

Assignment 5

In-house developed tests versus commercial tests: what are the implications of medical device regulation (MDR) for sustainability?

Problem statement

The newly introduced European rules for medical devices (MDR) and In Vitro Diagnostic Regulation (IVDR) affect manufacturers, importers and distributors of medical devices. For example, a product may now fall into a different risk class and therefore must meet stricter safety and quality requirements. These rules have consequences for healthcare institutions, healthcare providers and (indirectly) for patients.

This research assignment investigates the implications for clinical laboratories. In clinical laboratories, blood samples are analyzed to determine the concentration of certain medicines, such as antibiotics and anti-cancer drugs. These measurements are essential because some drugs may be harmful to the patient if dosed too high or will not have the desired effect if dosed too low. In the past, most labs developed their own test methods, manufacturing their own reagents, diluents, standard solutions. These are so-called 'in-house developed tests' (LDTs). With the introduction of the new IVDR, laboratories will be required to switch to commercially available test methods. This raises the question: what will the environmental, social and economic implications of the transition be?

Research question(s)

What are the environmental, social and economic costs and benefits of commercial tests vs. In-house developed tests? **Case study: IVD-R proof LC-MS assay kit**

Expected type of work

Literature review, interviews in the lab and/or with commercial suppliers, cost-benefit analysis, life cycle assessment

Suggested academic backgrounds

This research assignment is open to any graduating Master students from Leiden University, TU Delft and Erasmus Rotterdam

- MSc Health Economics, Policy & Law
- MSc Governance of Sustainability
- MSc Healthcare Management
- MSc Health Sciences
- MSc Industrial Ecology

Available data/reports or other relevant information sources for the assignment

McAlister S, Barratt AL, Bell KJ, McGain F. The carbon footprint of pathology testing. *Med J Aust.* 2020 May;212(8):377-382. doi: 10.5694/mja2.50583. Epub 2020 Apr 18. PMID: 32304240.
The carbon footprint of treating patients with septic shock in the intensive care unit.
McGain F, Burnham JP, Lau R, Aye L, Kollef MH, McAlister S. *Crit Care Resusc.* 2018 Dec;20(4):304-312.
The carbon footprint of an Australian satellite haemodialysis unit. Lim AE, Perkins A, Agar JW.