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 **Bundesministerium**
Soziales, Gesundheit, Pflege
und Konsumentenschutz

from 07.06.2022 to 10664/J (XXVII. GP)

sozialministerium.at

John Rauch

federal minister

Mr
Mag. Wolfgang Sobotka
President of the National Council
houses of Parliament
1017 Vienna

Business number: 2022-0,269,530

Vienna, June 3, 2022

Dear Mr President!

I answer the written parliamentary question No. 10664/J addressed to me by Deputy Hauser regarding "Medical obligations in the case of corona vaccinations" as follows:

Question 1: *What does the vaccinating doctor have to explain to the patient?*

According to the settled case law of the Supreme Court, the treatment contract concluded with the doctor includes the obligation to inform patients about the possible dangers and harmful consequences of the treatment. This obligation to provide information also applies to vaccinations (5 Ob 1524/94, 7 Ob 12/97h; RdM 1977, 22 and many more).

Before the vaccination is carried out, there is an obligation to inform the person to be vaccinated and - if they are not yet capable of making decisions - a person entrusted with legal representation in the

area of care and education (legal guardian, usually a parent) about the disease to be prevented and to explain the vaccination so that they can give consent to the vaccination (e.g. § 5a KAKuG, § 51 Para. 1 Doctors Act, § 2 Para. 2 Z 3 HebG).

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The function of the information is to protect the freedom of choice of the person concerned. The person to be informed should be given the information he or she needs to understand the nature, significance and scope of a medical measure. Information about the benefits and risks should therefore be given to the extent that the person concerned needs help in making a decision.

Furthermore, in connection with COVID-19 vaccines, reference may be made to the recommendations of the National Vaccination Committee, which can be found on the homepage of my department under "Fachinformation".

Question 2: *What are the consequences for a doctor if the patients*

- a) *not objective and*
 - b) *unsatisfactory*
- be enlightened?*

Since the attributes "objective" and "sufficient" in this context depend on the individual level of information and the patient's respective need for information, this question can only be answered to the effect that inadequate information that does not correspond to the state of medical science is a violation of medical professional duties. This can be punished under administrative and/or disciplinary law as well as have consequences under liability law.

Question 3: *What information or training is there for vaccinating doctors so that they can provide objective and sufficient information before corona vaccination?*

The diploma further training program of the Austrian Medical Association describes the scope of further training for all doctors who are entitled to practice their profession independently in Austria and serves to fulfill the further training obligation under medical law. Based on the data of the DFP calendar, in which all DFP-approved training courses are listed, a total of 273 DFP training courses on the subject of "vaccination" were offered throughout Austria in the years 2020 to 2022, 143 of which DFP training courses were specifically related to the topic "COVID-19 -Vaccinations".

In addition, the Academy of Doctors offers in cooperation with the Austrian Society for Vaccinology online training courses in the "Focus Vaccination" series for everyone

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Doctors and organizes the annual Austrian Vaccination Day, which in the last two years has also focused on COVID-19 vaccinations. Furthermore, the Austrian Society for Infectious Diseases and Tropical Medicine, the Austrian Society for General and Family Medicine and the Austrian Society for Children and Adolescent Medicine offer intensive training programs on the subject of vaccination and COVID-19 disease.

Within the framework of circulars from the Austrian Medical Association and the Federal Curia for Resident Doctors, all resident doctors are regularly informed about news on the subject of COVID-19 diagnostics, therapy and vaccination prevention. The recommendations for use of the National Vaccination Committee and updates from my department are immediately brought to the attention of all doctors by means of circulars.

Questions 4 to 7:

- *Were all patients informed about alternative options and treatment methods before being vaccinated with the corona vaccines?*
- *What have you done to ensure that as many suspected cases of vaccine damage as possible are reported to BASG?*
- *What have you done to ensure that as many suspected cases of vaccination damage as possible are reported to the Federal Ministry and are accordingly taken into account in further corona policy?*
- *What have you done to ensure that as many suspected cases of vaccine damage as possible are brought to the attention of the public and discussed publicly?*

The federal states are responsible for implementing the vaccinations. The scope of the medical education has been shown in the Austrian vaccination plan for years and I can assume that doctors work in accordance with the recommendations and the current state of science.

To ensure the safety of medicines, mechanisms for monitoring side effects were created in the Medicines Act (AMG) and the Pharmacovigilance Ordinance 2013 (PhVO 2013) even before the start of the COVID-19 pandemic. Section 4 of the PhVO 2013 stipulates that suspected side effects of medicinal products for human use must be reported. The notification must be made to the Federal Office for Safety in Health Care (BASG). Doctors, pharmacists and others

Healthcare professionals are required by law to report. Additionally

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Patients and their relatives can voluntarily report side effects directly to the BASG.

A side effect is any reaction to the vaccine that is harmful and unintended.

In the case of vaccines, this also includes the lack of an effect. In connection with side effects as a result of vaccinations against COVID-19, the BASG has updated the relevant information on the website, which is very easily accessible.

Question 8: *Are doctors obliged to inquire about the vaccination status in the case of clinical pictures that make vaccination damage appear possible?*

There is no explicit legal obligation to “assess vaccination status”. According to
According to § 49 ÄrzteG 1998, however, doctors are obliged to conscientiously look after all healthy and sick people who receive medical advice or treatment. As part of the anamnesis, all information necessary for the clarification of a clinical picture must be obtained. If there is a suspicion of a vaccination side effect or the lack of the expected effectiveness, doctors are obliged according to § 75g Drugs Act to report immediately to the BASG in accordance with the regulation according to § 75a AMG.

Questions 9 and 13:

- *What information or training is there for vaccinating doctors so that they can document possible side effects (suspected cases) of corona vaccinations and report them to BASG?*
- *What information or training is there for vaccinating doctors so that they can report the lack of effect of the corona vaccinations to BASG?*

The demand for high-quality medical training within the meaning of the Ordinance on Medical Training means that training must be designed exclusively in accordance with medical science and experience and be oriented towards improving medical care for the benefit of the patient. A balanced overview of the respective state of knowledge of medical-scientific alternatives is to be conveyed in every further training. Accordingly, a balanced presentation of the content of these training courses with appropriate information on the documentation and reporting of side effects or lack of effect can be assumed.

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Since there is a legal obligation for healthcare professionals to report suspected side effects associated with the use of vaccines, as with any other drug, I can assume that healthcare professionals know how to report a suspected side effect of a drug in accordance with their professional obligations.

In addition, my company points out the importance of this in the Austrian vaccination plan, as well as in the information and documentation sheets on vaccinations, in the recommendations for use, on the website of the Ministry of Social Affairs and in the communication materials on the vaccinations.

When fully vaccinated people contract COVID-19, this is called a vaccine breakthrough. In order to counteract "underreporting", the data of the epidemiological reporting system EMS is compared with that of the e-vaccination card.

Information on this is provided on the AGES website at [Coronavirus -AGES](#).

Questions 10 and 11:

- *What measures has the Federal Ministry taken to ensure that the reported side effects of the corona vaccines are clarified quickly?*
- *What does the BASG do after receiving a report about a possible side effect of the corona vaccination?*
 - a) *On average, how long does it take to clarify a suspected side effect?*
 - b) *What help is there for those affected by corona side effects, who are often very ill and need financial support, until they are cured and compensated (which often takes a long time)?*

The BASG is responsible for recording and processing the reported suspected side effects.

The processes for reporting side effects are harmonized across Europe (see Guideline on Good Pharmacovigilance Practices - GVP). If the side effect report is a valid case (fulfilment of the minimum criteria such as suspected vaccine, suspected reaction, information about the patient), it will be sent to the European

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Medicines Agency (EMA). The data is therefore also available to all other national drug authorities and the European drug approval authority for ongoing safety monitoring.

In close cooperation with the EU network of authorities, the risk-benefit ratio of all approved medicinal products is continuously monitored. A synopsis of the reports from all EU member states results in "signals" for relevant, hitherto unrecognized side effects. The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) analyzes all aspects relevant to the safety and efficacy of a vaccine. If necessary, new side effects are included in the product information and instructions for use of the respective vaccine or other measures are taken to ensure safe and effective use.

Question 12: *What has the Federal Ministry done to ensure that all doctors comply with their legal obligation to report the lack of effects of the corona vaccination?*

See answers to questions 4 to 7 and 9 and 13.

Question 14: *What has the Federal Ministry done to ensure that the medical association addresses the corona side effects and that all doctors are informed of their legal obligation to report all suspected cases of a side effect in full?*

There is a legal obligation to report suspected side effects according to the Medicines Act and it can be assumed that doctors follow their professional obligations.

For the rest, see the answer to questions 4 to 7.

Question 15: *What has the Federal Ministry done to ensure that the Medical Association all reminds doctors of their legal obligation to report the lack of effects of the corona vaccination?*

See the answer to questions 4 to 7 as well as 9 and 13.

Thanks to the data comparison between EMS and e-vaccination card, it is ensured that these cases are recorded completely.

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Question 16: *Does it happen in practice that doctors who have demonstrably disregarded their obligation to report side effects of medication are reported?*

- a) *If yes, how often has it happened in the past five years?*
- b) *If yes, what were the penalties?*

- c) *If so, were there any side effects of corona vaccines?*
- i. *If yes, in how many cases? ii. What were the consequences for the doctors?*

The Austrian Medical Association points out that there are no figures and data on administrative notifications regarding a violation of the reporting obligations according to the AMG of the Austrian Medical Association. Disclosures to the public regarding disciplinary proceedings and their possible outcome are prohibited pursuant to Section 194 of the Medical Act 1998, which is why no information in this regard can be given.

To date, the BASG has not reported any violations of Section 83, Paragraph 1, Item 14 of the Medicines Act.

Question 17:*It is estimated that only 6% of drug side effects are reported to the BASG, why are doctors not complying with their legal obligations?*

- a) *What has been done in the last five years to get the remaining 94% reported?*
- b) *Has the Federal Ministry addressed this problem to the medical association?*
- i. *If so, when and who was commissioned to change this circumstance? ii. How often has this topic been discussed with the medical association?*

On the part of the BASG, for example, in lectures at relevant specialist groups (Hospitals, pharmacist conferences, BASG talks on pharmacovigilance, etc.) on this Reporting of side effects and the importance of this for the benefit-risk profile of drugs/vaccines. BASG also regularly takes part in #MedSafetyWeeks, a social media campaign to raise awareness of adverse drug reactions.

Question 18:*Have all cases of vaccine breakthrough (lack of vaccine effect) been reported to the BASG?*

- a) *If no, why not?*
- b) *If not, shouldn't the authorities have passed this on after noticing it (phone 1450 is a medical consultation, BMSGPK, AGES, ...)?*

c) How many vaccination breakthroughs have there been in Austria and how many of them have been reported to the BASG?

Vaccination breakthroughs relevant for Austria are recorded by the Institute for Infection Epidemiology of AGES, which forwards all data to the BASG.

Concerning the evaluations becomes on the following information page referenced:
<https://www.ages.at/mensch/medizin/gesundheitsgerer-von-a-bisz/coronavirus#c12444>

d) What are the consequences if a person who has the legal obligation to report the lack of effect of a medicine repeatedly fails to do so?

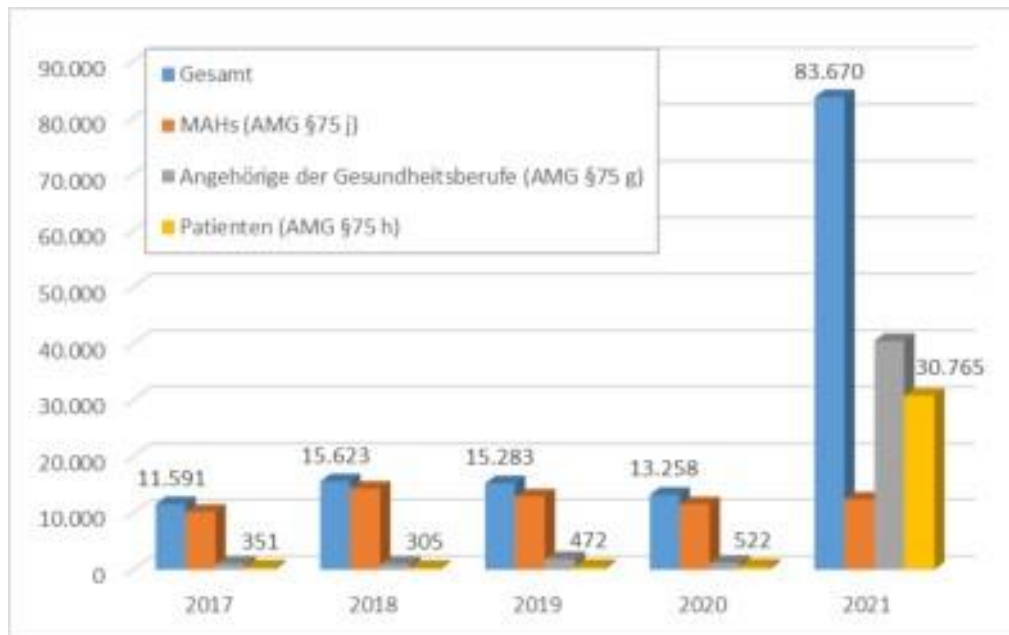
The relevant sanction standard can be found in § 83 para. 1 no. 14 of the Medicines Act, according to which the person who violates their reporting obligation pursuant to §§ 75g (75n or 75q) if the act does not constitute a criminal offense falling within the jurisdiction of the courts is guilty of an administrative offense and is to be punished with a fine of up to 7,500 euros, or up to 14,000 euros in the event of a recurrence.

e) If authorities gain knowledge that the reports to the BASG are not made (the published vaccine breakthroughs are not reflected in the statistics of side effects) and do not react, is this an abuse of office?

My department is not responsible for interpreting criminal law norms.

Question 19:*In how many cases were medical staff reported side effects of the corona vaccinations to the BASG?*

Total reports, broken down by reporter.



Question 20: *In how many cases were side effects of the corona vaccinations reported to the BASG by people who are not subject to reporting?*

See the answer to question 19.

Questions 21 and 22:

- In how many cases did the medical staff report the lack of effects of the corona vaccination to the BASG?*
- In how many cases was the absence of the effects of the corona vaccination reported to the BASG by people who are not required to report?*


See answer to question 18.

Question 23: *How often has it happened that a possible side effect of a corona vaccine was reported by medical staff and at the same time by other people?*

There is no numerical recording in this regard. If a message is recognized as a duplicate, the information is merged.

Kind regards

John Rauch

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