

## The Netherlands

### Recent and planned changes in pharmaceutical pricing and reimbursement and overview of the medical devices system

P H A R M A C E U T I C A L S	<b>Changes in pricing</b>	<b>Changes in reimbursement</b>
	<p>Recently there have been no changes and no changes have been planned for the near future.</p>	<p>Recently there have been no changes and no changes have been planned for the near future.</p> <p>At the moment the reference price system(methodology)is being reviewed. The results of this review might have consequences for the reference price system. This is jet to be considered.</p>
	<b>Other changes related to medicines</b>	
	<p>The Netherlands has recently started using managed entry agreements (MEAs) as a tool for reducing uncertainties and risks of reimbursing innovative pharmaceuticals as well as to allow for (early) access. Currently MEAs are used both in the inpatient and outpatient settings and are distinctly different from the standard way of pricing and reimbursement of pharmaceuticals in the Netherlands. Of the MEAs used in the Netherlands, financially based agreements have been introduced since 2012 and so far eight pilots* have been set up and are currently running. These financial schemes are negotiated at a central level and are mostly price/volume agreements or comprise a confidential discount agreed with the manufacturer of the relevant pharmaceutical(s). This type of scheme is only used in exceptional circumstances, for example in situations where there is a lack of competition or in case of a high budget impact.</p> <p>*Pilots: omalizumab,dabigatran, rivaroxaban, apixaban, aglucosidase alfa, agalsidase alfa, agalsidase beta, ruxolitinib, pifafenidon</p>	
M E D I C A L D E V I C E S	<ul style="list-style-type: none"> <li>• <u>Competent authority:</u> The Ministry of Health, which is in charge of the overall Medical Devices policy and legislation, defines the reimbursement status of medical devices in the Dutch healthcare system. The Ministry of Health is advised by the National Health Care Institute (ZiNL, formerly CVZ) on the reimbursement status of medical devices.</li> </ul> <p>The NZa is the governmental supervisory body for both health care providers and insurers. NZa sets conditions for market forces to operate and enforces these conditions. Its main task is to monitor the public interests in health care: health care must remain accessible, of good quality and affordable for consumers.</p> <ul style="list-style-type: none"> <li>• <u>Price regulation:</u> There is no price regulation and manufacturers and wholesalers are free to set their purchase prices. The VAT for most of the medical devices is 6%, occasionally it is 21%.</li> <li>• <u>Reimbursement:</u> The legislation is a semi open reimbursement system based upon functioning problems. Medical devices are reimbursed if they meet the criteria used by the National Health Care Institute (ZiNL, formerly CVZ).These criteria are necessity, efficacy, cost-effectiveness and feasibility.</li> <li>• <u>Price sources/prices known:</u> The specific price per medical device is not known. There is however detail information about the total expenditure by Health Insurance companies on all reimbursed medical devices (GIP data)</li> </ul>	