

John Rauch
federal minister

Mr

Mag. Wolfgang Sobotka
President of the National Council

houses of Parliament

1017 Vienna

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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).

The function of the information is to protect the freedom of choice of the person concerned. The person to be enlightened should be given the information he or she needs to understand the nature, meaning and scope of a medical measure to record. Information about the benefits and risks should therefore be included in the Extent to be given to the data subject decision-making assistance needed.

Furthermore, in connection with COVID-19 vaccines, reference may be made to the recommendations of the National Vaccination Committee, which can be accessed 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) not sufficient

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 administrative and/or disciplinary be punished as well as result in legal liability consequences.

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 DFP training courses of which were specifically related to the topic "COVID 19 vaccinations" dedicated.

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

Doctors and organizes the annual Austrian Vaccination Day, which in the last two years was also dedicated to 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 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:

- *Before being vaccinated with the corona vaccines, were all patients informed about alternative Possibilities and treatment methods informed?* •
What have you done to ensure that as many as possible Suspected cases of vaccination damage are reported to BASG?
- *What have you done to ensure that as many as possible Suspected cases of vaccination damage 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 as possible Suspected cases of vaccine damage reach the public and public to be discussed?*

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, in accordance with the recommendations and the status of the science work.

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. § 4 of the PhVO 2013 stipulates that suspected side effects of medicinal products for human use are to be reported. The notification must be made to the Federal Office for Safety in Health Care (BASG). Doctors, pharmacists and other health professionals are required by law to report. Additionally

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

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 are.

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

There is no explicit legal obligation to “assess vaccination status”. 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 the BASG immediately in accordance with the regulation according to § 75a AMG to report.

Questions 9 and 13:

- *What information or training is there for vaccinating doctors so that they can avoid possible side effects (suspected cases) of corona vaccinations document exactly and report to BASG?***
- *What information or training is available for vaccinating doctors, so that they report a 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, there is a balanced presentation of the content in these training courses with appropriate information on documentation and reporting to assume side effects or lack of effect.

After a legal obligation to report suspected side effects for relatives of Health professionals in connection with the use of vaccines as with all other medicines, I can assume that relatives of Health professionals, according to their job responsibilities, know how to make a reports a suspected side effect of a drug.

In addition, my company points out the importance of both the Austrian vaccination plan and the information and documentation sheets on vaccinations in the Application recommendations, on the homepage of the Ministry of Social Affairs and in the communication materials on vaccinations.

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

Information on this is provided on the AGES website under 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) How long does it take to clarify a suspected side effect in the Average?

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

Medicines Agency (EMA). The data is also available to everyone else available to national medicines authorities and the European Medicines Agency 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. From the synopsis of Reports from all EU member states result in "signals" for relevant, hitherto unrecognized side effects. The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) analyzes all of them 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 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 informs all 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.

Question 16: Does it happen in practice that physicians who fulfill their reporting obligation from have demonstrably disregarded drug side effects, be reported?

- a) If yes, how often did it happen in the last five years?**
- b) If yes, what were the penalties? c) If so, were there 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 received any notifications of violations of Section 83 Paragraph 1 Z 14 Medicinal Products Act carried out.

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 ensure that the remaining 94% also be 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?**

For example, the BASG draws attention to the reporting of side effects and the importance of this for the benefit-risk profile of drugs/vaccines in presentations to relevant specialist groups (hospitals, pharmacist conferences, BASG pharmacovigilance talks, etc.). BASG also regularly participates in #MedSafetyWeeks, a social media campaign to raise awareness intended to exacerbate undesirable drug effects.

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

- a) If no, why not?**
- b) If no, the authorities would not, after taking note (telephone 1450 is a medical consultation, BMSGPK, AGES, ...) have to forward this?**

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

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

With regard to the evaluations, reference is made to the following information page:
<https://www.ages.at/mensch/medizin/gesundheitserreger-von-a-bis/z/coronavirus#c12444>

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

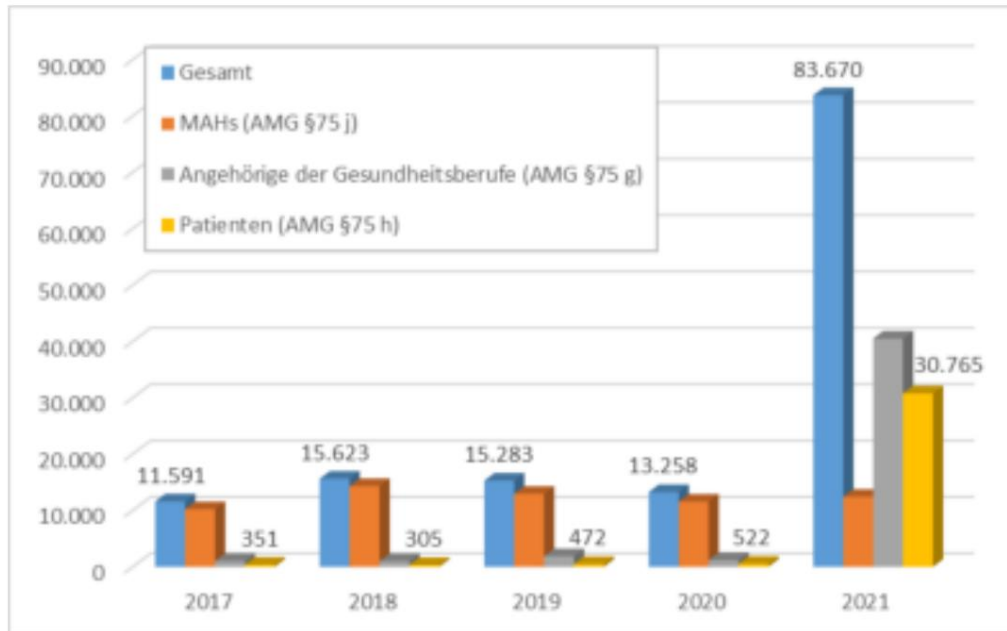
The relevant sanction standard can be found in § 83 para. 1 no. 14 of the Medicines Act, according to which the person who violates their reporting obligation pursuant to §§ 75g (75n or 75q) if the act does not constitute a criminal offense falling within the jurisdiction of the courts is guilty of an 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 vaccination breakthroughs can be found in the statistics of the Side effects not reflected) and not respond, it is a Abuse of office?

My department is not responsible for interpreting criminal law norms.

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

See the answer to question 19.

Questions 21 and 22:

- *In how many cases was the absence of the effects of the corona vaccination from medical staff reported to the BASG?*
- *In how many cases was the absence of the effects of the corona vaccination from Persons who are not subject to reporting reported to the BASG?*


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 by other people at the same time?*

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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