Rijksinstituut voor Volksgezondheid
en Milieu
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Welzijn en Sport*

RIVM response to the scientific audit report on Medical Technology

Introduction

Staff and management of RIVM would like to express their sincere gratitude to the audit committee for their work, their recommendations and insights. We commend the Audit Committee for showing great understanding and flexibility as the Covid-19 pandemic has had a large impact on process and timelines. In this response to the audit report the recommendations are addressed, indicating how they will be adopted and incorporated by the RIVM in general and its Centre for Health Protection (GZB) in particular.

Medical technology is a broad and vibrant area ranging from band aids to high-tech surgical robots. New European Regulations have strengthened requirements for safety and performance of medical devices and contain provisions for an increased involvement of scientific experts at multiple stages in the regulatory processes by instigating Expert panels, Expert laboratories and Reference laboratories. In addition, regulators are stepping up their market surveillance activities with potential increased needs for scientific support. Because of the immense scope and complexity of the medical technology field, choices have to be made on the focus of potential RIVM involvement. The recommendations in the audit report neatly align with the MedTech Field of Expertise's (FoE's) wish to re-evaluate its focus and strategy in the context of future regulatory and societal demands. Now that the Covid-19 crisis becomes less demanding the FoE is eager to make a start.

The MedTech FoE recognizes that it is driven on the one hand by potential health risks as perceived by its commissioners and on the other hand by those it perceives in its independent role as a scientific institute. In the development of new vision and strategy, GZB will particularly heed the committee's remarks regarding an optimal interplay between these drivers. Therefore, as recommended by the audit committee, GZB will in renewing its strategy focus on areas with high potential health risks, on operating as an Expert Laboratory in combination with desk research, on broadening its network and expertise, on improving its visibility and profile, and on funding. The development of strategy will be done in consultation with our primary commissioners, a multidisciplinary group of experts and stakeholders as to ensure broad support for our projects and our role. A detailed reaction to the recommendations will follow below, grouped according to the audit report. Obviously, the development of a new MedTech strategy is a cornerstone throughout all responses.

Detailed reaction to the recommendations

Recommendation 1 Vision & Strategy

- Establish a clear process for developing and communicating a pro-active strategy using the input of commissioners, stakeholders and experts. This will also help building a network of engaged and knowledgeable collaborators.
- Develop a vision and strategy with engagement and commitment of the RIVM leadership (Public health and health services, in collaboration with GZB). This requires ownership. Currently responsibility for strategy and priority setting is positioned at the operational level.

- Create a more open strategy process involving a broader set of (external) experts, coordinated by RIVM, could help to better articulate future strategies and the role of the MedTech FoE in that strategy.

Response 1:

At the end of 2019, the GZB strategy for MedTech was due to be realigned with the freshly published RIVM strategy for 2020-2025. However, the start was delayed by the Covid-19 pandemic weighing down considerably on all GZB activities and on MedTech in particular. The work on strategy is currently planned to start early 2022 and will make full use of the recommendations and insights gained from the audit committee.

One of the key elements in the recommendations is that the development of a new strategy requires the prominent involvement of our commissioners, stakeholders and other experts. The involvement of external experts and stakeholders in this process will help to bring focus, strengthen our network, broaden recognition and clarify our role. The MedTech FoE will develop a new strategy along the lines suggested in the recommendations, while guided in addition by the RIVM 2020-2025 strategy.

Recommendation 2, Priorities

- Take the lead in pro-active surveillance and anticipating future risks and opportunities.
- Establish an MDR portal. In a regulatory context, the interpretation of the MDR is not always clear. The implementation of the MDR in the Netherlands would benefit from an MDR portal at RIVM to support Dutch stakeholders, researchers, engineers and health care system including clinicians.
- Balance benefits and risks of topics and activities in line with the size of MedTech FoE. The small size of the FoE and low budget seems at odds with the sheer size of the medical technology arena, the wide range of devices and its potential for prevention and implementation to make healthcare affordable and sustainable. To balance benefits and risks will become even more important in the years to come, considering the growing number of applications and devices.
- Assess the importance of new developments and emerging technologies. Especially in digital health technologies, such as SaMD, and AI, that, when massively applied, will impact hugely the medical device arena. Regulatory bodies are exploring ways to be able to assess the benefits and risks of these type of developments and are in need of independent support.
- Consider designation as an EU expert laboratory. The RIVM laboratory –accredited through OMCL- is highly appreciated in Europe, and should be continued. The ‘hands-on’ expertise in laboratories for medical devices is typically not sufficiently covered by member states in the EU. RIVM laboratory reports are helpful in the European context.

Response 2:

The development of a new strategy will clarify priorities with regard to our role and profile, research areas, required expertise, and necessary collaborations. The prioritization of activities is an essential element to be discussed with commissioners and stakeholders in terms of short versus long term projects and the balance between regulatory and societal benefit. This requires decisions as regards ambitions, topics and budget. External experts are of particular relevance with regard to determining our role in new and emerging technologies and our track record enabling our EU Expert Laboratory eligibility, which is a clear ambition of RIVM. Several plans for a more pro-active surveillance such as a horizon scanning system to identify new risks

(MT-Scan project) and additional testing strategies to predict implant safety (V-Med) are currently proposed in SPR. This should help connecting societal with regulatory demands and possibly scientific challenges. The suggested MDR portal is considered a very useful tool for stakeholders. However, the provision of legal advice may not fit the RIVM role.

Recommendations 3; Staff

- Cherish the staff on their expertise in high-risk medical implants, and expand the staff considering the (to be developed) strategy with new competencies (e.g. digital and AI);
- Invest in health communication expertise and other broader oriented staff, e.g., by hiring a clinical physicist.
- Organize yearly 'heidagen' with staff with input from external experts to set up regular horizon scanning.
- Manage the major risk that the FoE has a very small staff with highly specialized persons by making a succession plan. If one person leaves RIVM there might be a knowledge-drain and no back-up seems to be in place.
- Make an education/training plan for development of the staff in view of emerging technologies. Provide back-up for knowledge and expertise between the staff.

Response 3:

The audit committee is thanked for their recognition of the commitment of the MedTech FoE staff. The necessity for further growth as a team through training of hard and soft skills is recognised. The recommendations made with regard to strategic staffing will be considered in the annual review of the GZB staffing plan. This plan addresses which competences the MedTech FoE needs, and which competences can be developed internally or should be acquired elsewhere within RIVM or externally.

Recommendation 4; Organisation & budget

- Establish clear, visible leadership, positioning and resourcing for Medtech FoE which is consistent with its role and strategy. Include considerations on the organizational embedding, also in discussion with external stakeholders and commissioners.
- Consider a budget increase to prepare for future developments in medical technology, beyond the high-risk medical implants, by making explicit agreements with the commissioners and by investing a larger part of the internal SPR.
- Balance the funding to the prioritized activities.
- Organise external review of reports for quality control purposes before submitting.

Response 4:

The development of vision and strategy will clarify how the MedTech FoE can operate best in terms of leadership, positioning, and budget. With respect to the internal SPR programme, additional budget has been allocated to further develop strategic initiatives in the MedTech area. Two proposals will be pursued on research topics that the audit committee has identified as having strategic importance (see also response 2). The MedTech FoE recognizes the importance of long-term projects with multiple external partners, funded by national and European funding programmes (one of the 2 main goals of SPR V-Med), that foster regulatory preparedness and improve healthcare for patients. For example, the EU Horizon Europe programme provides interesting opportunities for projects in the field of medical technologies. With regard to quality control of reports external experts are usually consulted in the course of a

project. Reporting needs to be independent and therefore the reviewing procedures oriented internally. External review of draft reports is done in exceptional cases. GZB will consider incorporating procedures for external review in the existing quality assurance routine.

Recommendation 5; Collaboration & network

- Benefit from the wealth of expertise of organisations willing to collaborate, both academia, clinicians, hospitals, researchers, representative and policy bodies. Build upon this willingness to significantly extend networking and access to research in a systematic way, which will create a win-win situation.
- Since the landscape of medical technology is diverse, initiate a national committee or working group on application of medical technologies/medical devices. RIVM could be part of a stakeholder group of experts (scientists, industry,) both national and at a European level.

Response 5:

We subscribe to the benefits that come with collaborations in the mentioned areas. For example, expanding our networks with clinicians will stimulate our knowledge generating research as well as increase our potential to provide ad-hoc to regulators and policy makers. In general, the development of the new MedTech strategy new collaborating partners will be identified and mark out which of the many existing collaborations needs to be intensified (as reflected in MT-Scan, V-Med, and SPR-Mechanotox). With respect to expanding our collaborations a National Committee or Working Group could provide a useful platform. This will be brought up for discussion with VWS with respect to the purpose and potential status of such a group and the specific role for RIVM.

Recommendation 6; Commissioners

- Initiate a frank discussion between commissioners and RIVM to align on how to best translate the science-and fact-based insights into language that is understandable for the general public. This will help to eliminate potential lack of trust, and make explicit mutual expectations.
- Be transparent on the findings of research considering the political context. While maintaining the role as independent scientific advisor, RIVM should be aware of the political context and therefore consider this context in reporting by carefully tuned wording. Be explicit and transparent on this, and align and agree with commissioners.
- Align with the commissioners, in particular IGJ on the activities of MEBI with the responsibilities of IGJ in reporting of adverse events, and clarify mutual needs and expectations. This is particularly relevant given the relatively low number of notifications that MEBI covers. In this context, a European approach may be beneficial.
- Develop an integrated strategy to improve effective signal detection in the event of serious failures of individual devices. Define the role of MEBI in an environment where parallel reporting options may create confusion for members of the public and decrease effectiveness of reporting.
- Acquire knowledge and expertise, also in the context of commissioned projects.
- Create a long-term basis of understanding with the commissioners. Commissioners do consider working based on a long-term strategy, but this would require not only a different administrative process regarding funding, but also a long-term commitment, based on common mutual understanding and trust.

Response 6:

The recommendations on commissioners are recognised as important. An increase in ad-hoc commissions on high profile cases has considerably increased the political proximity of our work and impacted the mutual communicating. In our reports, the MedTech FoE balances ‘science for society’ and ‘science for policy’ within the RIVM mission of publicly providing independent advice. Summaries for the general public are written with our communication experts. Yet, it may at times be challenging for our commissioners that RIVM reports both as a contractor and as an independent institute. This organisational situation is rather unique in the world and (inter)nationally appraised for contributing to transparency, objectivity, and flexibility. One approach to improve working relationships with commissioners could be to embark on long-term projects with less political proximity and clear, broadly supported roles. Conversations with our commissioners have started to match mutual expectations with the current (administrative) procedures amidst our legal duties and responsibilities. In addition, part of the strength of the MedTech FoE lies in its ability to provide ad-hoc support. For instance, in crisis situations or in situations (e.g. reports to MEBI) that might develop into a crisis. Therefore, broadly accepted roles should also be established for short-term projects.

Following the ground-breaking work done in MEBI over the past 4 years its further development is planned to be discussed with the commissioners in 2022. Among the topics to be evaluated are MEBI’s positioning and scope. We agree with the audit committee that there must be clarity about MEBI’s role in public health. A solid positioning will stimulate collaborations and increase the number of notifications.

Recommendation 7; Communication & Visibility

- Create a higher profile. Outside their existing strongholds and commissioners, the profile in other domains of medical technology and in other networks (clinical, science, e-health broadly) is too low to be effective. Active public and organizational engagement are needed, for which substantial additional human resources are needed.
- Communication with the public needs to be aligned with the commissioners, considering the scope and role of the RIVM.
- Raise awareness within RIVM and with the commissioners of the importance and potential risks of medical technologies and their application and use and how to manage benefit versus risks in health care.
- Explore the option of benefitting of the laboratory expertise in analysing medical devices to play a more prominent role in the European context including work sharing and accepting each other’s results with other Member States.

Response 7:

The recommendation on alignment with commissioners on public communications is understood as being connected to the dual role of RIVM described in response 6. Alignment is customary but as regards content RIVM act as an independent institute that transparently provides independent advice. Roles in public communication requires broad support -internally and externally- and thus will be part of the MedTech strategy development.

As regards visibility, we will expand our internal and external networks to increase our profile. Intensifying our collaborations with European and international regulators and policy makers will also increase our visibility, as well as expand our portfolio of potential commissioners. This will also facilitate the suggested collaborations with other EU government laboratories with the objective of sharing workload, expertise

and mutual recognition of results (as is the case for pharmaceuticals). Such collaborations should provide momentum to becoming designated as a EU Expert Laboratory. Our primary commissioners will be consulted on the possibilities and mutual expectations.

Project proposals are being developed on anticipatory governance (e.g. through horizon scanning), novel laboratory techniques (e.g. on mechanotoxicity as a novel aspect of toxicological assessment), prioritisation using the MEBI database, managing benefit versus risk in health care. These initiatives are also aimed to improve our national and international profile.