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EIT Health Think Tank

Optimising Innovation Pathways: Future Proofing for Success

Introduction of digital products and services

Sweden Round Table Meeting

APRIL 2020

Executive summary

- Sweden has close collaborative links within the Nordic region and there are some similarities between systems in the individual Nordic countries
- Within Sweden, a total of 21 politically elected healthcare regions are responsible for providing and paying for healthcare, taxing their citizens, and deciding the taxation levels
- Despite a national Health Information Exchange (HIE), interoperability challenges exist amongst the different healthcare regions
- Sweden was one of the first countries, together with UK, to adopt value-based pricing
- Swedish County Councils (healthcare regions) invest around SEK 8.5 billion annually in healthcare IT, of which SEK 6 billion (USD 0.9 billion) is used for the purchase of equipment and supplies
- In terms of Global rankings:
  - For several years, Sweden has been leading the European Innovation Scoreboard
  - Sweden was in second place (behind Switzerland) in the Global Innovation Index 2017 (Source: Cornell University, INSEAD, and the World Intellectual Property Organization, 2017)
  - Sweden was in fourth place on the Global Entrepreneurship Index 2017 (Source: The Global Entrepreneurship and Development Institute (GEDI), 2017)
- There are around 100 health tech companies identified in Sweden: 52 focus on sustainable hospitals, 27 focus on assisted living, 15 focus on smart digital solutions, and 6 focus on personalised care. (Source: Nordic Health Tech Ecosystem)

Our sincere thanks to **Orderly introduction of products and services** who co-hosted the roundtable meeting alongside EIT Health Scandinavia.

Erik Forsberg
Managing Director, EIT Health Scandinavia

Contents

Introduction

In recent years, there has been rapid growth in the field of medical and health technology.

Not only has the number of players in this sector increased, but the diversity of products and services has evolved exponentially. While there are clear benefits in this change in dynamic, we must consider the impact this has in terms of how adequately innovators (those developing products and services) are able to navigate the path to market in a field that is highly regulated and often complex and slow to evolve in line with new technologies. This is particularly relevant when we consider that we are seeing more and more solutions being developed by innovators who are not sector specific, and therefore may lack relevant experience and understanding of the specificities of the healthcare market.

The regulatory and reimbursement landscapes are also ever-changing, posing new challenges in terms of development, testing, implementation, usability and adoption of new healthcare solutions. As a result, innovators and other stakeholders can face further hurdles in simply keeping abreast of how to access the healthcare market. In light of this environment, the EIT Health Think Tank selected the topic 'Optimising Innovation Pathways: Future Proofing for Success' for consideration and debate in its 2019 Round Table Series.

The Round Table Series took place in various locations across Europe organised in conjunction with the EIT Health regional hubs. Sweden was selected as the focus of the Scandinavian Round Table, because of the high level of overall digitalisation in Sweden, the interesting stage of Swedish policy-making on the introduction of digital products and services, and the existence of a specific national project for organised introduction of digital products and services. This meant that there was highly relevant policy development and an existing national process, which would strengthen the Think Tank and connect it very well to the actual Swedish policy processes. Meeting which took place on the 1st October 2019 and saw participation from key stakeholders involved in healthcare innovation in Sweden including healthcare providers, innovators from industry and SME's, policy makers, regulatory bodies, industry organisations, patient organisations.

Each host regional hub selected to focus on a choice of innovation type relevant to the national context – Scandinavia selected digital health solutions, i.e. products and services.

The current situation:
a focus on today's innovation pathway

The innovation pathway, or route to market for new products and services, is in several aspects comparable in Sweden to the rest of Europe. Although presented in a linear format in figure 1 below, it is in fact a continuous and modular pathway whereby all parts are interconnected and reliant on each other.

The regulatory and reimbursement (market entry and adoption) stages of the pathway were historically developed to support the introduction of more traditional treatments such as pharmaceutical medicines or medical devices. Compared with well-established processes, the digital health pathway is less established and currently more complex to navigate as a result. This is particularly relevant when assessing the regulatory processes, which is struggling to keep pace with the rapid introduction of new technologies. In the current landscape, where new technological discoveries are constantly being made, there is increasing need for a more agile regulatory framework.

Such reform of the regulatory pathway in Europe, has indeed been addressed recently as evidenced by the European Medicines Agency with the proposed introduction of new guidance for medical devices and in-vitro diagnostics which are planned to be introduced in 2021.

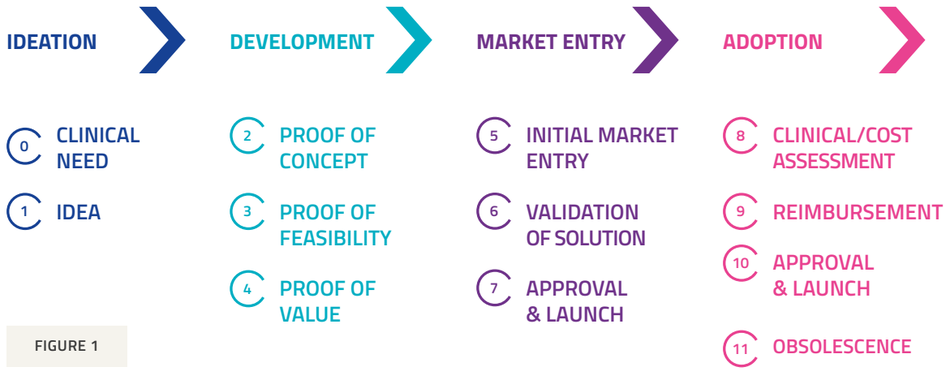

FIGURE 1

A 'checklist' of requirements that innovators should expect, and the approach required, at various stages of the pathway would be of value. The ongoing work by "Organised introduction…" to initiate a "requirements library", to facilitate and streamline product development and procurement of digital services by jointly clarifying the requirements and regulations of state regulators and purchasers, would provide a valuable and clarifying guide for all innovators approaching the Swedish market.

Ideation – grasping the ‘unmet need’

The term ‘unmet need’ refers to the clinical shortfall of solutions for a disease, condition or patient experience in managing, maintaining or regaining their health.

While unmet clinical need is a crucial consideration in the ideation phase, there is also a need to focus on overall need, including patient needs and the needs of existing healthcare systems such as hospitals. A key challenge for digital health solutions is not the technology itself, but the requirement for change management and adaptation to reflect new processes and workflows. Therefore, it is more important than ever to assess the full context for any product or service through engagement with stakeholders.

There are often barriers in Sweden for industry to engage directly with stakeholders within the healthcare system as well as patients and citizens, due to factors such as conflict of interest or trust.

However, access to the healthcare sector is a prerequisite in order for companies to understand challenges and assess how best to cooperate. Clearer working methods and agreements need to be in place for collaboration between companies and the healthcare sector. Structures are needed to allow for interaction so experience can be shared and needs can be properly interrogated and prioritised. Processes for ethical communication between these stakeholders need to be developed in order to create an ecosystem that supports cocreation and evidence generation.

While reimbursement, at this stage of the process, will be a long way in the future, procurement strategy needs to be considered from the very beginning. Within the current healthcare services landscape, it is important to acknowledge the reality that time and resources are limited. Truly transformative solutions are those likely to gain uptake as opposed to those without a clear value.

Development and market entry

Developing a product or service for the Swedish market has many steps that are intrinsically linked to the market entry phase of the innovation pathway outlined in figure 1. Market entry must be at the forefront of innovators’ minds throughout the development phase as comprehensive data are required to evidence the proof of concept, feasibility, efficacy, safety and value of a new solution.

There is currently insufficient definition of the standards and requirements for clinical trials of digital health products and services, which makes the generation of evidence to support regulatory submissions a blurry area for innovators. The ‘randomised clinical trial’ model traditionally associated with pharmaceuticals is often not appropriate for digital technologies, and real-world data are often more informative in supporting the value proposition of such solutions. Digital health products and services constantly generate ‘real-world’ data while being used, which allows for continuous assessment – this introduces a vastly different evidence generation environment when compared to traditional pharmaceuticals. Additionally, methodologies in this space must take into account the iterative development process for digital technologies.

Guidance on evidential requirements for digital health solutions need to be clarified to support innovators in navigating regulatory submissions, and companies, innovators and researchers need to be part of the discussions alongside regulators to move towards a framework that is better suited to digital health solutions. At the earliest phase, innovators should also consider their future launch strategy including whether this should include markets beyond their immediate geography. Clinical studies should ideally be undertaken at an international, multicentre level to support wide adoption and meet different national requirements.

The new Medical Device Regulations (MDR) places further uncertainty on innovators in the context of regulatory requirements, and may pose particular challenges for smaller companies such as start-ups in navigating the new process and assigning the necessary resources. It would be helpful for innovators to be provided with guidance on how to navigate the new regulation and its requirements, as well as training and mentoring opportunities to support the shift in process as well as the wider regulatory engagement required when bringing a digital health solution to market. Funding mechanisms to enable start-ups to survive this changing landscape would also be highly beneficial.

Adoption – gaining reimbursement and long-term use

Regulatory approval, or CE marking, is confirmation that the solution meets European standards relating to safety and efficacy. This, however, is not a declaration of cost-effectiveness which leads to adoption. Progressing through all stages of the pathway does not necessarily guarantee adoption.

From the perspective of healthcare funding, there is often a focus on the 'cost replacement' that a new innovation can provide over an existing solution. This can provide a challenge for digital health solutions as the focus of such innovations are not necessarily related to immediate cost savings, but rather impact on other factors such as care quality, patient adherence or prevention of disease, which lead to significant cost reductions in the long-term. In light of this, new finance models are required in moving away from the current annual budget cycle. Good health economics input and experience is important when generating evidence of overall value, due to the complexities of different stakeholder budgets and economic workflows. Innovators should be supported in navigating the changing reimbursement landscape, including guidance and training on how to build a reimbursement strategy focusing on long-term health values and cost reductions.

Innovators must consider the impact of new innovations within existing systems when calculating the value for reimbursement. Innovations that disrupt or add to existing systems or processes are unlikely to be attractive propositions, and within a cost and resource stretched landscape healthcare providers are looking for streamlining and efficiency. Where change in process or systems is justified, change management must be thoroughly considered.

Patient choice is also a key driver of adoption, and it will become increasingly important that products and services are effective in line with patient expectations. Patient associations play a vital role in advocating the needs of patients, and while they cannot support specific products, they can push for greater choice, and for better conditions for enabling new solutions.

Conclusions and recommendations for optimising the path to market in Sweden

The body of evidence collected during the Round Table Series, demonstrated that there are a number of key stages within the innovation pathway where improvements could be made to aid and speed up the route to market for promising innovative solutions. Participants of the Swedish Round Table Meeting were asked to agree on a set of recommendations that, if implemented, could help to optimise the pathway for digital health solutions.

Importance of methodologies, agreements and forums for collaboration between companies and relevant stakeholders

Digital health solutions should consider the 'clinical need', the 'patient need' and the 'system need'. While the underlying needs may be similar, the environment and context can be vastly different. Therefore, innovators should be supported in interacting with relevant representatives in order to gain insight, share experiences and gather feedback on their product or service in a trusted and ethical way.

Clarify the evidence generation requirements for digital health solutions to demonstrate true value and facilitate conversation between innovators and regulatory and reimbursement bodies to future proof guidelines

There should be further discussion around the appropriate body of evidence required for regulatory bodies and healthcare regions for digital health solutions as a distinct methodology in contrast to evidential requirements for medicines and medical devices. Innovators themselves, from large and small companies should be encouraged to provide their input and experiences so that equitable guidance can be encouraged.

Support innovators in navigating the new Medical Device Regulations (MDR)

The introduction of the medical device regulation in 2021 is expected to slow access to digital health solutions due to changing guidance as well as regulatory capacity. While estimations have been calculated, it is not clear what the full impact will be on digital health solutions, and guidance is lacking for innovators in approaching the new regulation. Smaller companies, such as start-ups, will find the resource and financial requirements of the new guidance challenging and guidance, training and funding to help them overcome such challenges is advised.

Provide education and support for innovators on preparing value-based reimbursement strategies

Many current healthcare funding processes are heavily focussed on cost replacement, which presents a challenge for digital health solutions which aim to improve more long-term outcomes such as adherence or disease prevention. It is therefore essential to prove the longer-term improvement benefits and cost reduction potential of digital health solutions. However, evidential requirements, such as health economic data, are unclear for innovators and support should be available to provide clarity on how smaller companies can develop a compelling value proposition to aid reimbursement and adoption.

Participants

Round Table Meeting agenda attendees

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