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**Amoxicillin-clavulanate prescribed in a patient with known penicillin allergy**

Амоксицилин-клавуланат прописан пацијенту са познатом алергијом на пеницилин

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## Amoxicillin-clavulanate prescribed in a patient with known penicillin allergy

### Амоксицилин-клавуланат прописан пацијенту са познатом алергијом на ПЕНИЦИЛИН

#### SUMMARY

**Introduction** Prescription of penicillin requires extra caution in order to avoid its administration in a person allergic to this antibiotic. We present a case of a patient allergic to penicillin, to whom a doctor prescribed this medicine by mistake.

**Case outline** An 18-year-old female patient turned to an otolaryngologist because of a sore throat, difficulty breathing, and light clogging in the left ear in the previous couple of days. The patient tolerated oral intake of only liquid foods. She reported frequent attacks of tonsillopharyngitis, and allergy to penicillin. Tonsillopharyngitis was established by a physical examination. The doctor prescribed oral therapy, including a penicillin-based antibiotic Augmentin® (amoxicillin + clavulanate potassium) 1000 mg 2x1 tablet for seven days. The pharmacist in the local pharmacy knew the patient and was aware of the fact that the girl was allergic to penicillin, so she did not take the prescribed penicillin-based remedy. In that way, an extremely serious professional medical error did not get essential features of a criminal act according to the Serbian Criminal Code.

**Conclusion** When prescribing antibiotics, it is necessary that the physician should be extremely careful not to prescribe a medicine for which there is a "cave" warning in medical documentation, because this error can become a ground for legal prosecution against doctor, as well as professional sanctioning.

**Key words:** penicillini, prescribing, alergi, alert

#### САЖЕТАК

**Увод** Прописивање пеницилина захтева додатну опрезност, како се не би издао рецепт или налог за инјекцију особи алергичној на овај антибиотик. Приказујемо случај болесника алергичног на пеницилин коме је лекар грешком прописао овај лек.

**Приказ болесника** Осамнаестогодишња пацијенткиња обратила се оториноларингологу због гушобоље, отежаног дисања и лаке запушености левог ува током претходна два дана. Толерисала је перорални унос само течне хране. Наводи честе атаке тонзилофарингитиса и алергију на пеницилин. Физикалним прегледом установљен је тонзилофарингитис. Лекар прописује пероралну терапију између осталог и пеницилински препарат Аугментин® (амоксицилин+клавуланска киселина) 1000 мг 2x1 тбл током седам дана. Фармацеут у локалној апотеци је познавао девојку, знао да је алергична на пеницилин, тако да није ни добила прописани пеницилински препарат. На тај начин изузетно озбиљна професионална медицинска грешка према Кривичном законiku Србије није добила суштинске карактеристике кривичног дела.

**Закључак** При прописивању антибиотика неопходна је изузетна пажња лекара да не препише лек за који у медицинској документацији постоји упозорење "cave", јер та грешка може постати основа за кривично гоњење лекара, као и професионално санкционисање.

**Кључне речи:** пеницилин, прописивање, алергија, упозорење

## INTRODUCTION

The number of antibiotics (AB) is large, and so are the expectations of their use. In contemporary clinical practice, however, problems have been identified relating to: the use of insufficiently tested AB, non-indicated use of AB, not prescribing AB in indicated cases, side effects of AB, inadequate combinations with other drugs, prescribing and administering AB to patients who are not allowed to take them because of sensitivity [1].

When assessing the contribution of AB to health, they are one of the most important groups of drugs: the introduction of ABs, especially of penicillin, is believed to have prolonged the life span of each inhabitant of our planet for 10 years [2]. As an AB of narrow spectrum, with proven efficacy and low cost, penicillin has always been and remains a drug of choice in

treating streptococcal tonsillopharyngitis. However, it requires extra caution in order to avoid its administration in a person allergic to this AB.

We present a case of a patient allergic to penicillin to whom a medical doctor prescribed this medicine, as an illustration of a serious medical error that has all elements of a potential criminal offence.

## CASE REPORT

An 18-year-old female patient was examined by an ENT (ear, nose, and throat) specialist for sore throat, difficulty breathing, and light clogging in the left ear in the previous couple of days. Due to pronounced pain when swallowing, the patient was able to tolerate only liquid foods and because of that she significantly reduced oral intake of food and liquid. The patient reported frequent attacks of acute tonsillopharyngitis, as well as allergy to pollen and penicillin, the latter being written down as a medical warning in the medical examination report of the ENT specialist: CAVE PENICILIN! (Figure 1.).

Physical examination showed: soft palate and mucous membranes were diffusely extremely hyperemic. Tonsils inflamed, moderately enlarged, juicy, pus negative. The other finding was unremarkable.

A penicillin-based AB Augmentin® (amoxicillin + clavulanate potassium) 1000 mg 2x1 tablet was prescribed for the following seven days. Lemod solu i.m. for five days, in reduction (80, 60, 40, 20, 20 mg). Tantum verde sol. 0.15% 150 ml to gargle several times a day. Brufen tablet 400 mg as needed.

The pharmacist in the local pharmacy knew the patient, and was aware of the fact that patient was allergic to penicillin, so the patient did not take the prescribed penicillin-based remedy. In that way, occurrence of potentially serious and even fatal allergic reactions to penicillin was avoided.

## DISCUSSION

AB treatment of the acute bacterial tonsillopharyngitis is recommended, as in the presented case, in patients with severe general condition and three or four Centor criteria (fever, tender cervical lymph nodes, coatings of the tonsils, and lack of cough) [3]. The drug of choice is penicillin. The phrase "cave penicillini" is commonly seen in medical notes and records. Up to 10% of the general population report a history of penicillin allergy [4], more frequently in females than in males [5]. Additionally, once an allergy is recorded in the medical chart, it will most likely remain there for the rest of the patient's life.

In hospital and outpatient medical examination of the patient, a subjective patient statement (anamnesis) is the main guideline in detecting a known allergy to penicillin [6]. A positive statement should, as with our patient, be supported by a medical warning written in the health booklet, medical records, and the physician's report stating "cave penicillini". According to the Australasian Society of Clinical Immunology and Allergy (ASCI), record details of allergy incident including drug name, description of reaction, severity, date, and name of the person making the report [7]. ASCIA recommendation protocols describes the different adverse reactions to the administration of penicillins, and categorizes ABs into red (contraindicated), orange (avoid in serious penicillin allergies), and green (safe) categories—a very useful reference tool. In patients with a history of clinical signs of life-threatening penicillin allergy (anaphylaxis, angioedema, laryngeal oedema, wheezing/bronchospasm, diffuse erythema, urticaria), penicillins, cephalosporins and other beta-lactam ABs should be avoided (Figure 2). In non-severe penicillin allergy (fever, vomiting, erythema, seizures, etc) cephalosporins and carbapenems can be used with caution. Some reactions (e.g. diarrhea, nausea) are not considered allergies and do not warrant prohibiting penicillin use [7].

Independently of the medical history, the current standards of good pharmaceutical practice also provide for taking a short "pharmaceutical anamnesis" from the patient [8]. By doing that, the pharmacist gets familiar with the patient's health and remembers those patients who are often ill and with verified allergies to drugs (in this case to penicillin). Pharmaceutical healthcare [9,10] involves co-operation of pharmacists with the patient and other healthcare professionals when issuing drugs, with the aim of achieving appropriate results and improving patients' quality of life. As with most other drugs, serious practical medical problems can arise in the practical application of AB, which in certain cases may raise a question about potential criminal responsibility of doctors due to mistakes and low conscientiousness at work [11].

Negligent work of a doctor does not necessarily cause deterioration in patient's condition in all cases. According to the Article 251 of the Criminal Code of the Republic of Serbia (CCRS) [12], a necessary condition for the existence of a criminal offence is that a detrimental effect occurs in the form of deterioration of the health status of a person due to negligent provision of medical aid (NPMA), including use of the obviously inappropriate therapeutic agent.

Did the doctor commit a NPMA criminal offence by prescribing Augmentin® in this case? The pharmacist working in the local pharmacy knew the patient who came to take the prescribed medicine, and she was aware of the fact that the patient was allergic to penicillin. Therefore, the pharmacist warned her and did not issue her the prescribed medicine, so that this grave professional mistake of the doctor did not lead to harmful consequences in the form of deterioration of the patient's health.

According to the Article 251 of the CCRS [12], there is no conviction without harmful effect of the physician's negligent treatment, which practically means that if a doctor obviously behaves negligently and makes a serious professional mistake, but that does not lead to deterioration of the patient's health, there is no criminal offence. In the presented case the ENT specialist, who made a serious professional error proscribing the penicillin to the allergic patient, avoided a legal accusation and a sentence owing to the appropriate procedure of the pharmacist.

What were the possible scenarios under the Criminal Code in the reported case? If penicillin is administered to a patient said to be allergic without producing subsequent allergic reaction there will be no grounds for criminal responsibility of treating doctor. If urticaria occurs, as a slight form of health deterioration, the sentence is up to 3 years in prison (YP); life threatening edema of larynx - up to 8 YP; and for anaphylactic shock with lethal outcome - up to 12 YP (severe and fatal forms of health deterioration are included in the Artical 259 of the CCRS, named "Severe acts against health of the people"). Furthermore, in cases with definitely confirmed court sentence for severe acts against health of the people (Artical 259 of the CCRS) [11], the Medical Chamber of Serbia immediately permanently take away the medical licence to the sentenced physician.

The presented case is very interesting as an illustration of a serious medical error that has all features of a potential criminal offence, except the last one, and that is a harmful

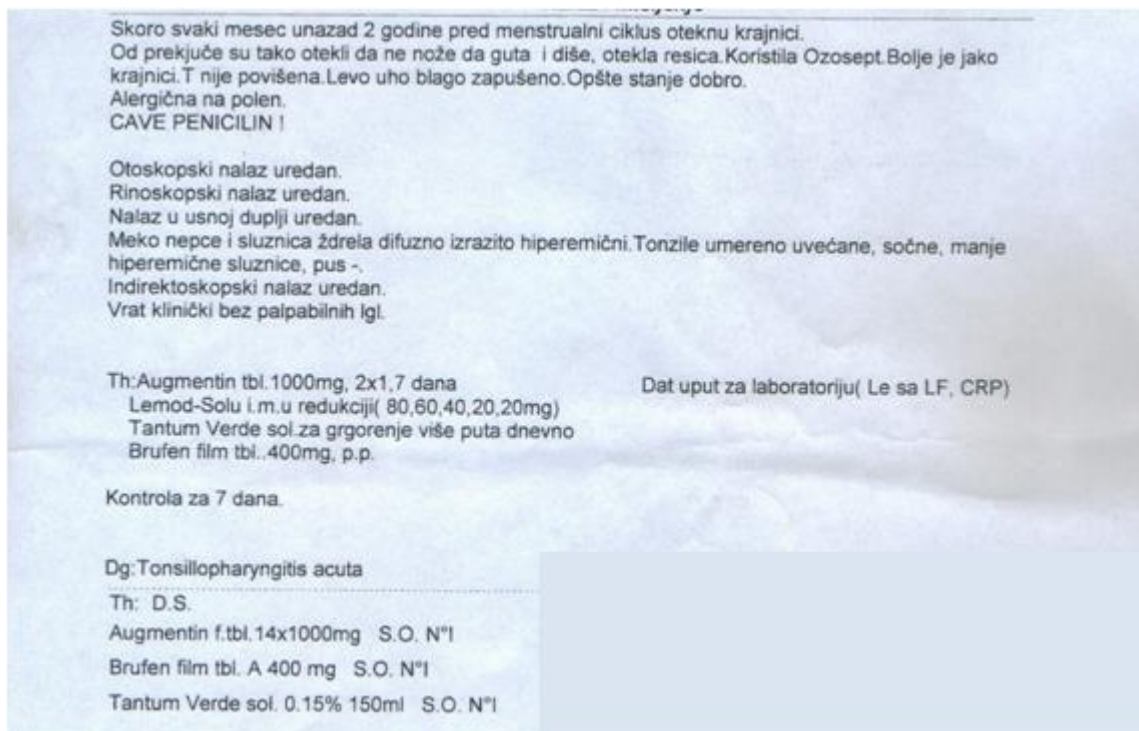
consequence in the form of deterioration in the patient's health status, which in this case, by pure chance, did not arise thanks to the pharmacist. Nevertheless, the doctor's practice was a serious professional failure. Therefore, when prescribing AB, it is necessary that the physician should be extremely careful not to prescribe a medicine for which there is a "*cave*" warning in medical documentation.

**Informed consent statement:** Consent was obtained from the patients for publication of this report and any accompanying images.

**Conflict of interest:** None declared

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**Figure 1.** The medical examination report with medical warning CAVE PENICILIN!





Figure 2. Penicillin allergy [7]