Medical device assessment in Kazakhstan

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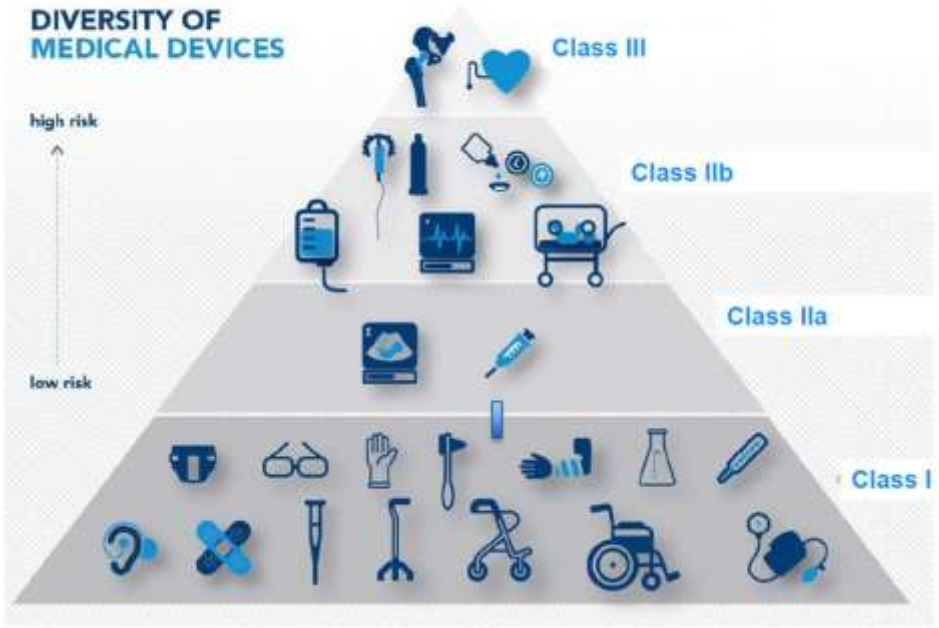
Background



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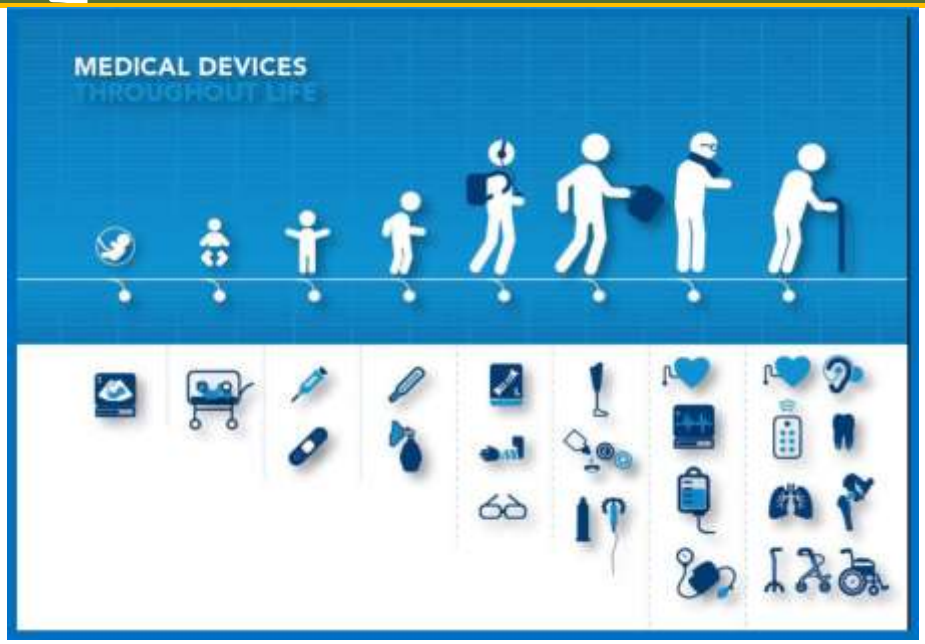

Specific challenges for evaluation of medical devices

- Manufacturers / vendors of new healthcare technology increasingly required to demonstrate value for money
- Early-stage decisions often performed under pressure
- Value to users and service providers often poorly established
- Medical devices typically brought to market at high risk, often by small companies
- Risk: Technical, Clinical, Commercial...

Regulation of Medical Devices in Kazakhstan

National Center of Expertise of Drugs, Medical Devices and Medical Equipment

- **Conducts assessment of safety and quality of devices (required for entry into the market)**
- **Sets reference pricing for devices that are purchased through public funds (state benefit package)**
- **Conducts assessment of marketing materials for devices**
- **Organizes the national nomenclature of devices harmonized with the Global Medical Device Nomenclature (in development) – currently includes 9689 devices**

Key Elements of Market Access for Medical Devices in Kazakhstan

Elements	Context	Kazakhstan
Health system	○ More than 70% expenditure on devices comes from public health system in the EU ○ Variations in Kazakhstan	○ Mixt state benefit package & statutory health insurance provided to all (17 million patients)
Hospital payment system	○ Heavy investments on medical devices are concentrated in the hospitals	○ Public sector: Capital and national budget distributed amongst regional/municipal bodies
Mechanism to support innovative devices?	○ Rather than routine HTA processes, additional routes are available for early access of innovative devices	○ No specific mechanisms available to support innovative high cost devices ○ However, greater adaptability in private sector as hospital need to be competitive (i.e., market mechanisms); greater resistance in public sector on new/expensive device uptake

Key elements of market access for medical devices in Kazakhstan

Elements	Context	Kazakhstan
Classification system	○ Devices are classified from a regulatory level into different grades based on level of risk and invasiveness	○ NCEDMDME registration (Class I, II, III)
Process of assessment for low risk devices (Classes I-II)	○ Not all devices are assessed by HTA; generic and low risk devices pass through simpler routes	○ Public sector: does not assess lower risk devices (i.e., Class I/II); however, some higher risk/ more novel Class I/II devices may still be subject to assessment ○ Private sector: mainly price orientated (i.e., will assess lower risk/Class I and II devices based on comparative price)
Process of assessment for high risk devices (Classes II-III for EU)	○ Devices are assessed by ○ various HTA bodies only under given circumstances	○ Public sector: Higher risk devices (primarily Classes III and IV) are assessed ○ Private sector: Novel/high risk devices assessed by individual hospitals

Key elements of market access for medical devices in Kazakhstan

Elements	Context	Kazakhstan
Assessment bodies (HTA)	○ Different bodies are involved in HTA assessment process of the devices	○ Public: NCEDMDDE or RCHD ○ Private: hospitals
Data requirements	○ Data requirements are not as transparent for medical devices as they are for pharmaceuticals ○ Very basic guidance is provided by HTA bodies	○ Public: Technical, clinical, economic data; ○ QoL data also considered; no QALY limits but there are standards and some health economic evidence is expected; ○ Private: economic data, but less robust and rigid process; should provide technical and clinical data also
Length of assessment	○ Assessment periods vary across different countries and sometimes may be much longer than given in the guidance	○ Public: 2-3 months ○ Private: as little as 1 months
Final decision	○ Final assessment decision may be made at the national/ regional level	○ MoH has 30 days to publish a final reimbursement deliberation; ○ Public: Ministry of Health (MoH)/Health Insurance Fund ○ Private: hospitals

Key elements of market access for medical devices in Kazakhstan

Elements	Context	Kazakhstan
Budget holders	○ Budget holders are responsible for final uptake of medical devices in hospitals	○ Public: Government; MoH will decide who should pay for the device E.g., very expensive novel technologies may be funded from the national budget, while all others funded by the state or municipality budgets ○ Private: hospitals
Pricing (inpatient devices only)	○ Pricing covered by various bodies can be split into ambulatory and hospital sector	○ Government (MoH, regions, municipalities depending on who pays for it) ○ Tendering/negotiating with manufacturer
Early scientific advice	○ Similar to pharmaceutical ○ sector, seeking early scientific advice is considered beneficial in countries where the possibility exists	○ Not available
Templates	○ Guidance templates are provided by national and regional bodies for submitting the required information for HTA assessment	○ Yes (guidance)

Key elements of market access for medical devices in Kazakhstan

Elements	Context	Kazakhstan
Stakeholders	○ Highly influential stakeholders in decision-making (i.e., scored 5 and 4)	○ Public: HTA, government departments ○ Private; hospitals
	○ Less influential stakeholders in decision making (i.e., scored 1-3)	○ Physicians in hospitals, ambulatory physicians, patients, nurses, and health economists ○ Pharmacists ○ Purchasing groups or national/regional procurement
Benefits	○ Advantages of the current procedures for the device manufacturers	○ If you can demonstrate that the product is clinically and economically effective, chances of successful reimbursement are high ○ Prices for medical devices are not controlled

Challenges in HTA of Medical Devices in Kazakhstan

- **Production of robust clinical and economic evidence;**

a good economic analysis needs local data whereas clinical data does not need to be local / foreign studies in reliable centers anywhere in the world are acceptable

- **Economic evaluation is very new in Kazakhstan, local data is scarce;**
- **Public health system is very ambitious; budget constraints are very important**

Trends in HTA of Medical Devices in Kazakhstan

- **Private segment will grow substantially - the population obtaining private insurance is growing, and with this the level of investment and access to new technologies willalso increase;**
- **MoH will introduce more medical devices for coverage; however, they will likely train medical societies and nurses to develop a network which will contribute to the decision making process;**
- **Continued investment in local production and incentives for Kazakh companies to produce locally;**
- **Robustness of technology evaluation will increase in private sector;**
- **Increased patient power/importance of patient organisations**