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The EU HTA Regulation and the Italian HTA for Medical Devices Plan 2023-2025

ISPOR Europe 2023

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Improving healthcare decisions

EU Health Technology Assessment Regulation 2021/2282

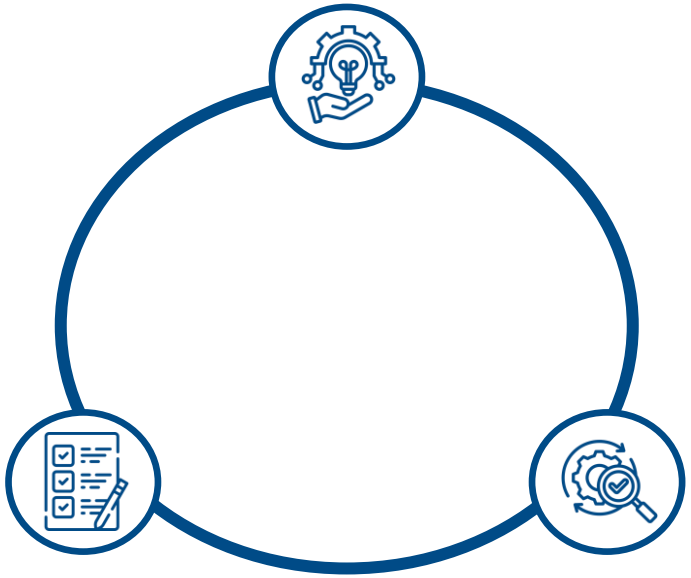
Medical Device Regulation 2017/745

Italian Health Technology Assessment Plan for Medical Devices 2023-2025

Italian Medical Device Payback actual situation

EU Health Technology Assessment Regulation 2021/2282

The development of health technologies is a key driver of economic growth and innovation in the EU area.



HTA processes include multi-dimensional and multi-disciplinary activities to analyze the clinical, social, organizational, economic, ethical and legal implications of a health technology.

Scientific evidence-based process that allows authorities to determine the relative effectiveness of new or existing health technologies. Focus on the added value of a health technology in comparison with other new or existing ones.

Targets

Scientific evidence as a driver to guide decisions on economic resource allocation in health care.

Achieve a high level of patient safety providing a well-functioning internal market.

Facilitate Company's documentation submission for assessment evaluation.

Promote collaboration among member states to facilitate market access and early availability of health technologies for patients.

Joint evaluations criteria should be inclusive and reflect the needs of all member states.

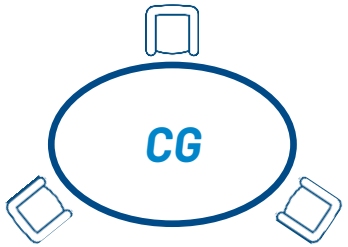
REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU

EU Health Technology Assessment Regulation 2021/2282

Coordination Group

Member States shall designate their members of the Coordination Group.

Coordination Group meetings shall be chaired and co-chaired by two elected members from the Coordination Group.



The members of the Coordination Group shall designate their national or regional authorities as members of subgroups.

Coordination Group Activities

- Joint Clinical Assessment
- Joint Scientific Consultation
- Identification of emerging health technologies;
- Development of methodological and procedural guidance

EU Health Technology Assessment Regulation 2021/2282

Joint Clinical Assessment

Health technologies involved in Joint Clinical Assessments

MEDICINAL PRODUCTS

MEDICAL DEVICE

IN-VITRO DIAGNOSTIC MEDICAL DEVICE

12 January 2025

CANCER & ADVANCED THERAPIES

After 12 January 2025

MEDICAL DEVICE

IN-VITRO DIAGNOSTIC MEDICAL DEVICE

13 January 2028

ORPHAN DRUGS

13 January 2030

ALL MEDICINAL PRODUCTS

Selected for Joint Clinical Assessment based on one or more of the following criteria:

- unmet medical needs
- first in class
- potential impact on patients, public health or healthcare systems
- incorporation of software using artificial intelligence, machine learning technologies or algorithms
- significant cross-border dimension
- major Union-wide added value.

Medical Device Regulation 2017/745 – *News & Objectives*

Post-market surveillance and vigilance

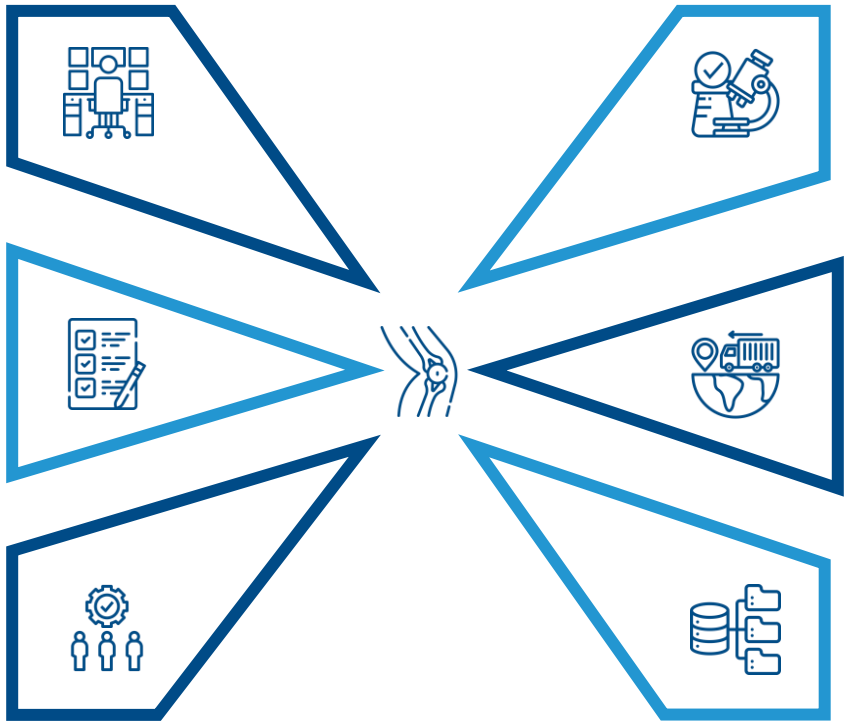
- Data analysis about quality, performance and safety.
- Systematic clinical follow-up to update the clinical evaluation.
- Notified Body surveillance: unannounced audits, product sample checks, reports on safety & performance.

MD reclassification and conformity assessment

- New classification rules: update of technical documentation.
- Implantable and Class III devices: stronger clinical requirements and regular inspection.
- Risk class identifies steps required for CE marking.

Qualified Person "Responsible for Compliance"

The manufacturer must identify one person ultimately responsible for all compliance aspects.



Modification of clinical evaluation requirements

- Stricter equivalence statement in reference to the use of clinical data in literature to justify not conducting a clinical investigation.
- Class III devices: performing clinical investigations when clinical evidence is not available to support safety and performance claims.
- Clinical data collection during device marketing to assess potential safety risks.

Requirements for Importer/Distributor

- Responsible for: CE Marking, Instructions for Use and Labelling.
- Complaints & Non-Conformity register, product recall system.
- Quality System plan.

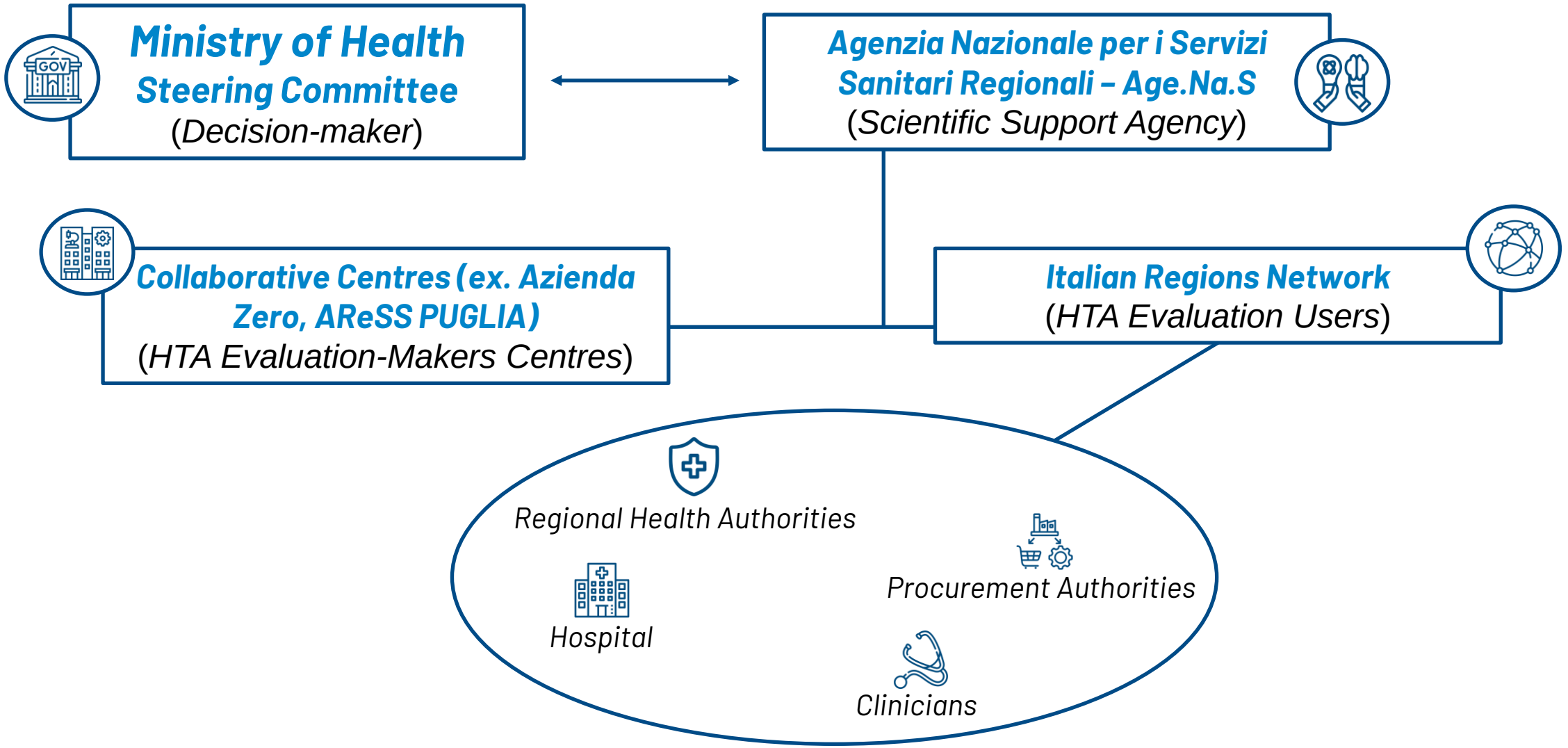
EUDAMED & Unique Device Identification (UDI)

UDI will enable stakeholders to access information about economic operators, devices, certificates, clinical and performance investigations, market post-market surveillance.

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical device, amending Directive 2001/83/EC, Regulation 8EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Italian Health Technology Assessment Plan for Medical Devices 2023-2025

Actors & Stakeholders



Italian Health Technology Assessment Plan for Medical Devices 2023-2025

Actors & Stakeholders

Ministry of Health

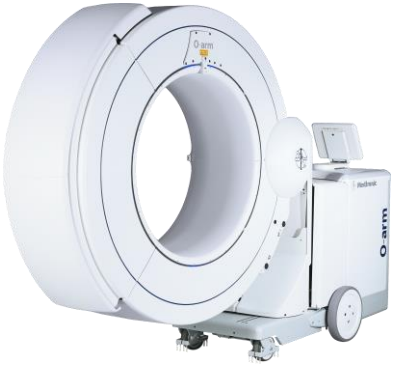
Steering Committee (*Decision-maker*)

- Final approval for the use of medical devices
- Definition of technological priorities to be evaluated for use and reimbursement
- Analysis and definition of evaluation methodology for new technologies and medical devices
- Governance of health expenditure for the procurement of medical devices

Agenzia Nazionale per i Servizi Sanitari Regionali – Age.Na.S

(*Scientific Support Agency*)

- Coordination of the Collaborative Centres activities
- Coordination of medical device governance activities
- Technical support for the definition of evaluation priorities
- Monitoring medical device utilization
- Evaluation of Health Technology Assessment procedures



Italian Health Technology Assessment Plan for Medical Devices 2023-2025

Actors & Stakeholders

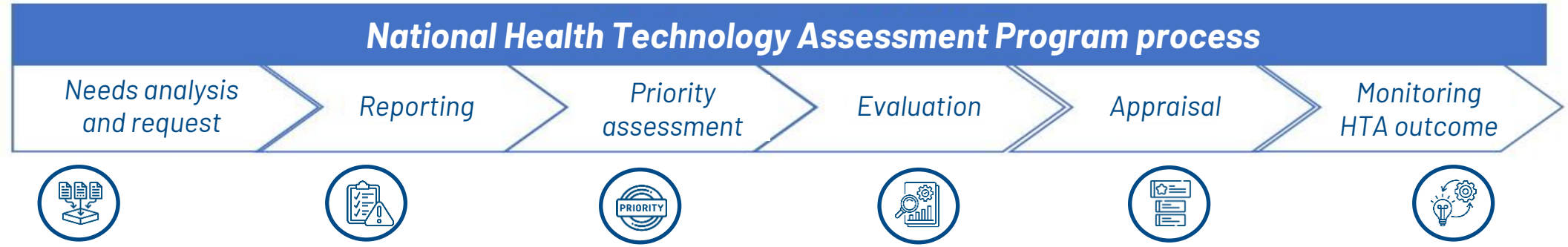
Collaborative Centres (ex. Azienda Zero, AReSS PUGLIA)
(*HTA Evaluation-Makers Centres*)

- Collecting clinical evidence on new health technologies and medical devices
- They prepare evaluation documents related to new technologies and medical devices
- They are private and public centres registered on a special list provided by AGENAS

Italian Regions Network
(*HTA Evaluation Users*)

- Established for the definition and use of tools for medical device governance and Health Technology Assessment & Horizon Scanning procedures.
- Gathers information and connects medical device user stakeholders.

Italian Health Technology Assessment Plan for Medical Devices 2023-2025



The analysis of needs:
- at regional level is a planning tool
- at national level makes it possible to have a better understanding of needs and market developments.

Emerging, early deployment, widespread or presumed obsolete technologies may be proposed for evaluation.

Prioritization criteria: impact on the care pathway, clear ethical and social implications, potential organizational impact, potential economic impact, technical relevance in the care pathway, uncertainty about comparative effectiveness (with other devices) and epidemiological significance for the clinical condition concerned.

Evaluations are carried out at national level;
Regional level: evaluations are carried out for relevant technologies for regional scenario.

The Appraisal Committee judges the technology under appraisal with recommendations for use within the NHS: USE, NON-USE, USE FOR CLINCIAL RESEARCH or CONDITIONAL USE.

Use of new healthcare technology within healthcare facilities with the aim of verifying its effectiveness, safety, organizational impact and costs.

Italian Medical Devices Payback actual situation

Art. 9 comma 9 L. 78/2015

The exceeding of the regional expenditure ceiling is borne by the MD companies:

40% in 2015

45% in 2016

50% from 2017.

Art. 18 comma 1 D.L. 9/8/2022

If the **reimbursement obligation** is **not fulfilled**, the **debts for the purchase of medical devices of each regional health service will be offset up to the full amount**.

Art. 8-9 D.L. 30/3/2023

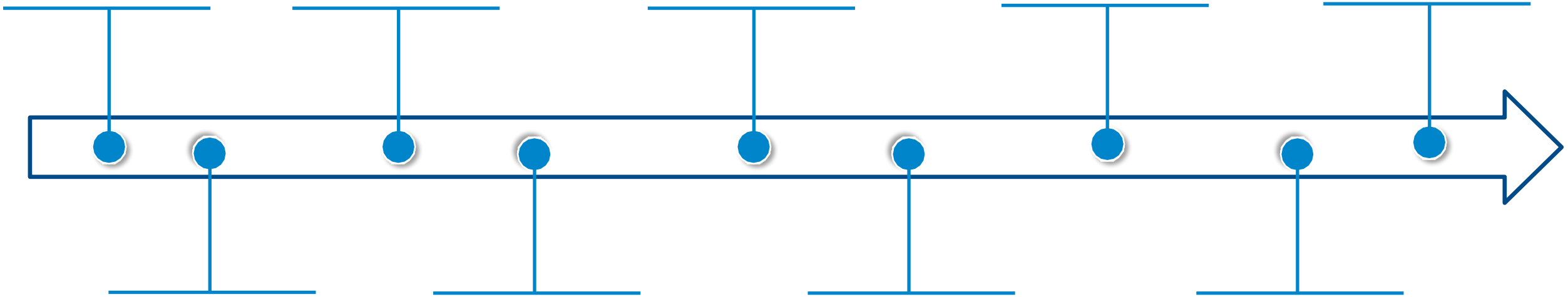
- **Government contribution of 1,085 million €** for the repayment of the ceiling overrun (2015-2018);
- **2nd payback deadline extension** to **30/6/2023 to the extent of 48% of the amount** for companies which not activated appeal procedures;
- MDs Companies may take the **amount of VAT as a tax deduction**.

TAR LAZIO 30/6/2023

The Administrative Court of Latium upheld the requests for suspension of the payback of the overrun of the ceiling.

CONFERENZA STATO-REGIONI 9/11/2023

From 2023, each year, MD companies will have to **transfer 0.75% of their annual sales income net of VAT to the 'Medical Device Governance Fund'**.



D.L. 6/7/2022

Certification of the exceeding - 4,4% Healthcare National Fund:

2015: 416.274.769 €

2016: 473.793.126 €

2017: 552.550.000 €

2018: 643.322.535 €.

Art. 4 comma 8-bis L. 24/2/2023

1st deadline postponement to 30 April 2023 by which MD companies are required to repay the ceiling 2015-2018.

Art. 3-bis D.L. 10/5/2023

- **MD companies that have not initiated appeals procedures** (or that intend to abandon the appeals filed) **shall pay by 31/7/2023** (3rd extension) the remaining quota in the amount equal to 48% of the amount indicated by regions.
- **For other companies the obligation to pay the full quota remains unchanged**.

Art. 4 D.L. 28/7/2023

4th deadline extension to 30/10/2023 of the for the payment of the amounts due as payback.

Points of discussion

The European Regulation determines the timing of dossier submission and evaluation for medicinal products only.

Once the Medical Device “Appraisal” process is complete, which are the next steps for pricing, tendering and making the device available to patients?

Currently, the goal of the National HTA Plan for Medical Devices is the annual evaluation of about 5/6 devices; who will evaluate all other devices likely to be introduced on the market? Hospital? The Local Health Authorities?