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Technology in medical consumption articles – a dead end?

The high cost threshold system or public procurement

The Swedish pharmaceutical subsidy system is based on a high cost threshold system for consumer products such as prescription medicines sold to end consumers via pharmacies. The relatively generous system also includes some medical devices; certain consumption articles prescribed for self-care use are included, as these in practice for the patient are considered to fulfil a similar function to prescription medicines.

The rationale is that the high cost threshold system shall subsidy required self-care products, including consumption articles. Medical devices not deemed consumption articles shall instead be covered by publicly funding through procurement from hospitals and other health care institutions. As regards medical devices, the general idea is that the products will be publicly funded whether they are deemed consumption articles or not.

It is, however, not necessarily that easy; the difference between being deemed a consumption article or not makes a major difference for any manufacturer of a medical device for the Swedish market as it entirely shifts where the product is put to the market. A consumption article included in the high cost threshold system will be branded and marketed towards patients and their doctors, as the buying decision in fact is when the doctor prescribes the product in question. If the product instead is excluded from the high cost threshold system, then the product is required to pass a public procurement process in order to reach the market. As known, public procurement is a complex process that requires significant efforts to comply with all requirements while competition often is fierce. The relatively high number of appeals of the Dental and Pharmaceutical Benefits Agency's decisions regarding inclusion of consumption articles in the high cost threshold system indicates that the manufacturers are willing to fight to reach the consumption article market segment.

Real time diabetes monitoring device excluded from the high cost threshold system

Recently, a judgement by the Supreme Administrative Court surprised many as the court annulled the lower courts judgements and excluded a diabetes monitoring device from the high cost threshold system. The device, which enables continuous

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monitoring through transmitting of test results to a computer, was by the lower courts accepted as a consumption article. The Supreme Administrative Court, however, ruled that the cost of the device (approximately SEK 5,000), together with the extended life-span compared to regular insulin monitoring devices meant that the device could not be deemed a consumption article.

Reasons to be cautious when incorporating technology in consumption articles

One of the consequences of the case is that the inclusion of technology in previously low tech consumption articles may not be worthwhile for the manufacturers, if the result is that the product is excluded from the high cost threshold system. At a time when mobile and wireless technology is becoming cheaper and easier to incorporate in other products, this development is surprising. Whether the Supreme Administrative Courts interpretation of section 18 of the Pharmaceutical Subsidies Act is correct or not, in particular in relation to the purpose of the high cost threshold system may be discussed. What is more important though is the question whether the high cost threshold system should exclude devices that due to smart technology extend its life-span.

If the TLV continues to restrict such devices from the high cost threshold system based on the recent judgement, a review of the system may be appropriate. In any case, manufacturers of consumption articles should be aware of the potential side effects of upgrading devices with technology that may effectively exclude the device from the high cost threshold system.



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