Pharma Flash

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Updates in regulating medical devices reimbursement

*The Ministry of Health submitted a draft amendment to Act No 48/1997 Sb., on Public Health Insurance (the "**PHI Act**"), in response to the judgement of the Constitutional Court, ref. No. Pl. Ú S 3/15 of 30 May 2017 (the "**Judgement**") that repealed the regulation of reimbursement of prescription medical devices.*

Recap of the Judgement

In its Judgement, the Constitutional Court repealed the key provisions of the PHI Act governing the calculation of the payment for medical devices reimbursed from the public health insurance for out-patient services, which we covered in our Pharma Flash from June 2017 (available here). The Constitutional Court repealed the regulation of reimbursement of medical devices provided by prescription (e.g. incontinence pads, prosthetics, wheelchairs, hearing aids, glucometers and other aids for people with diabetes). The Court specifically repealed provisions stipulating that the insured are entitled to reimbursement of the most economical medical devices as determined by health insurance companies in a market survey.

The Ministry of Health has drafted an amendment to the Public Health Insurance Act. The bill reacts to the judgement of the Constitutional Court repealing, as of 1 January 2019, a section of the Act on the regulation of the reimbursement of prescription medical devices. Although the Constitutional Court noted that the regulation of reimbursement of medical devices used in hospital treatment (i.e. separately charged material) has the same defects, it did not repeal these provisions. The Ministry of Health failed to address this issue in its bill too.

As of 1 January 2019, Section C of Annex 3 of the PHI Act, containing the list of prescription medical devices reimbursed from the public health insurance, will therefore be virtually left blank. The aim of the proposed bill is to "ensure wide-ranging availability of fully reimbursed medical devices while minimising economic impacts on the public health insurance scheme", according to the explanatory notes.

Changes envisaged by the bill

If adopted, the bill will introduce changes in the classification of reimbursed prescription medical devices and in the method of classification.

The mentioned Annex 3 will undergo the most crucial changes – it will be fully replaced. The new table that will replace the existing list of medical devices reimbursed from the public health insurance for out-patient services features a total of 7 classifications:

- classification tree
- description
- prescription limitations
- indication restrictions
- volume restrictions
- financial cap
- reusability

The new table is more detailed and specific, which should lead to simpler and more exact classification of devices into reimbursement categories. It is noteworthy that as opposed to the existing regulation, the financial cap for the reimbursement is not set as a percentage with a maximum amount in CZK but instead as a maximum amount in CZK per unit (ml, g, cm^2).

We believe that specifically Annex 3 will be subject to an extensive debate and a number of adjustments during the law-making process before becoming final.

The classification method is also stipulated in great detail. The reimbursement of prescription medical devices will be based on the classification in the specific reimbursement category pursuant to Annex 3. The producer (or the authorised representative of a producer established in a third country, or a person authorised in writing by the producer or the authorised representative of the producer established in a third country), acting as the declarant, will electronically inform the State Institute for Drug Control ("**SIDC**") on the classification, deletion or change of the medical device in the reimbursement category, or a category of principally interchangeable medical devices within the reimbursement

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category, if created by the SIDC. The declarant may request an opinion on the classification from the SIDC.

The SIDC can also decide to delete a medical device from a reimbursement category, e.g. in the case where the medical device has been placed in a category to which it does not belong, given its functional characteristics or the designated purpose or use.

Medical devices and aids reimbursed as at 31 December 2017 will be reimbursed starting from 1 January 2019 in the same amount as at 31 December 2017, until the date of publication of the new reimbursement amount. Medical devices reimbursed as at 31 December 2018, but not as at 31 December 2017, will be reimbursed starting from 1 January 2019 in the same amount as at 31 December 2018, until the date of publication of the new reimbursement amount.

For the sake of completeness, we should mention that the consultation stage has ended and the bill is currently back with the Ministry of Health. It is expected to be submitted to the government's law-making council work groups, then to the government itself. In the best-case scenario, the first reading in the Chamber of Deputies could take place already this June.

Quo vadis, reimbursement regulation?

Interestingly, the Constitutional Court held that the regulation of reimbursement of medical devices used in hospital treatment (i.e. separately charged material) has the same defects as that relating to the reimbursement of prescription medical devices. Nonetheless, the Court did not repeal the provisions in question.

The bill submitted by the Ministry of Health therefore only addresses the changes in the area of prescription medical devices, not those used in hospital treatment. The question remains whether and when the regulation of the reimbursement of hospital medical devices will be amended.

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