

# THE AUSTRIAN «ATYPICAL MODEL» OF CRIMINAL PROTECTION OF THE CIRCULATION OF MEDICAL DEVICES

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**Annotation.** The Austrian model of criminal protection of the circulation of medical devices is considered. The authors note that atypicality of the Austrian “model” of criminal law protection of circulation of medical devices is due to several factors.

It is analyzed that the main ones are those related to: a) the legislative definition of the concept of pharmaceutical products, since the content of this concept “legislatively outlines” the limits of criminal protection and affects the mechanism of ensuring this protection; b) determination of the limits of criminal protection of medical devices depending on the requirements of the Austrian Federal Law on Medical Devices.

The authors note that the atypicality of the Austrian “model” of criminal protection of medical devices is influenced primarily by the absence of a legislative definition of the concept of “medical devices”, as well as the “negative sign” of the corresponding types of administrative offenses, indicated in the sanction of part 1 § 80 of the Austrian Federal Law on Medical Devices (2021).

The authors also focus their attention on the fact that the atypicality of the Austrian “model” of criminal protection of medical devices is also due to the fact that the aforementioned Federal Law on Medical Devices in its § 80 contains provisions on “administrative punishment (Verwaltungsstrafe)” for violations of the established procedure for the circulation of medical devices, which affect the provision criminal law protection of medical devices and its limits.

It is proven that the specified “negative sign” directly affects the definition of offenses of those specific types, which are provided for in the Austrian Code of Criminal Procedure and encroach on the circulation of medical devices. The peculiarities of such limits under Austrian criminal law should be connected primarily with the fact that the specified “negative feature” is fixed in the sanction of part 1 § 80 of the Austrian Federal Law on Medical Devices (2021), “does not eliminate” the formation of relevant signs of acts and illegality as mandatory structural elements of criminal offenses of certain types.

**Key words:** criminal law protection, medical products, medical devices, Austrian “model” of criminal protection, Austrian criminal law.

## 1. Introduction.

In order to understand the specifics of the limits of the criminal law protection of the circulation of medical devices and the impact on the mechanism of ensuring this protection of the legal consolidation of the concept of medical devices, we suggest turning to the European experience of criminal law regulation of the specified issue, namely to the Austrian model of criminal law protection of the circulation of medical devices.

## 2. Analysis of scientific publications.

The investigated issue did not receive adequate coverage in domestic scientific sources, therefore it is of particular relevance.

### 3. The aim of the work.

The aim of the article is to investigate the Austrian model of criminal protection of the circulation of medical devices.

### 4. Review and discussion.

The atypicality of the Austrian "model" of criminal law protection of circulation of medical devices is due to several factors. The main ones are those related to: a) the legislative definition of the concept of pharmaceutical products, since the content of this concept "legislatively outlines" the limits of criminal protection and affects the mechanism of ensuring this protection; b) determination of the limits of criminal protection of medical devices depending on the requirements of the Austrian Federal Law on Medical Devices (Bundesgesetz betreffend Medizinprodukte) dated October 28, 2021 [1]. So, let's analyze the mentioned factors.

1. Austrian legislation provides legal protection of medical devices as a mandatory component of pharmaceutical activity despite the fact that the mentioned Austrian Federal Law on Medical Devices does not contain an independent "exhaustive definition" of the concept of medical devices, as is done, for example, in the German Law on Medical Devices (Gesetz über Medizinprodukte) in edition of on August 7, 2002 [2]. Thus, in the mentioned German Law, the concept of "medical devices" is defined in quite detail and covers instruments, apparatus, devices, software, substances and preparations made of substances or other objects, used alone or in combination, including software, specially intended by the manufacturer for use for diagnostic or therapeutic purposes and used for proper functioning, a medical device for use by humans through their functions for the following purposes:

a) detection, prevention, monitoring, treatment or alleviation of diseases, b) detection, monitoring, treatment, alleviation or compensation of injuries or disabilities, c) examination, replacement or modification of an anatomical structure or physiological process or d) regulation of conception. Medical devices can be intended for the maintenance of the human body and are characterized by the fact that the intended main effect on the human body is not achieved either by pharmacologically or immunologically active agents, or by metabolism, but the mechanism of action of such products can be provided by the named active agents (part 1 § 3). In addition, according to part 2 § 3 of this Law, medical devices are also devices that contain a substance or a preparation of substances that can be considered as medicinal devices in the sense of part 1 § 2 of the German Medicines Act, if they are used separately and which, in addition to the functions of the products, may have an effect on the human body. In part 3 § 3 of the German Law on Medical Devices, a medical devices is also a product containing a substance that is used separately as a component of a medicinal products or a medicinal devices that is made from human blood or blood plasma within the meaning of Art. 1 of Directive 2001/83/EC of the European Parliament and the Council of Europe of November 6, 2001 on the Community code relating to medicinal products for human use (L 311 of November 28, 2001) [2].

An approach to the definition of the concept of medical devices, similar to the German one, is not provided for in the mentioned Austrian Federal Law, and therefore the content of the concept of medical devices is determined on the basis of the analysis of the provisions of this Law, which regulate the circulation of medical devices. Thus, in his part 1 § 1 ("Scope") states that this Austrian Federal Law regulates the safety, functionality and quality of medical devices during its installation, operation, use and maintenance, during the manufacturing and use of medical devices in healthcare facilities, during cleaning, disinfection and sterilization of medical devices, conducting clinical trials and effectiveness studies, risk prevention, registration and monitoring, as well as distribution and advertising of medical devices.

Therefore, the criminal content of the concept of medical devices, which determines the limits of criminal protection of their circulation, must in any case take into account the answer to the question of what features of handling medical devices are able to ensure the achievement of goals related to

protection individual and/or public health. This requires finding out not only the characteristics of the medical devices itself, but also the types of behaviour that form the handling of medical devices.

2. The atypicality of the Austrian “model” of criminal protection of medical devices is also due to the fact that the aforementioned Federal Law on Medical Devices in its § 80 contains provisions on “administrative punishment (Verwaltungsstrafe)” for violations of the established procedure for the circulation of medical devices, which affect the provision criminal law protection of medical devices and its limits. In part 1 § 80 of the above-mentioned Law (this paragraph is included in the 13th chapter, which has the following title: “Regulations on administrative punishment (Verwaltungsstrafbestimmungen)”), types of actions are defined, which attract a monetary fine of up to 25 thousand euros, and in case of their repeated commission - up to 50 thousand euros. Therefore, in order to find out the atypicality of the “model” of the criminal protection of medical devices under the legislation of the Republic of Austria (hereinafter - Austria), it is necessary to find out: a) the specifics of the criminal nature of the provisions of § 80 of this Federal Law, as well as b) the impact, which have the provisions of this paragraph to determine specific types of criminal offenses encroaching on the established order of circulation of medical devices. To clarify these main points, it is necessary to deal with the legal nature of the “administrative penalty (Verwaltungsstrafe)” provided for in part 1 § 80 of the above-mentioned Austrian Federal Law.

First, the criminal law system of Austria (as well as the criminal law system of Germany) provides for two independent types of criminal offenses, which are enshrined respectively in the provisions of the main and a number of additional criminal laws: a serious criminal offense (Verbrechen) and a less serious criminal offense (Vergehen). Austria’s main criminal law is the Criminal Code of 1974 (Strafgesetzbuch). “Criminal Code (hereinafter - CC)” is the official abbreviated name reflected in the title of this Austrian legislative act. The same title also reflects the official expanded name of this legislative act: “Federal Act on Conduct Threatened by Judicial Punishment (... über die mit gerichtlicher Strafe bedrohten Handlungen), dated January 23, 1974” [3]. In this case, it is important that in the system of Austrian criminal law, criminal offenses attract only judicial punishment (that is, the punishment applied by the court, which directly corresponds to the title and content of the provisions of the Austrian Criminal Code). After all, in the system of Austrian law there are also punishments applied by other state authorities, which are not courts. “Misdemeanor (Übertretung)” is not a type of criminal offense [4, p. 305-307] - it is not provided for by criminal law and is a type of “non-criminal offense” for which a different punishment is applied, which is not judicial (see below).

Secondly, in the system of Austrian law, “administrative punishment (Verwaltungsstrafe)” is an independent type of measures of an administrative nature, which is applied by an administrative authority (Verwaltungsbehörde) for a misdemeanor (Übertretung) that violates the relevant administrative prescriptions (...wegen Übertretung von Verwaltungsvorschriften) [5]. “Administrative punishment” is provided at the general level in the independent Austrian Administrative Punishment Act of January 1, 1991 [6], which is included in the Austrian system of administrative law on misdemeanors and contains general provisions about them and their types, regardless of the branch “affiliation” of the committed misdemeanor. Part 1 § 1 of the Law on Administrative Punishment has the following definition of an administrative misdemeanor (Verwaltungsübertretung): “An act (action or inaction) can only be punished as an administrative misdemeanor when it was under the threat of punishment before its commission (...mit Strafe bedroht war)”. §§ 10–18 of the Law on Administrative Punishment defines three types of such punishments: fine, imprisonment and confiscation [5].

At the field-specific level, types of misdemeanors (Übertretung) are defined in various legislative acts that regulate various types of administrative activity in the field of traffic, construction, pharmaceutical activities, etc. One of such legislative acts is the above-mentioned Austrian Federal Law on Medical Devices, which in part 1 § 80 defines the types of actions that: a) constitute an administrative offense of a specific type, which carries the appropriate administrative penalty, and also b) are included in the content of the act as a structural element of this type of administrative offense. In part 1 § 80 of above-mentioned Federal Law on Medical Devices defines types of actions.

Those committed by a person who: places a medical device in circulation, makes it available for circulation, puts it into operation, builds, installs or uses contrary to the requirements of Regulation (EU) № 745/2017 or Regulation (EU) № 746/ 2017 or this Federal Law; as a manufacturer, authorized representative, importer, dealer or other natural or legal entity fails to fulfill its obligations stipulated by Regulation (EU) № 745/2017 or Regulation (EU) № 746/2017 or this Federal Law; as an authorized body does not meet the requirements

of Regulation (EU) № 745/2017 or Regulation (EU) № 746/2017; demonstrates a medical product for demonstration purposes that is contrary to the requirements of Regulation (EU) № 745/2017 or Regulation (EU) № 746/2017; violates the provisions of Art. 6 of Regulation (EU) № 745/2017 or Regulation (EU) № 746/2017; combines a medical product in violation of Art. 22 of Regulation (EU) № 745/2017 without submitting the declaration provided for such a combination; sterilizes a medical product in violation of Clause 3 of Art. 22 of Regulation (EU) № 745/2017; while conducting clinical trials or efficacy studies violates the requirements of Regulation (EU) № 745/2017 or Regulation (EU) № 746/2017 or the requirements of Section 3 of this Federal Law; violates the requirements for monitoring and attention in accordance with the provisions of Regulation (EU) № 745/2017; as a business entity violates the requirements of Articles 94, 95 and 97 of Regulation (EU) № 745/2017 or Articles 89, 90 and 92 of Regulation (EU) № 746/2017; manufactures and uses medical products in healthcare facilities contrary to the requirements of Section 9 of this Federal Law; does not comply with the obligation to report in accordance with Section 37 of this Federal Law; fails to comply with an order under sections 43 and 44; violates Commission Regulation (EU) № 722/2012 of August 8, 2012 on special requirements relating to the use of tissues of animal origin, active for implantation, and medical products; violates the requirements established for the activity of a medical devices consultant contrary to § 48 of this Federal Law; does not instruct personnel or instructs them in violation of the requirements of § 52 of this Federal Law; does not carry out an inventory or carries it out in violation of the requirements of § 53 of this Federal Law; cleans, disinfects or sterilizes a medical device in violation of section 62 or section 63; carries out business activities in violation of the special rules established part 1, 5 of Chapter 65 in this Federal Law; carries out business activities without the necessary license, which is provided for in accordance with part 3 of section 65 of this Federal Law; supplies a medical devices contrary to a prescription provided for in accordance with sections 66 or 67 of this Federal Law; uses labeling or product appearance or advertising in accordance with Article 7 of Regulation (EU) № 745/2017 as misleading or as such that is capable of creating false expectations among consumers; violates the provisions of section 11 of this Federal Law on advertising of medical products, etc.

Thirdly, the Austrian Law on Administrative Penalties is relevant for the legal protection of medical devices within those "limits", which are defined by a special instruction in the sanction provided for in part 1 § 80 of the above-mentioned Federal Law on Medical Devices. The construction of this sanction is as follows: *"Whoever ... commits, if it does not constitute (bilden) an act in the structure of criminal behavior (strafbare Handlung) that falls under judicial jurisdiction (Zuständigkeit), is found guilty of committing an administrative offense (Verwaltungsübertretung) and is subject to a fine of up to 25,000 euros or up to 50,000 euros in the event of a repeated offense"*. It should be recalled that in Austrian criminal law, the conformity of the behavior of the composition of the act is included in the structure of the criminal offense on an independent "level" (on other "levels" are presented: illegality and guilt). Therefore, the named prescriptions of the sanction under part 1 § 80 of the above-mentioned Federal Law on Medical Devices nevertheless have specific criminal law significance and are taken into account when determining the content of the acts included in the structure of criminal offenses provided for by the relevant criminal law. In other words, this means that the provisions of the sanction of part 1 § 80 *"... if it does not form (bilden) the composition of the act in the structure of criminally punishable behavior..."* so to speak "in a negative way" indicate that the provisions of part 1 § 80 of the above-mentioned Act the types of acts may determine the content of criminally punishable conduct (strafbare Handlung), but such criminally punishable conduct and the corresponding components of the act are not provided for in the Federal Law on Medical Devices. So, in part 1 § 80 of the above-mentioned Austrian Medical Products Act indicates the "negative sign" of the corresponding types of administrative offenses: *"...if this does not constitute an act in the structure of criminally punishable conduct..."*.

In part 1 § 80 of the above-mentioned Austrian Law defines types of actions that, taking into account the above sanction requirements, can be considered in the content of certain types of criminal offenses and their components of actions, but these types of criminal offenses and their components of actions are not provided for in the Federal Law on Medical Devices, but in the relevant acts of criminal legislation (see below).

Fourthly, the Austrian Federal Law on Medical Devices does not single out medical products and their circulation as mandatory elements (signs) of the relevant types of criminal offenses and the composition of acts in their structure. Medical devices and their circulation can be elements of only "general" types of criminal offenses, that is, those types that are provided for in the main criminal law of Austria - CC.

There are no “special” types of criminal offenses in the Austrian Federal Law on Medical Devices, and the constructions of “general” types of criminal offenses provided for in the Criminal Code as the main criminal law of Austria do not include features related to the circulation of medical devices. Therefore, the types of criminal offenses provided for in the Austrian CC, although they do not directly contain signs of violation of the order of circulation of medical devices, but may be related to such circulation and its violation. In this case, punishment for the commission of such “general” types of criminal offenses is applied only on the basis determined by the Austrian CC. Moreover, the above-mentioned provisions of sanctions of part 1 § 80 of the Federal Law on Medical Devices directly affect the specific content of acts and illegalities in the structure of criminal offenses of the types provided for in part 1 § 110 of the Austrian Criminal Code punishes anyone who treats another without his consent, even if it is in accordance with the rules of medical science, with imprisonment for a term of up to six months or a fine of up to 360 daily wages. Therefore, it is not excluded that in the process of such treatment, the circulation of medical devices may be “used”, and what has been done may be connected with those types of violation of the circulation of medical devices specified in part 1 § 80 of the Federal Law on Medical Devices (see above). If, as a result of the illegal circulation of medical devices, bodily injury or damage to health is intentionally caused, then despite the lack of direct indication in the Austrian Criminal Code of the signs of this circulation and/or types of its violation, the act may be recognized as such a type of criminal offense as: “Bodily injury” (§ 83), “Grievous bodily injury” (§ 84), “Bodily injury with serious lasting consequences” (§ 85), “Bodily injury with fatal outcome” (§ 86), etc. If a person who provides care for the sick or works in a medical-technical or sanitary support service negligently causes bodily injury or harm to health with loss of working capacity lasting more than fourteen days, then the committed offense is a criminal offense provided for in § 88 of the Austrian Code of Criminal Procedure (“Negligent bodily injury”) [7].

Fifth, if we compare the criminal law provisions of the German Law on Medical Devices and the Austrian Federal Law on Medical Devices, their certain “common point” is the recognition of certain types of violations of the order of circulation of medical devices established by these legislative acts, such as inherent “insignificant level” of harmfulness, which does not allow to recognize them as serious criminal offenses (*Verbrechen*) and impose a punishment for them, which is characteristic of a serious criminal offense, - in the amount of more than one year of imprisonment. However, if according to the German Medical Devices Act, the corresponding types of violations of the order of circulation of medical products are recognized as less serious criminal offenses (*Vergehen*), then according to the Austrian Federal Medical Devices Act, the corresponding types of violations are administrative offenses (*Verwaltungsübertretung*), and entail such an administrative measure - of a legal nature, such as “administrative punishment (*Verwaltungsstrafe*)”.

## 5. Conclusions.

1. The atypicality of the Austrian “model” of criminal protection of medical devices is influenced primarily by the absence of a legislative definition of the concept of “medical devices”, as well as the “negative sign” of the corresponding types of administrative offenses, indicated in the sanction of part 1 § 80 of the above-mentioned Austrian Law with the wording “... if it does not constitute an act in the structure of criminally punishable conduct...”.

2. The specified “negative sign” directly affects the definition of normative limits of the content of acts and illegality in the structure of criminal offenses of those specific types, which are provided for in the Austrian Code of Criminal Procedure and encroach on the circulation of medical devices. The peculiarities of such limits under Austrian criminal law should be connected primarily with the fact that the specified “negative feature” is fixed in the sanction of part 1 § 80 of the above-mentioned Austrian Law, “does not eliminate” the formation of relevant signs of acts and illegality as mandatory structural elements of criminal offenses of certain types. The specified “negative feature” is a kind of “switch” between the composition of acts and illegality in the structure of criminal offenses of the types provided for by the Austrian Code of Criminal Procedure and in the structure of the types of administrative offenses specified in § 80 of the Austrian Federal Law on Medical Devices. That is, in the case when the types of actions provided for in § 80 of this Law “... do not form a composition of the act in the structure of criminally punishable conduct ...”, then they are characteristic of the composition of actions and illegality in the structure of the specified administrative offenses. If such “formation” takes place, it can be said that the types of actions provided for in § 80 of this Law form, inherent in the composition of actions and illegalities in the structure of criminal offenses of the specified types. Therefore, the types of actions defined in § 80 of this Austrian Law are equally characteristic



of the content of the specified mandatory elements of the structure of administrative misdemeanors and criminal offenses of certain types, and "... the formation of the composition of the action in the structure of criminally punishable behavior ...", about which is referred to in the sanction part 1 § 80 of the above-mentioned Law, occurs "at the expense" of other elements of the composition of acts and illegality in the structure of a criminal offense (primarily consequences in the form of damage to a person's life or health).

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