Pharma Flash

November 2018

The ePrescription System: Draft amending the Act on Medicines is under discussion in the Parliament

*In response to the current regulation on mandatory electronic prescriptions, the Ministry of Health drafted an amendment[1] to the Act on Medicines[2]. The amendment primarily aims to create a legislative basis for the electronic prescription information system (the "**ePrescription System**") and to regulate patients' medicine records, thus enabling physicians and pharmacists, among other persons, to inspect data in the system in connection with medicines prescribed and dispensed to patients. Apart from that, the draft also introduces other changes, such as the specification of price as a mandatory identifier of medicines, broader authorisation of pharmacy assistants, and new sanctions reflecting the proposed adjustments.*

Need for an amendment

The existing Act on Medicines only allows for issuing electronic prescriptions and dispensing prescribed medicines, but it does not address the technical details of the electronic prescription and the possibility to use in any way the data contained within the system on prescribed and dispensed medicines when providing health services to individual patients.

In response to the existing situation, the Ministry of Health drafted an amendment introducing a number of changes connected as well as unconnected with the valid and effective mandatory e-prescription regulations.

The draft amendment has already gone through the comment procedure in individual ministries and other relevant bodies, and on 10 October 2018, the government submitted it to the Chamber of Deputies[3]. Provided the proposed wording is passed, in the best-case scenario, the draft is expected to come into effect on 1 January 2019. Given the lengthy law-making process, the date of effect will probably have to be postponed.

ePrescription System and the role of the State Institute for Drug Control

The draft amendment lays down the ePrescription System, an information system enabling and supporting electronic prescriptions for medicines. The founder, operator and administrator of the eRecept system is going to be the State Institute for Drug Control[4], according to the amendment.[5]

The actual ePrescription System is to comprise a range of components, namely (a) a central depositary of e-prescriptions, (b) a registry of medicines with restrictions, (c) a medicine record, (d) administration of consents, (e) an activity log, (f) web and mobile app services for physicians, pharmacists and patients, and (g) services providing statistical data from an anonymised database kept within the ePrescription System, containing data that does not enable the identification of the specific individual.

Patient's medicine record

The medicine record is part of the ePrescription System and enables not only patients (or their legal representatives), but also physicians, pharmacists and other persons defined by law to inspect certain data kept in the system in connection with prescribing and dispensing medicines to individual patients.

Physicians and pharmacists

Physicians and pharmacists may inspect patients' medicine records only in connection with providing health services to individual patients.[6] For this purpose, information in patients' medicine records will be accessible for a period of 1 year, and it will be possible to ascertain data on prescribed medicines as well as to identify physicians or pharmacists. It will also be possible to determine generic substitutes for medicines prescribed.

Physicians and pharmacists will no longer have to rely solely on information provided by their patients, which could in turn lead to enhanced selection of suitable treatment, prevention of contraindications and the overall improvement of the health services provided[7].

Digitalisation of paper prescriptions

To ensure that the patients' medicine records contain comprehensive information, the amendment imposes a duty upon pharmacists to transfer data from paper prescriptions to electronic prescriptions. Data from the paper prescription will appear in the patients' medicine records, and the file will thus be complete. The date of effect of the digitalisation provisions will be postponed until 1 January 2020.

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1 *Chamber document no. 302/0 sent to MPs, available at: http://www.psp.cz/sqw/historie.sqw?o=8&T=302.*
2 *Act no. 378/2007 Sb., on medicines and amendments to certain acts (the Act on Medicines), as amended.*
3 *Currently, the Chamber of Deputies is discussing a draft amendment to the Act on Medicines regarding the protection against forgery (protective features).*
4 *The State Institute for Drug Control is the Czech regulator of the pharmaceutical industry.*
5 *The original narrowly defined authorisation concerning merely a central depository of e-prescriptions is thus replaced.*
6 *Physicians may do so only for the specified purpose relating to the prescription of medicines and only those physicians with some relation to the patient, such as treating physicians. Pharmacists may do so only when dispensing prescribed medicines for the purpose of checking the suitability of the medicine dispensed or for the purpose of a consultation with the patient upon request.*
7 *Under the existing regulation, physicians are allowed to inspect records only regarding medicines that the physicians themselves have prescribed; pharmacists may only check medicines on simultaneously presented prescriptions.*

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The Ministry of Health has submitted a draft amendment to the Act on Medicines which aims to better reflect the technical solutions of e-prescriptions. One of the key changes involved is the fact that physicians and pharmacists will be allowed to inspect individual patients' data regarding prescriptions and dispense medicines in the ePrescription System provided the patient has not opted out from this permission. Another proposed change is the possibility of patients to obtain information not only regarding their data but also on the access of other entitled persons to their data contained in the ePrescription System. This, however, is merely a draft, which the Chamber of Deputies discussed at the first reading on 2 November 2018 and which is yet to be discussed by competent committees. The proposed date of effect of the amendment is 1 January 2019, which, however, will have to be postponed.

Consent

The draft amendment implies that patients automatically give their consent to physicians' and pharmacists' inspection of data displayed in patients' medicine records (*opt-out principle*). Nevertheless, patients may opt out from this general consent or give their consent only to selected physicians or pharmacists.

Activity log

In medicine records, patients may inspect not only their data displayed to physicians and pharmacists but also all data relating to them including the activity log. The log displays and maintains information on all activities performed by entities registered in the eRecept system. Patients may also find out who viewed their data.

Additional changes

The amendment also introduces other changes besides those mentioned above. These include namely the transfer of the provision laying down exemptions from the duty to issue e-prescriptions and essential elements of e-prescriptions[8] to the wording of the Act on Medicines; moreover, the prescription of medicines for veterinary care will be regulated in a separate regulation.

Last but not least, the amendment introduces changes that do not directly relate to e-prescriptions. These include namely a broader authorisation for pharmacy assistants who can dispense medicines upon request and broader mandatory identifiers of medicines, which already include codes and names allocated by the State Institute for Drug Control and will also include the price of the medicine under the amendment. This will namely affect the marketing authorisation holders, distributors and pharmacies.

In relation to the envisaged changes, the amendment also contains new sanctions (e.g. up to CZK 20 million in relation to the information system data protection) and a proposal for a change in the authorisation of bodies in charge of offences linked to the forgery and other abuse of medical prescriptions. The amendment proposes the State Institute for Drug Control as the authority in charge.

Conclusion

Despite being a mere draft, the amendment proposes a number of changes that will have an impact on the majority of entities in the pharmaceutical market. Entities affected will include information system suppliers and health service providers in connection with the changes necessary to ensure compatibility of information systems.

To conclude, it is worth pointing out that the Act on Medicines is not the only regulation that will undergo changes in connection with e-prescriptions. The explanatory report relating to the amendment has already envisaged changes in the related implementing decrees which will lead to other changes in the industry.

[8] *Existing exemptions are laid down in Decree No. 415/2017 Sb.*

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