Pharma Flash

January 2019

New reimbursement regulation for consumer medical devices

*On 1 January 2019, the amendment to the General Health Insurance Act[1] came into effect, introducing a **new system of reimbursements for medical devices used during outpatient care, i.e. consumer medical devices**. The amendment covers consumer medical devices that are prescribed on a **prescription** and that patients pick up in pharmacies or at dispensing sites, e.g. glucose meters or other diabetic aids, orthoses, wheelchairs, crutches, hearing aids, glasses, contact lenses or incontinence pads.*

The amendment was drafted in response to the 2017 judgement of the Constitutional Court, which declared the hitherto reimbursement regulation of consumer medical devices – which was based on code listings issued by health insurance companies – unconstitutional and repealed it as of 31 December 2018[2]. The lawmakers were thus under pressure to quickly adopt a new regulation complying with the Constitution.

The elementary principles underlying the new reimbursement regulation are as follows:

- The new regulation **only** applies to medical devices **prescribed** as part of **outpatient care**.
- **It does not apply to** the reimbursement of medical devices provided for inpatient care[3], i.e. **hospital medical devices** – so-called **separately billed material** (e.g. implants, cardio stimulators, valves, cannulas, catheters, probes, staplers, devices for laparoscopy or stents).
- The **State Institute for Drug Control ("SUKL")** will act as the regulating body while the **Ministry of Health** will act as the appellate body.
- Individual types of medical devices are divided into **reimbursement categories**, listed in Appendix 3 to the General Health Insurance Act (the so-called categorization tree). The Act itself lays down a reimbursement limit as well as other reimbursement conditions (prescription and indication restrictions) for each category. The reimbursement limit for the category of glucose meters, for instance, is set at CZK 435 per piece (excl. VAT), and this category is also subject to prescription, indication and volume restrictions.
- The reimbursement category is the cornerstone of the new reimbursement regulation. In principle, each specific medical device should be classified under one of the reimbursement categories.
- The new reimbursement regulation is based on the **notification principle**. Individual medical devices will not be classified by administrative decisions issued in formal proceedings. Instead, the **manufacturers themselves will notify SUKL of the classification of their medical device in a given reimbursement category**.
- Only in the event SUKL discovers – either on its own or as a result of a complaint lodged by a health insurance company or a competitor – that the manufacturer classified the device incorrectly will it open formal administrative proceedings for the failure to place the medical device in the appropriate reimbursement category. If SUKL fails to open proceedings within the statutory deadline, the medical device will be automatically classified in the reimbursement category as notified by the manufacturer. Even then SUKL can still decide, based on statutory grounds, to declassify the device from the reimbursement category.
- Manufacturers will be able to file their notifications **only starting from 1 June 2019**. However, unless the manufacturers manage to fulfil the notification duty as regards the currently reimbursed medical devices **by 30 June 2019**, these "historically" reimbursed medical devices will **no longer be reimbursed** as of 1 August 2019.

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[1] *Act No. 282/2018 Sb., amending Act No. 48/1997 Sb., on General Health Insurance and amendments to and supplementation of certain related acts, as amended.*
[2] *See Judgement of the Constitutional Court Ref. No. Pl. ÚS 3/15 of 30 May 2017.*
[3] *See Section 15(5) of the General Health Insurance Act, which is not affected by the amendment.*

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- The "historically" reimbursed medical devices notified in a timely manner will start to be reimbursed pursuant to the new legal regulation as of 1 December 2019.

- Medical devices that will be entered in the reimbursement system for the first time and duly notified already in June 2019 will be reimbursed from 1 October 2019.

- **Unclassified medical devices** that cannot be placed in any reimbursement category will be reimbursed only if **approved by the Ministry of Health**; the reimbursement limit will amount to 50% of the final price. If, however, the manufacturer enters into **risk-sharing agreements** with all health insurance companies, the reimbursement limit will amount to 100%, so the medical device will be fully reimbursed.

- **Custom-made medical devices** are governed by a special regime and do not have to be notified[4]. No transitional period applies to these devices and the new reimbursement regulation is, as opposed to serially manufactured medical devices, applicable already from 1 January 2019.

- The Act expressly regulates **highest price agreements** made between the manufacturer and insurance companies and **price competitions**.

- Detailed rules are set out with regards to the so-called **circulation** regime, under which a health insurance company remains the owner of the medical device that is provided to the patient for use.

- The types of medical devices that may be distributed by **contractual dispensing sites** are specified in detail. According to the explanatory memorandum, the aim of the lawmakers was to eliminate the risk that the dispensing site would be supplying an entire range of medical devices[5]. The other types of medical devices may be dispensed only in standard pharmacies.

Needless to say, the above overview of the main features of the new reimbursement regulation is not exhaustive. Since this is a complex area posing numerous questions, we are organising a training session on this topic, and we will keep you posted on when it will take place.

The Ministry of Health, SUKL and the health insurance companies are cooperating in order to respond to questions regarding the reimbursement regulation and post their answers on the website of the Medical Device National Information System[6].

To conclude, we want to point out that the lawmakers have rather surprisingly not made any changes to the reimbursement regulation of hospital medical devices. In fact, the Constitutional Court has ruled that the reimbursement regulation of hospital medical devices – which is also based on code listings issued by health insurance companies – suffers from the same defects as the reimbursement regulation of consumer medical devices[7]. However, the Constitutional Court has not repealed it as it had not been proposed by the petitioners. It appears, therefore, that the rules governing reimbursement of hospital medical devices are awaiting their potential repeal by the Constitutional Court at a later time. Manufacturers and other stakeholders will have to get used to the fact that there is a **dual system of medical devices reimbursement in the Czech Republic** as there are completely different rules governing consumer versus hospital medical devices.

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[4] *See Table 2 in Appendix 3 of the General Health Insurance Act.*
[5] *See Document of the Chamber No. 199, Chamber of Deputies, 8th term, since 2017, available at: http://www.psp.cz/sqw/historie.sqw?o=8&T=199.*
[6] *See https://www.niszp.cz/cs.*
[7] *See points 143 and 150 of the cited judgement.*

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