

CORRESPONDENCE

**Take Home Maintenance Medication in Opiate Dependence**

by Dr. med. Stefan Gutwinski, Lena Karoline Bald, Prof. Dr. med. Andreas Heinz, Dr. med. Christian A. Müller, Ane Katrin Schmidt, Corinde Wiers, Prof. Dr. med. Felix Bempohl, Prof. Dr. med. Jürgen Gallinat in volume 23–24/2013

**Dispensing Maintenance Medication to Take Home not Allowed**

Providing take home maintenance medication is strictly not allowed! The cited guidelines from the German Medical Association (*Bundesärztekammer*) (Item 9, *Verschreibung zur eigenverantwortlichen Einnahme des Substitutionsmittels* [Prescribing for the purposes of the patient taking substitution medication under their own responsibility] regulate take-home prescriptions. The German Medical Association’s guidelines are very clear that providing substitution drugs from the practice’s own dispensary is prosecutable.

Giving maintenance medication to take home furthermore constitutes an infringement of §43 of the German Drug Act, which establishes the monopoly of pharmacies in this context. In the German Narcotics Law, §29 categorizes the provision of narcotics as “unauthorized circulation of a narcotic drug” and a criminal offense (see also the judgment of the Administrative Court in Cologne of 24 April 2012, reference number: 7 K 7253/10).

The substituting physician is only allowed to dispense a take-home prescription (if the patient is allowed and able to “take home”) to the patient in person, but never the substitute drug itself. The terminology “take home” prescription has often led to misunderstandings in this respect.

DOI: 10.3238/arztebl.2013.0688a

**REFERENCES**

1. Gutwinski S, Bald LK, Heinz A, Müller CA, Schmidt AK, Wiers C, Bempohl F, Gallinat J: Take home maintenance medication in opiate dependence. *Dtsch Arztebl Int* 2013; 110(23–24): 405–12.

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**Not Registered**

The article caused irritation. From the first line, or even in the title, the term “Mitgabe”—i.e. issuing, or dispensing—is used. This implies a hospital or surgery’s dispensing a substitute drug to be taken by the patient under his/her own responsibility. This is not provided for within the Narcotic Drugs Prescription Ordinance (*Betäubungsmittel-Verschreibungsverordnung, BtMVV*) (§ 5) and therefore not permitted within the framework of the German law governing the prescription of medicines.

The guideline of the German Medical Association dated 19 February 2010, No 9, 3rd sentence, is (suggest, for clarity’s sake: “also”) unequivocal: “Eine Mitgabe von Substitutionsmitteln aus dem Praxisbestand ist hingegen strafbar [providing substitution medication from the practice’s own dispensary is a punishable offense].”

Furthermore the authors report that patients from 20 psychiatric hospitals participated in their study. Providing take home medication from the hospital’s dispensary is legally not permitted, and professional and ethical regulatory guidelines naturally also apply to the inpatient setting.

Regarding the methods, the authors wrote: “5032 patients were registered at the Berlin Medical Association as being on maintenance treatment.”

According to § 5a section 2 of the German Narcotics Law, any doctor prescribing substitution medication is under obligation to report immediately the start and end date of every case of substitution treatment in coded form to the substitution registry held at the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*) in Bonn.

Ignoring this rule is a regulatory offense under §17 of the narcotics law. On the basis of this obligation, the BfArM is able to determine the number of registered cases of substitution treatment at federal and state levels.

Hence none of the 5032 described patients are registered with a medical association. The deficiencies described unfortunately limit the value of the overall conclusion. Further remarks are unfortunately not possible in view of the space restrictions imposed by *Deutsches Ärzteblatt’s* instructions for authors.

DOI: 10.3238/arztebl.2013.0688b

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**In Reply:**

We understand the worries expressed by our colleagues, that the term of take home maintenance medication may imply that the substances come from practices’ own dispensaries. We welcome the opportunity to explain potentially misleading phrases. Our study relates to the only legal form of take home substitution treatment—namely, that of taking home maintenance medication from the pharmacy after presenting a

doctor's prescription. For this reason we did not mention any "take home maintenance medication from a practice's dispensary. If we reported the fact that a proportion of patients were "recruited" from a hospital, the "take home maintenance medication" relates to the outpatient treatment these patients received before entering hospital (1).

The legal situation that our correspondents thankfully clarified in their contributions was previously the topic of a comprehensive article by Rainer Ullmann, also reported in *Deutsches Ärzteblatt* (2), which we cited in our article, pointing out "current German law." Like ourselves, Ullman used the German term "Mitgabe [giving someone something to take with them]" rather than the English term "take home" prescription. These terms are used as equivalents in the literature (2, 3), and for this reason, we wrote that this approach is known as "take home" dispensing (1). We explicitly agree with Ms Piekoschowski, that the English term "take home" is misleading when combined with the terms "prescription/daily dispensing", because it creates the impression that they relate to two different approaches. For this reason too, the term 'take home maintenance medication' is consistently used in our article consistently, in order to outline its legal status.

You pointed out the registration of substitute medication with the BfArM. The number of 5032 patients receiving substitute medication, as reported in our article, refers to the response from Berlin's Association of

Statutory Health Insurance Physicians (*Kassenärztliche Vereinigung Berlin, KV-Berlin*), which communicated to us on 23 September 2011 that at that moment, "5032 patients" were registered as receiving substitute medication. We assume that the data from BfArM and KV-Berlin are identical. We regret having written erroneously in our article that these patients were registered with a medical association, instead of with the "KV-Berlin." DOI: 10.3238/arztebl.2013.0688c

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#### Conflict of interest statement

The authors of all contributions declare that no conflict of interest exists.