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USE OF MEDICAL DEVICE ASSESSMENT CRITERIA IN CONITEC EVALUATIONS

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Background & Objective

- CONITEC published a methodological guideline for evaluating Medical Devices in 2013, including 15 criteria in 5 domains:
  - CLINICAL (Literature Review, Facilitators, and Barriers)
  - TECHNICAL (product description)
  - OPERATIONAL (Human Factors and Ergonomics, Workplace Safety, Usability, Training, Learning curve, Infrastructure, Accessories, Maintenance, Risk Factors, Sustainability)
  - ECONOMIC (CEA, CUA, BIA)
  - INNOVATION DOMAIN.
- **This work evaluates the MD assessment criteria used in CONITEC reports and factors related to this utilization.**

Methods

- All MD health technology assessment reports produced by CONITEC between June 2013 and December 2023 were obtained from the agency's website, excluding clinical tests, formulas, food supplements, molecules, and unavailable reports.
- Fifteen criteria were evaluated in 5 domains, reflecting the guidelines.
- Each report gained 1 point per criterion appropriately mentioned.
- The maximum score for a report is 15/15 and for a criterion is 60/60.

Results

- **60** reports were evaluated: 15 classified as diagnostic devices and 43 as therapy.
- The most analyzed criterion was Health Economics (**57/60**), followed by Literature Review (**56/60**) and Technical (**55/60**) (Figure 1).
- The least analyzed criteria were Sustainability (**0/60**), Ergonomics (**2/60**), and Workplace Safety (**3/60**) (Figure 1).
- The average score across reports was **5.9/15**. The average varied according to the year of publication, varying from 4.0/15 in 2014 to 8.4/15 in 2023 (Figure 2).
- The rate was not different between industry (5.2) and internal (5.7) submissions; however, the percentage of positive recommendations was higher for internal demands (82%), compared to industry (40%).

Figure 1. Medical devices criteria accordingly to citation.

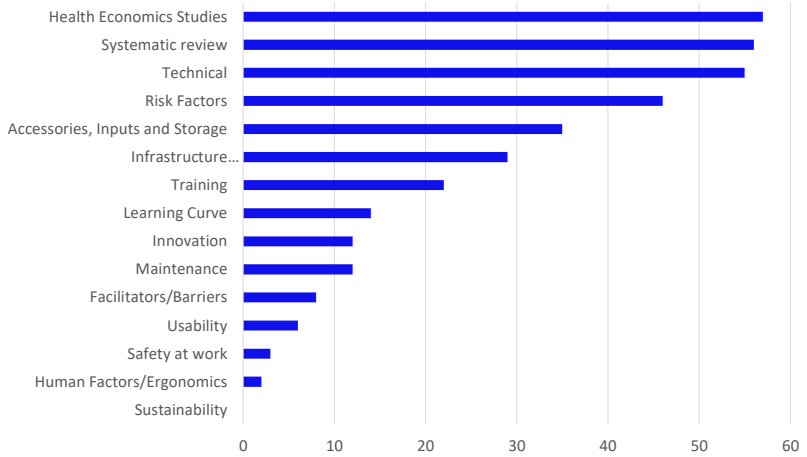
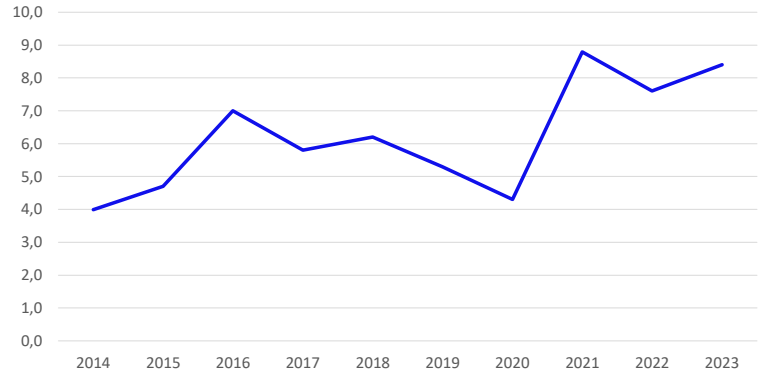


Figure 2. Time series of average score for MD assessment criteria use.



Conclusion

CONITEC reports' methodology has visibly improved over the years. In medical devices, this improvement emerged mainly after the division of the plenary into committees (2022). However, it is still necessary to improve assessments, based on clear criteria specific to medical devices, since the evidence is totally different from pharmaceutical products.