The legislation for the medical devices

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Sumary

- Multiple perspectives on the theme can be:

interests of the patient, managerial, regulatory.

- The regulatory framework in a general way:
  - Law on Health Protection
  - Statute of public healthcare institutions
  - Quality as founder of the medical and sanitary institutions
- The policies on medical devices (MD)
- The normative framework that governing the movement and use of medical devices
  - The current situation
  - The import of medical devices
  - The legislation for the medical devices
- Conclusion

The normative framework in a general way

- The legislation adopted over piecemeal time and without a clear understanding of the aims that are pursued– 20 laws.
- Irrelevant considerations that are relied.
- It was not constituted a logical frame and general functional which describes the structure and correlations.
- The health legislation is broken and incoherent.

The law on Health Protection

- Adopted at the 28.03.1995 has been amended 22 times.
- It does not define the structure of the health system as required by art. 36 of the Constitution.
- It not explain the basic elements(for example medical assistance, family medicine, etc., types of medical care).
- It contains contradictions with other laws.

The statute of public medical and sanitary institutions

- It not defined what is PMSI as a legal form.
- The quality as founder of the PMSI of the District Councils – contradiction with the legislation that governing local government activity.
- The Government Decision on charges for health services approved by the no. 1020 of 29.12.2011 (p.4 Annex 2).
- MD Acquisition from founder account.

The policies on medical devices

- There isn’t a policy document which would refer separately to MD.
- Only a few very general provisions likely would have some relevance.
- The National Health Policy, HG no. 886 of 06.08.2007.
- The strategy of development of the health system in the period 2008 - 2017, HG no. 1471 from 24.12.2007 (Annex action plan).

The normative framework regarding the circulation and use of MD

The law no. 411 at art. 54 prevides

"the activities related to medical devices are regulated by law" and

"the promotion activities related to medical devices is provided by specialized structure of the Ministry of Health".

Regulatory framework, the current situation

- The law on medical devices has not entered into force.
- Practically the only special law is Regulation establishing the conditions for placing on the market and use of medical devices, approved by Government Decision no. 96 of 21.01.2007.
- The copy adapted to European Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Regulatory framework, the current situation (Regulation)

- It provides a number of functions for MOH. How many were made?!
- The MOH is only as body control and monitoring circuit medical devices in relation to their safety. It not refer to policy.
- A string of functions for MOH relating to cooperation with the European Union (reporting).

The import of the medicine devices

- Basic Act is the Regulation on how licensing for import and export of goods approved by GD nr.777 of 13.08.1997.
- MOH has not approved some procedures in this regard. There are no set assessment criterias of applications for authorization.
- It should be noted separately Order no. 86 of 31.03.2009.
- The Diagnostic Center is "transformed" in the public authority (regulation and control)!

The Law on the Medical Devices

- Enters into force on 20.01.2013
- For the law to work it is need for the Government to adopt a series of measures aimed at:
  - Creating Medicines and Medical Devices Agency, art. 7 item 2).
  - Creating "Medical Devices Committee" art. 8.
  - Conformity assessment procedures of medical devices which transpose European directives applicable to medical devices, art. 4 item 2).
  - Procedures for monitoring and verifying the results of the management of medical devices that is applied for Medicines and Medical Devices Agency, art. 7 alin. 1) lit. f).
  - The criteria on designation and notification of conformity assessment bodies medical devices, art. 12, letter a).
  - Regulations on testing devices that are intended for clinical investigations, art. 17.
  - The medical device vigilance procedure, art. 21 item 3.

The Law on the Medical Devices (further)

- Besides Government other public authorities have obligations that arising from the law.
- The law reproduce vague provisions of the Regulation.
- The law suffer in terms of clarity, coherence and eloquence.
- There are contradictions : Newly created agency will have the authority and control tasks and the task of supplying PMSI with MD- conflict of interest.

The Law on the Medical Devices (further)

- The institutionalization will require coordinated effort of several public authorities - difficult.
- A dearth of specialists.
- Gaps and contradictions in the law.
- Annex. What is the purpose of classification?

Conclusion

- PMSI statute is unclear.
- Impossibility to use means from insurance to finance MD.
- Entry into force of the law will not change the situation PMSI financing
- It takes a number of operational regulations.
- The main element, ensure the functionality of existing MD remain unknown.

Thank you for attention!

- Questions.