CHARLOTTE PIESTER • MARIANNE ROSAGER

MED TECH MARKETING

A BUSINESS MODEL FOR MEDICAL TECHNOLOGIES AND MEDICAL DEVICES

HANS REITZELS FORLAG

MEDTECH MARKETING

HR

CHARLOTTE PIESTER • MARIANNE ROSAGER

MED TECH MARKETING

A BUSINESS MODEL FOR MEDICAL TECHNOLOGIES AND MEDICAL DEVICES

HANS REITZELS FORLAG

MedTech Marketing

A Business Model for Medical Technologies and Medical Devices

1st e-book edition, 2017

© Charlotte Bruun Piester, Marianne Rosager and Hans Reitzels Forlag, 2017

ISBN 978-412-7190-3

Publishing editor: Lasse Wolsgård
Copy editor: Dorte Steiness
Cover design: Lisbeth Neigaard, VINK Design
Cover image: photo by Hans Ole Madsen. The cover picture is of the School in Sydhavnen. JJW Architects have designed a robust, adaptable building that interacts with the surrounding quarter and the harbour and facilitates encounters between pupils, at all levels.
Illustrations pp. 33, 53, 60, 88, 154, 180, 187, 197, 204, 236: John Buchwald
Photos: Colourbox, unless stated otherwise
Photos pp. 20, 345, 346: Hans Ole Madsen
Photos pp. 309-322: Coloplast
Photos pp. 323-342: HARTMANN Group
Photos pp. 347-349: private photos
Layout and typesetting: Kit Hansen
Type set in: DIN Shrift & ITCLegacy

Printed edition:
Printing: GRAFOTISAK / GPS Print
Printed in Bosnia-Herzegovina 2017
ISBN: 978-87-412-6885-9

This publication may only be reproduced
in accordance with agreement with Copydan Tekst & Node and the Danish Ministry of Education.

hansreitzel.dk

Contents

Preface 11

MedTech description 12
How to use this book 14
Who can use this book? 16
What will the reader get from this book? 17
Limits of our advice/disclaimer 18
Acknowledgements 19
About the authors 20

PART ONE INTRODUCTION

1 The MedTech Market 23

2 The MedTech industry 25

2.1 Marketing in the MedTech industry versus the pharmaceutical industry 26
2.2 What challenges do we face in the MedTech industry? 27
2.3 What trends influence the MedTech industry? 32
2.4 Value 34
2.5 A balance between total creativity and strict regulations 34
2.6 A final note before moving on 35

3 Conceptual clarification and description of MedTech Marketing 37

3.1 Classical marketing (as the foundation for MedTech Marketing) 37
3.2 What is MedTech Marketing? 41

4 Introduction to the Sinua MedTech Marketing model 49

4.1 The Sinua MedTech Marketing model 50
4.2 Evidence – the extra dimension 51

PART TWO HOW TO DO IT

5 Getting started 57

5.1 Do I have to do it all? 57
5.2 An in-depth examination of the model 58
5.3 Keeping track 60

6 Phase one: Idea 65

6.1 The origin of the idea 65
6.2 Description of the idea/innovation 71
6.3 The impact of the innovation 72
6.4 Industry and company fit 78
6.5 Risk factors and minimising risks 79
6.6 Competition 80
6.7 Patents – intellectual property 82
6.8 Summary 85
Checklist 86

7 Phase two: Business 87

7.1 Market value and market estimate 88
7.2 Pricing 94
7.3 The business model 100
7.4 The business case 101
7.5 Different funding opportunities 105
7.6 Kill your darlings 106
7.7 Summary 107
Checklist 107

8 Phase three: User 109

8.1 Who are your customers (users, healthcare professionals and payers)? 110
8.2 Customer segmentation 111
8.3 The customer journey and buying decision 113
8.4 Sales funnel and sales cycle 120
8.5 User involvement 121
8.6 Whom to involve 124
8.7 Key opinion leaders (KOLs) 125
8.8 How to involve users 127
8.9 When to involve users 128
8.10 Summary 129
Checklist 129

9 Phase four: Positioning 131
9.1 Intended use 132
9.2 Features and benefits. 132
9.3 Key messages 136
9.4 Value proposition. 137
9.5 Competitive positioning 140
9.6 Summary 146
Checklist. 147

10 Phase five: Legislation. 149
10.1 What is a MedTech product? 150
10.2 Patient safety first and foremost 151
10.3 Market access and commercial tactics 152
10.4 A MedTech product or not? 155
10.5 Intended use 157
10.6 Instructions for use (IFU) 162
10.7 MedTech Europe. 162
10.8 MedTech US. 167
10.9 MedTech in the rest of the world (RoW). 173
10.10 Software 174
10.11 Clinical evaluations and trials 174
10.12 Post-marketing surveillance (PMS) 178
10.13 Country-specific regulations 178
10.14 Reimbursement and local coding systems 179
10.15 Summary. 184
Checklist 185

11 Phase six: Documentation 187
11.1 What is needed versus tactics. 188
11.2 Hierarchy of evidence. 189
11.3 Types of documentation 194
11.4 Proof 207
11.5 Summary. 208
Checklist 209

12 Phase seven: Communication. 211
12.1 The communication plan 213
12.2 Sales channel 217
12.3 Sales funnel and communication 218
12.4 Targeted communication 219
12.5 Tools 221

12.6 Test-marketing phase 225
12.7 When MedTech Marketing communication works 225
12.8 Summary 226
Checklist 227

13 Rounding off 229

PART THREE
ORGANISATION AND IMPLEMENTATION

14 Organisation 233

15 Implementation 237
15.1 Ideas to inspire your work with MedTech Marketing 238

PART FOUR
DIFFERENT VIEWPOINTS ON MEDTECH MARKETING

Introduction 243

16 The business view: How to transform your innovation into a commercial success, by Tonni Bülow-Nielsen 245
16.1 Introduction 245
16.2 Building value with your commercial plan 250
16.3 Mapping out your first 100 days post-investment 253
16.4 Optimise your innovation 254

17 The customer view, by Michel Nemery & Henrik Holm 259
17.1 Introduction 259
17.2 A healthcare professional's viewpoint 261
17.3 A healthcare purchaser's viewpoint 268

18 The regulatory view: Focus on the regulatory framework for MedTech products, by Peter Huntley 271
18.1 MedTech versus pharmaceutical 272
18.2 Introduction to MedTech regulation 273
18.3 Classification of MedTech products 274
18.4 MedTech usability and risk profile 275
18.5 EU and US definitions of medical technologies 276

18.6 A closer look at the elements leading to the CE mark (Europe) 278
18.7 Who certifies MedTech products? 282
18.8 Changes in the EU regulatory framework 283
18.9 Reimbursement 287
18.10 The value proposition – it all starts here 290

19 Building new skills in healthcare innovation – the need for a new graduate degree, by Finn Valentin 293

19.1 Why do we need a new degree in healthcare innovation? 294
19.2 The programme 298
19.3 A dream scenario 303

PART FIVE BEST IN CLASS

Introduction 307

20 Case 1: Coloplast 309

20.1 Introduction: "Leading intimate healthcare" 309
20.2 Medical Marketing in Coloplast 311
20.3 Medical Marketing today 312
20.4 Main tasks of the Medical Marketing organisation 313
20.5 When Medical Marketing becomes a competitive advantage 317
20.6 The internal value of the Medical Marketing discipline 319
20.7 How to manage Medical Marketing in difficult times 320
20.8 Medical Marketing employees 321
20.9 Key learning points 322

21 Case 2: HARTMANN Group, Germany 323

21.1 HARTMANN is "Going further for health" 323
21.2 History of the HARTMANN Group 324
21.3 Key figures 325
21.4 Challenges faced by HARTMANN 325
21.5 Positioning of the portfolio 327
21.6 Evidence is the HARTMANN MedTech Marketing way 328
21.7 The transformation 331
21.8 The new evidence-based organisation 333
21.9 The beauty and burden of complexity 339
21.10 Key learning points 342

PART SIX CURRICULUM VITAE

Authors 345

Viewpoints – Specialist input 347

Bibliography 351

Part one 351
Part two 353
Part three 362
Part four 363
Part five 363
Background info 364

Index 365

Preface

Welcome to *MedTech Marketing*. This book seeks to give an overview and an explanation of MedTech Marketing and act as a source of inspiration, with a strong focus on idea development, launch and sales of MedTech products and services. It uses a new, structured model to process the complex commercial elements needed to gain success in the market – from start-ups to large international corporations.

The model is based on many years of accumulated extensive experience of the commercialisation of MedTech products worldwide, and provides guidance on how to reach a unique position in the market in order to maximise growth and earnings for the individual company.

The model is also used in teaching at different universities, like the master programme in Innovation in Healthcare at Copenhagen Business School.

"All industries should have a sub-genre book like this one. A coherent work targeting the specifics surrounding MedTech Marketing – the possibilities, challenges and how to do it. It is a highly relevant and needed book!"

STEFAN KIRKEGAARD SLØK-MADSEN, PRICE & SALES RESEARCHER, CBS

Before the real introduction, the following pages strive to establish the context for the MedTech market and offer advice on how this book should be used.

Happy reading!

MedTech description

The starting point for the description is based in the healthcare industry.

The healthcare industry in itself can be described and split into different categories in various ways. The Industry Classification Benchmark (ICB) and the Global Industry Classification Standard (GICS) both compartmentalise the industry into the two following primary groups:

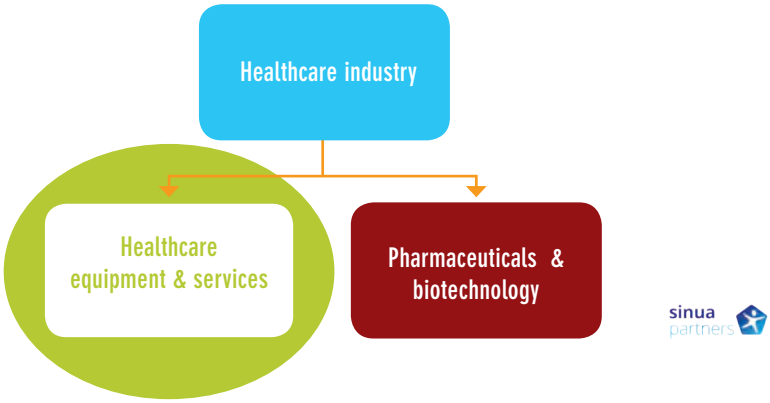

FIGURE 0-1. MedTech in the healthcare industry. Source: Sinua Partners 2016

1. Healthcare equipment and services.
2. Pharmaceuticals & biotechnology.

The focus of this book is the healthcare equipment industry and not the pharmaceutical & biotechnology industry, Figure 0-1.

Around the globe, there is a myriad of definitions and words aiming to describe healthcare equipment. The two most frequently used descriptions are medical devices and medical technologies, in short MedTech. Medical devices are widely used; however, the range of healthcare equipment is broader than just medical devices. MedTech Europe (MedTech Europe 2015) embraces the broad range of equipment in their description of medical technology (MedTech):

> “Medical technology is any technology used to save the lives of individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us. Medical technology can be familiar, everyday objects such as sticking plasters, syringes or latex gloves. Alternatively, it can be pregnancy tests, spectacles, wheelchairs and hearing aids. Meanwhile, at the high-tech end of the scale, medical technology includes total body scanners, blood glucose monitoring devices, ultrasounds, life-supporting machines, implantable devices such as heart valves and pacemakers, and replacement joints for knees and hips. There are more than 500,000 medical technologies currently available in EU and they all share a common purpose: improving, extending and transforming peoples’ lives.”

To substantiate the above, the Global Medical Devices Nomenclature (GMDN) has categorised the numerous MedTech products and has so far identified 16 categories. The categories do not yet cover the newest technologies like apps and software for machine learning, but are expected to increase alongside the introduction of additional innovations.

MedTech is used throughout the book. In some of the references and definitions, quotes are reproduced verbatim and therefore the terms “medical technologies”, “medical devices” and “medical marketing” will be used in these specific examples.

MedTech products will be used as a description covering:

- MedTech products with or without software, regardless of classification
- MedTech solutions
- MedTech apps and data collection
- MedTech services
- MedTech innovations.

How to use this book

This book seeks to give an overview and an explanation of MedTech Marketing, and act as a source of inspiration.

You can read the book from beginning to end, or you can focus on the areas of most interest to you. If you read it from start to finish, you might find there are a few repetitions; these are intended to give meaning to readers who approach the book less systematically.

We seek to provide an overview of how all of the elements of MedTech Marketing combine and interact, including references to and suggestions of strategic models. The strategic models are included for inspirational reasons, as they provide an excellent foundation for common comprehension; the models are not described in depth, however, and you may seek further information elsewhere.

Many of you will be specialists within a particular area covered by the book, with highly specific competencies; if this is the case, please bear in mind that you may find some of the descriptions superficial or simplistic. This is because we have chosen to give an overview, highlighting all the links to MedTech without, however, describing them in detail.

The book is a hybrid book, consisting of five parts:

Part 1 addresses **MedTech Marketing in general**:

- giving a description of MedTech Marketing and its components, in the context of trends and challenges in the industry
- introducing the MedTech Marketing model.

Part 2 explains **how to do it**:

- including an in-depth exploration of the MedTech Marketing model
- describing the various commercial elements that are important to be aware of when working with innovations from the idea to market and after launch
- After each chapter, a summary serves as a wrap-up, which also can be read prior to reading the chapter, as a brief overview.

Part 3 covers the **organisation and implementation** of MedTech Marketing.

Part 4 gives different **viewpoints into MedTech Marketing** from several highly respected specialists:

- **The business view** is covered by Tonni Bülow-Nielsen, Managing Partner, Vækstfonden, describing his first-hand experience of the commercial challenges that arise within MedTech Marketing.
- **The customer view** is provided by:
  - Chief MD Michel Nemery, Department of Radiology, Herlev and Gentofte Hospital, shares his thoughts on how innovation and collaboration with the industry can be achieved.
  - Henrik Holm, Public Procurement Consultant, Region Sjælland, shares his views on what gives the most value for the purchase organisation group when buying a MedTech product.
- **The regulatory view** is covered by Peter Huntley, CEO of MEDICOINDUSTRIEN, who shares his great regulatory knowledge and gives his insights into the significant changes in the EU regulations, which have recently been updated (and implemented).
- **New skills needed in healthcare** comes from Finn Valentin, Professor at Copenhagen Business School.

Part 5 titled **Best in class**, shares how two large corporations, Coloplast & HARTMANN Group, work with MedTech Marketing, demonstrating how MedTech Marketing matters, differs and creates value.

Who can use this book?

This book is for everyone who works with MedTech, regardless of the country in which they are based, although the core focus of the book is in Europe and the United States.

This includes:

- everyone working within the MedTech industry, no matter what the territory, what phase of the life cycle their business has reached, and what size it is. The information in this book is equally valuable for start-ups, small, medium and large organisations.
- companies with connections to the MedTech industry and/or the healthcare sector
- students who want to get to grips with MedTech and to understand the various models and regulations they need to deal with
- the many employees in the primary and secondary healthcare sectors who work with MedTech, including, for example, purchase departments
- investors dealing with MedTech.

What will the reader get from this book?

The objective of the book is to inspire individuals and companies by introducing them to MedTech Marketing. It presents a business model that makes the complex simple and a mindset that will create new opportunities and introduce new ways of working, in order to ensure you have a competitive advantage that leads to growth and success.

The book answers such questions as:

- What is MedTech Marketing?
- Why should you work with MedTech Marketing?
- How do you perform MedTech Marketing?
- What are the gains of MedTech Marketing?

These pages will:

- introduce MedTech Marketing as a unique discipline
- show that MedTech Marketing is an international, interdisciplinary area
- demonstrate that MedTech Marketing is a working tool
- provide insight into why and how MedTech Marketing contributes to success
- highlight the consequences if MedTech Marketing is absent
- demonstrate how new, complex and abstract theories can follow a simple model.

The book also offers:

- guidance on how to create a unique position via the MedTech Marketing model, thus reaching the "sweet spot" in the marketplace
- knowledge of regulatory, clinical and health economic processes
- a plan offering an overview of the entire MedTech Marketing process
- real-life cases
- inspiration.

Limits of our advice/disclaimer

This book offers our best and most sincere knowledge about MedTech Marketing.

Our model is based on more than 50 years of combined experience in the industry. However, we recognise that our professional colleagues might have other priorities when working within the MedTech industry. This will often be the case when a new model is described for the first time within an industry, even when it is based on well-known and internationally recognised models.

Some legal statements

- Readers who use the information given in the book do so at their own risk.
- The authors or publisher are not responsible for any damage resulting from using the information and recommendations contained in this book.

With these disclaimers behind us, we hope you will enjoy the book and find it rewarding, helpful and refreshing.