law) for events or states of affairs subject to a negative normative classification and

legally attributable to a defined entity in a particular legal system. Liability for a failure in providing safe medicinal products and medical devices (and in many situations the damage they cause) may be borne by many entities participating in clinical trials of medicinal products and medical devices e.g. in the production or distribution process in addition to their application in treatment procedures (including in particular by entities rendering medical activities which participate directly in the process of a patient treatment) as well as producers, researchers, sponsors, liable entities, pharmacies, pharmaceutical warehouses and the State. As regards the issue of the safety of medicinal products and medical devices, a variety of liability principles may apply. Such principles are classified in accordance with the criterion of the type of legal regulations governing individual types of liability, i.e. the principle of civil, criminal, administrative liability and in the instance of particular entities, also a professional liability.

In the Polish legislation, the issue of liability for failing to ensure the safety of medicinal products and medical devices, and for damages they have

* Corresponding author: e-mail: arabiega@wpia.uni.lodz.pl

caused, is governed, in particular by: the Act of 6 September 2001 Pharmaceutical Law (1), the Act of 20 May 2010 on medical devices (2), as well as Acts specifying the principles for individual types of liability i.e. the Act of 23 April 1964 Civil Code (3) (here-in-after CC), the Act of 6 June 1997 Penal Code (4). The current wording of the provisions of the Pharmaceutical Law Act and the Act on medicinal products with regards to the aspects of the safety of medicinal products and medical devices constitutes, to a large extent, an expression of the implementation of EU law. Domestic regulations have incorporated some EU regulations (prior to or after the accession to the European Union), whereas others – those not requiring implementation – can be applied directly.

Definition of a medicinal product and a medical device

Polish law includes legal definitions of the terms ‘medicinal product’ and ‘medical device’ modeled on EU regulations, including the 2001/83 Directive (5), 2001/82 Directive (6), 93/42 Directive (7). Under the provisions of the Pharmaceutical Law act, a ‘medicinal product’ is a “substance or substance mixture, presented as having properties preventing or treating human or animal illnesses or administered to diagnose or to restore, improve or modify physiological bodily functions through pharmacological, immunological or metabolic action” (Art. 2 (32) of the Pharmaceutical Law Act). The legislator provides a rather broad definition of the term ‘medicinal product’. It includes products, which are alleged not only to have an impact on the diagnosis process, prevention or treatment of a medical condition but also influence physiological bodily functions. In the first instance, the product is defined from the perception of the manner of presentation (“image” definition). In the second, however, it is defined from the perspective of the impact on processes taking place in the body (“functional” definition) (8). The broad scope of the notion of a ‘medicinal product’ designated with its legal definition indicates that the sole determination of certain properties to individual products suffices and defines a particular product as ‘medicinal’, which serves to prevent any circumvention of the Pharmaceutical Law regime, including product safety and quality.

The act on medical devices, however, specifies a medical device as a tool, piece of equipment, software, material or other item, used individually or in conjunction with something else, including with software intended by its producer for special use for

diagnosis/therapeutic purposes and essential for its proper use, or intended by its manufacturer for human use to: diagnose, prevent, monitor, treat or mitigate the course of an illness; diagnose, monitor, treat, mitigate or compensate the effects of an injury or impairment; test, substitute or modify anatomic or physiological processes; birth control, with the fundamental intended effect (in the human body or on the body) not achieved as a result of the application of pharmacological, immunological or metabolic substances but the effects of which may be supported with such means (Art. 2 section 1 (38) of the Act on medical devices). As is the case with the term ‘medicinal product’, the scope of the term of ‘medical device’ is broad, including all types of devices used during or in connection with providing health care services and produced mainly for medical purposes in a broad sense (such as equipment for diagnostics, laboratories, and orthopedic devices).

Specification of entities providing medical activities

The category of medical entities carrying out medical activities includes entities of diverse legal statuses whose scope of operations includes, in particular, providing health care services comprising: health examination, recognizing and preventing illnesses, treatment and rehabilitation of patients and providing doctors’ advice. Under those activities, persons performing medical professions (mainly doctors) provide, apply and prescribe medicinal products/medical devices. The Act of 15 April 2011 on medical activities (9) recognises two basic categories of entities involved in medical activities: the medical entities (until the aforementioned act on medical activities defined as health care facilities, conducted on a private-legal and public-private basis became effective) and professional practices of doctors and dentists and the professional practices of nurses and midwives.

Diversity of entities liable for damages caused by medicinal products and medical devices and civil liability principles applied

Civil liability for damages caused by medicinal products and medical devices may be borne by many entities, including: entities participating in the manufacturing process, marketing authorisation (for instance the producer and the so-called quasi-producer [importer, distributor]), trading entities (pharmacies, pharmaceutical warehouses), as well as entities involved in medical activities participating in the process of providing health care services to a patient (for instance a medical entity (e.g. a hospital

or doctor), directly. The principles of those entities' liability depend on the circumstances of a damaging event as well on the category of the entity which is to assume respective liability. As focused on later in this paper, the liability of entities involved in medical activities requires only a signal reference to the liability principles for other entity categories.

Until the year 2000, the producer's (as with the distributor's, importer's) liability was based on the fault principle (Art. 415 PC). Only with the Act of 2 March 2000 regarding the protection of certain consumer rights and on liability for damage caused by a hazardous product (10) implementing EEC Directive no. 374/85 of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (11) introduced objectified (regardless of the fault) producer liability principles into the Polish legal system. Currently, the producer is liable for damages caused by medicinal products and medical devices under strict liability (Art. 449¹ CC), unless they demonstrate that: 1) they have not introduced a medicinal product or medical device onto the market, 2) market introduction did not constitute the producer's business operations, 3) the hazardous properties of a product have emerged after its introduction onto the market, unless those properties stemmed from principles present in the product previously, 4) the hazardous properties of a product could not be foreseen at the moment of its market introduction, with consideration to science and technology at the moment of the product's introduction (the so-called development risk) and 5) if such properties stemmed from application of the law (Art. 449³ CC).

However, in the instance of entities involved in trading with those products (pharmacy, pharmaceutical warehouses), they bear warranty liability (within the vendor's liability towards the consumer) or liability for a failure to perform or inappropriate performance of an obligation (Art. 471 CC). In addition, they bear tort liability subject to Art. 415 CC only in the instance of their fault, for example, trading with a medication with an expired sell-by date or failing to meet the quality requirements due to inappropriate storage etc. (12).

Civil liability of entities conducting medical activity for damages caused by medical products and medical devices

The civil liability regime of entities conducting medical activity for damages caused by medicinal products and medical devices depends on the official and procedural law status of such an entity and

the type of their relationship with the patient, assuming the form of liability in tort (A) or contract (B).

Ad. A) Liability in tort for damages caused by medicinal products or medical devices shall be assumed by the entities which provide, apply and prescribe medicinal products/medical devices under publicly funded healthcare (pursuant to an agreement with the National Healthcare Fund). A patient (beneficiary) using financial benefits from public funds does not conclude any agreement with the entity granting those benefits (health service provider), therefore the health service provider's liability is in tort. Such an entity's liability may be of a liability nature foremost: for culpable damages caused by doctors and/or other medical personnel employed (under the so-called vicarious liability and therefore under respondeat superior liability) and, secondly for fault involving inappropriate work organization within the subject entity and its inappropriate functioning, i.e. for a so-called organisational fault.

The basis for liability in the first instance may be Art. 430 CC, which attributes liability to the party which, of their own account, commissions the provision of activity to a person, who – during the activity performance – reports to their management and is obliged to observe their instructions. As a consequence, in the instance of damage caused to a patient by a doctor providing services under an employment agreement within an entity carrying out medical activities, the doctor is absolved of individual liability subject to the employee's immunity and liability for the act shall be assumed by the entity carrying out medical activities (e.g. the hospital) (13). The prerequisites for liability of a medical facility subject to Art. 430 CC in conjunction with Art. 415 CC, which must be shown, involve damage caused by medical staff, culpable activity or negligence of staff, a normal casual link between such activity or negligence and the damage caused as well as causing damage during the performance of the activity entrusted, where even the smallest degree of a fault suffices to attribute liability for the damages (judgment of the Court of Appeals in Warsaw of 3 June 2014, I ACa 1494/13). These are situations, which due to a failure to exercise the duty of care by a doctor resulted in the application of an inappropriate medicinal product or a medical device, also due to unfamiliarity with its properties or side effects, also its misuse on a 'wrong' patient (14). Failure to exercise one's duty of care (a legal obligation for professionals) determines their fault. Principally, an analogous perception of liability for medical malpractice, based on the construct of a physician's lia-

bility for a culpable negligence is assumed in the American liability model. Medical malpractice (in American literature) is defined as any act or omission by a physician during the treatment of a patient that deviates from the accepted norms of practice in the medical community and causes injury to the patient (15), as regards medicinal products they may be in essence: administering the patient the wrong medication or the wrong dosage of medication, prescribing the patient a medication that the patient is allergic to or medication that reacts negatively with other medications that the patient is taking, and failing to warn the patient of the common side effects of the medication (for examples: case *Coombes v. Florio* (16)). In the United States, a patient alleging medical malpractice must generally prove the following legal requirements to make a successful claim for medical malpractice: (a) the existence of a patient-physician relationship, (b) violation of the “standard of care”, (c) failure to meet “the standard of care” was a substantial factor in causing the damage, and (d) the existence of damages (17). All of the indicated elements require evidence (*Wischmeyer v. Schanz* (18)). Practically, the courts in all states may hold a physician liable for their operations or operations of their subordinates (as in the case *Ware v. Timmons* (19)), as well as their employer pursuant to the vicarious liability principle – respondeat superior (20). In the case *Cintron v. St. Joseph’s Hospital* (21), it was confirmed that the hospital was responsible for its employees in the course and scope of their employment. The doctrine of ‘respondeat superior’, as a rule, will not be applicable if a doctor or other health care professional is an independent contractor and commits a malpractice while treating a patient in a hospital. In such an instance the hospital cannot be held liable for the doctor’s negligence. However, the hospital can be held liable for its own negligence, for example, in granting attending privileges to an unlicensed or incompetent physician (22).

The entity carrying out medical activities may also bear, apart from vicarious liability for damage by the fault of the doctors employed and other medical staff, liability of fault with a defective organization of the treatment process (Art. 415 CC, alternatively Art. 416 CC) (23). Such a construct is applied when the damage caused to a patient arose due to, including but not limited to, administration of a wrong medication due to a mistake resulting from its storage or inappropriately stored medication, which affected its action (judgement of the Supreme Court of 27 October 1983, II KR 219/83) (24), restrictions for doctors as to the choice of medicinal products or

medical devices (such as a lack of medication, dressings, specialist apparatus and – as indicated by the Court of Appeals in Lublin in the judgement of 10 January 2002, I ACa 576/01 – “no surgery facilities”), the use of faulty equipment or devices (medical devices, judgement of the Regional Court in Lublin of 4 April 2002, I C 656/99; judgement of the Supreme Court of 22 August 1980, IV CR 299/80) (12). However, in a situation when the reason for equipment inefficiency resulted in bodily damage and/or disturbance of a patient’s health constitute latent defects originating in the production process, i.e. construction errors or defects resulting from the use of inappropriate materials. Liability for damages is then, as per principle, attributed to the producer of the medical apparatus and irrespective of their fault, if the entity providing healthcare services with the use of such apparatus -with due care exercised within performance of the obligation to inspect – was not able to detect such defects, therefore, could not have avoided causing damage. Nevertheless, the literature shows appeals that the entity providing healthcare services should assume ultimate liability for damages resulting from the use of faulty medical equipment with recourse to the producer (12, 23).

In particular situations, liability for damage caused by a medicinal product may be founded on the equity principle (Art. 417² CC). Such liability is recognised when there are no grounds for granting damages in accordance with general principles (due to the inability to attribute liability for damage caused by a medicinal product or a medical device due to a lack of a fault by a doctor/entity providing, using, prescribing a medicinal product or medical device) but the rules of equity argue in favor of compensation for damage on a person or harm. The aggrieved party must present the context that, in accordance with the laws, the damage on a person (the so-called legal damage) resulted from the authoritative operation of a medical facility and the circumstances (particularly the inability of the aggrieved party to work or their difficult financial situation) indicate that the rules of equity require so. In case-law practice, the regime of liability based on the rules of equity applies with respect to damages caused in instances of forced application of medicinal products/medical devices, for example in a situation of obligatory vaccination, obliging the State Treasury to compensate them (judgement of the Court of Appeal in Poznań of 22 January 2013, I ACa 1160/12; judgement of the Provincial Court in Bydgoszcz of 26 October 1994, I C 1805/93; judgement of the Supreme Court of 20 August 1968, II CR 310/68). The literature also features proposals in

which the courts apply an extended interpretation of Art. 417² CC and, in the system, include the entities liable in equity (aside from the State Treasury). This also includes medical entities conducting medical activities financed by public funds (under an agreement with the National Healthcare Fund) therefore are within the tasks commissioned by public authorities (25). Although the case-law practice recognizes State liability for obligatory vaccination injuries, the Polish legal system, unlike the systems effective in other countries such as the United States, does not assume a separate mechanism to compensate for vaccination injuries. The federal system of indemnifying obligatory vaccination injuries – introduced in the United States by way of an act National Childhood Vaccine Injury (1986) – referred to solutions adopted in other countries such as Germany (in 1971), Japan (in 1976), Great Britain (in 1979), assuming a no-fault model for vaccination injuries (26). It assumes the classification of vaccines to a special product category where the sole liability for damages is assumed by the State (the treasury), under the principles effective for a manufacturer, physician or another entity administering such medication. In the instance of the American liability model, it is essential to show that complications arising from the use of a vaccination against a disease covered by the Vaccine Injury Table persevered for at least six months, resulted in hospitalization, a necessity of a surgical intervention or the death of a patient. Awarding compensation pursuant to the no-fault model excludes the potential to make a claim against such a vaccination producer, whereas making a claim pursuant to the no-fault model is unavailable if civil proceedings have been instigated against the producer of such a vaccination (27). The American model of no-fault liability bears similarities to Polish case-law practice within the scope of contributing the liability for a vaccination injury to the State. However, its advantage – in comparison to the Polish approach – is a separate alternative manner of compensating damages dedicated solely to this particular category of medicinal products. Aside from the common systems of product liability, systems of compensation for vaccination injuries are effective in 19 countries (28). The literature presents postulates to create a global vaccine-injury compensation system administered at a global or regional level (29).

B/Contractual liability for damages caused by medicinal products or medical devices is assumed by the entities which deliver, use, prescribe medicinal products and medical devices under healthcare services not financed by public funds granted sub-

ject to a treatment agreement (in most instances similar to a commission agreement under Art. 750 CC, or an agreement for specific work – Art. 627 CC) concluded with an entity conducting medical activities i.e. a medical entity or a professional practice of a doctor, dentist, nurse or midwife. In such a situation, in the event of a failure to complete an obligation or its undue performance, regulations on the regime of contractual liability apply, depending on the circumstances, i.e. Art. 471 CC (if damage arises due to the organisation's own fault in conducting medical activities) or Art. 474 CC (if damage arises due to the fault of doctors or other medical staff employed).

If non-performance or undue performance by a debtor of an existing obligation is, parallelly, a tort (it is always causing damage to a person – bodily damage or disturbance of health) they may be liable either *ex contractu* or *ex delicto*. In this instance, there is a concurrence of contractual liability with liability in tort (Art. 443 CC). In practice, in most instances where an agreement to provide medical services was concluded, the aggrieved parties base their claims on tort framework, as pursuing claims within a contractual regime deprives them of the opportunity to redress any damage.

A traditional model of civil liability for medical damages pursued through court proceedings completes the extra-judicial system of no-fault compensation for damages – introduced in 2011 into the Polish law with an amendment of an act on the rights of a patient and the Commissioner for Patients' Rights (30) – resulting from medical events based on the Swedish insurance model for the benefit of a patient (NFPI – No Fault Patient Insurance) (31). It is, however, notable that it may also be applicable in, including but not limited to, the instance of damage caused to a person in the form of bodily damage or disturbance of health or a patient's death as a result of a medicinal product or medical device application contrary to current medical knowledge (32).

CONCLUSIONS

Polish regulations governing the issue of liability for medical damages, including those caused by medicinal products and medical devices, specify diverse mechanisms of compensation for damages based on the grounds of tort and contract. Nevertheless, they do not guarantee optimal protection for the aggrieved parties as, principally, they do not recognize the mechanism of redressing non-culpable damages suffered by an individual as the

result of sudden and unexpected events connected to treatment (medical accidents) to a broader extent (26). The requirement to indicate the existence of the fault of a person of a medical profession or an entity conducting medical activities under the tortious regime, has limited potential in attributing liability for equity reasons and in the instance of a contractual regime as well as an extra-judicial mode of compensation for damages resulting from medical events, its limited applicability in many situations prevents or at least significantly restricts redressing all damages caused by medicinal products and medical devices. A solution to be considered is the model of American approaches, a separate model of compensation for damage caused by individual categories of medicinal products such as vaccinations, in particular including them in the obligatory vaccination system.

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