MARKET SIZING AND FORECASTING IN THE MEDICAL DEVICE & DIAGNOSTIC MARKETS

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Dr Christophe Homer
Director of Medical Devices & Diagnostics, Healthcare

Liz Bates
Director of Forecasting, Healthcare

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Introduction

Understanding the market potential for a product is an integral part of any business plan. Assessing market size, identifying existing and new competitors, as well other drivers/constraints on growth, will inform a business development plan and forecast.

This report will provide an overview of the key factors to take into consideration when sizing and forecasting for a product in the Medical Device and Diagnostic (MD&D) markets.

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Defining the market

Defining the target market should be the first step in determining the market size – this is typically approached by considering the different areas of the market.

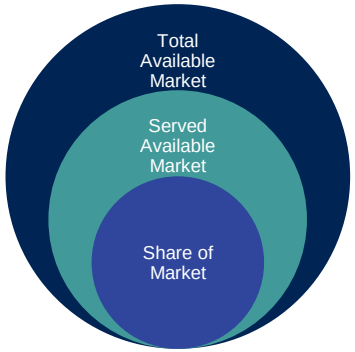
Total Available Market (TAM) – The potential for the product regardless of any restrictions in the market. This is often required for investors who want to understand the full market size in a specific region.

Served Available Market (SAM) – The size of the market that can be fulfilled or served by the product. It can also be referred to as the addressable market. This is typically smaller than the total market.

Share of Market (SOM) – The final target market. That is the size of the serviceable market that can be captured by the product. This is also referred to as the penetrated market.

The goal is to understand what SOM can be obtained, but an understanding of the wider market (TAM) and how the product fits into it provides a full overview of the marketplace. An incorrect assumption at an earlier stage of market sizing could result in producing too little or too much stock to fulfil demand.

In order to identify the size of these respective market cohorts, a full understanding of the patient, or product, pathway is required to estimate the share of market the product could/does obtain. The complexity of calculating the size of sector of the market will vary according to the market being sized and the business question that is being asked.



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Sizing the market

When it comes to sizing the market, a ‘top-down’ or ‘bottom-up’ approach can be used.

The top-down approach starts with the broad market size, which can be estimated from epi data, sales/volume data (depending on the product) etc., and drills down to the share that the target market represents. This method is typically quicker to calculate and is good for use in validation, but it may not provide full information on the current competitive set or detail beyond the share of market.

The bottom-up approach focuses on building up the TAM using the main components in the target market – who are the competitors, what market share do they have, etc. The bottom-up approach relies on audit or survey data to build the base within each geographic region. A robust survey combined with desk research will provide a good starting point for this approach.

Both approaches can be combined to estimate the market potential – in an ideal world, the market size derived from drilling down from the total market using epi or market sales data *should* match the served market when it is built from the bottom up. Discrepancies in the market size could highlight if there are any caveats in the data, such as only a proportion of the audited sales being covered, or an over/underestimate on the epi data for example, that haven’t been factored in.

The approach will be determined by the business question – a top-down sizing method may be more appropriate for a go/no-go decision in early phase development, whereas a pre-launch analysis will require a more detailed robust approach to inform sales force strategies and manufacturing.

Triangulating the market size against market data (import or company report data) and other published sources validates the final market size. Existing data in the MD&D market can be difficult to find. Audited sales are not as readily available as they are in other markets. Market sizing in new areas or certain geographies, such as Asian or South American countries, can be challenging if there is little data available to benchmark against.

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MD&D Nuances

The MD&D market is vast, ranging from everyday, low risk (Class I) products, such as plasters and stethoscopes, to high-risk devices (Class III), such as artificial limbs and pacemakers. Products with higher risk to patients are subject to more market controls, with Class III devices requiring pre-market approval. Most countries follow a similar structure in their classification – Class II may be split in some cases. The US classification is similar to the EU, ranging from Class I to Class III based on how risky the product is perceived to be for the patients.

Medical Device Groupings

LOW RISK

CLASS ONE

- e.g. sterile dressings, plasters, wheelchairs, gloves, nappies, stethoscopes

MODERATE RISK

CLASS TWO*

- e.g. hypodermic needles, x-ray devices, tooth implants, syringes
- ventilators, intensive care monitoring equipment, blood bags

HIGH RISK

CLASS THREE

e.g. pacemakers, coronary stents, orthopaedic implants

*Class II is split into IIa and IIb in Europe

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Key factors to take into consideration

The factors to take into consideration when market sizing will often depend on the type of device. One way of viewing the market, aside from classification, is to consider capital equipment and non-capital equipment.

Capital equipment

Capital equipment, such as imaging, IVD, beds and operating room lighting, can be standalone or supplementary, typically lasts 5-10 years and will be used by many patients across different specialties and may require a large upfront cost. Capital equipment will be purchased when outfitting a newly constructed or refurbished clinic/department as a result of expansion and when the existing equipment needs replacing. The market is not restricted to new equipment – there is also a refurbished market where old equipment can be serviced and reused.

Take the example of MRI scanners; a new scanner is launching, and we need to understand the market potential:

To identify the current market size, we need to account for the number of hospitals/clinics/units in the geography that have imaging centres (TAM). We then need to consider the served market (SAM) – in the case of capital equipment, this is known as the installed base. That is, how many scanners are in each setting, when they were purchased, the replacement cycle, the product life span, and when they will be replaced, to get to our final target market (SOM).

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Key factors to take into consideration

Non-capital equipment

Non-capital equipment is typically lower cost, may be single-use and include surgical masks, scalpels, blood glucose monitors and stents, for example. In this case, we need to focus on how often the product is used and how many are used per case, e.g. the number of stents, implants, screws/rods etc will vary in each case.

If we are sizing the blood glucose test strip market, we need to identify: the number of diagnosed patients with diabetes in active care (TAM), the number of patients who need to self-monitor blood glucose levels (SAM) and then the number of patients who meet the criteria for glucose monitoring, how many test strips they use and how often they test (SOM).

Alternatively, in sizing the stent market we would need to identify the number of patients in need of a stent/how many stent surgeries are performed each month/year (TAM), on average how many stents per patient and the type of stent (bare metal, drug eluting and bioresorbable), how often the stent needs replacing, the number of doctors who can perform stent surgery and the preferred stents used by surgeons.

As is common in the MD&D market, stents are not a standalone product – they are used with guidewire, balloon and catheter and will be sold in a pack. When sizing a device that comes as part of a pack, or with associated services, we need to take into account the reusable and disposable components.

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Sizing checklist

Regardless of what area of the market we are sizing, the final numbers will need to be validated against other sources. Depending on the device, sales data for existing markets may be available through import data and company reports. Market data may be available through some research companies or trade associations within the industry. Availability will depend also on the geography – e.g. more information is available in the US and European markets compared to Asian and South American markets.

Assumptions will need to be made and tested at each step of the process as a wrong assumption in the early stages could be amplified at each further stage, rendering the final estimate of the market size inaccurate.

In all aspects of market sizing, a well-balanced sample frame targeted towards practicing physicians/purchasing managers and the use of wholesale/pharmacy data, or other market data sources, will provide comprehensive market sizing from the healthcare providers' point of view.

Beyond the initial business question, and approach to market sizing, other factors to take into consideration include:

The healthcare system of the market (including structure and policy)

Indication (e.g. acute vs chronic, curable vs managing symptoms/prolonging life)

The different healthcare specialities involved in patient care

Variability in management practice of the indication between healthcare providers

Availability of published or independent data on patient epidemiology or volumes of drug usage for the indication of interest.

Factoring in the wider picture will ensure that all factors that could impact a market size are taken into consideration when calculating the final market size.

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Sizing checklist

MD&D market sizing checklist:

- Geography: which countries are to be sized?
- Capital/non-capital equipment
- Customer segment: public vs private, hospital vs retail etc
- Market type: potential, addressable, penetrated
- Top down or bottom up approach?
- Unit of measurement: single use vs. reuse, value/volume, price levels
- Associated product: (test kits, reagent for IVD platforms)
- Replacement cycle: can the equipment be refurbished or reused
- Services: maintenance, cleaning, digital connectivity, cyber security, warranty, etc.
- Product definition: what is the precise specification? Where is it used? How often is it used?

Good practice in market sizing:

- Be transparent
- Set up a balanced, representative sample frame
- Avoid self-selection bias
- Adjust for double counting of patient loads
- Keep surveys short and concise
- Run pilots
- Run data quality checks
- Triangulate the results with clients volume/sales data.

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Forecasting

Conducting a thorough market sizing exercise will identify any challenges in the chosen market ahead of preparing a forecast. For example, is the product entering an established mature market or is it entering a market that is new, and/or a niche market where there is very little or no information available?

The availability of new devices can help shape a future market by enabling patients that do not currently receive treatment, or are treated with a very different approach, to use the product. Forecasting into an established market, or a white space, can prove challenging – the aim is to conduct primary research with payers/decision makers and HCPs to understand the complexities of the market and to have clear market definitions and assumptions.

There are four key stages to generating a forecast:

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Forecasting

Market Size

The market size provides the starting point for the forecast which in turn will provide an estimate of how the product and the market will perform over the forecast period.

Assess the Market Landscape

It is vital to understand if the market is new or established and to identify the current and future competitor set. Questions to consider include: Which companies are in the current competitive set? What is the size of the competitor companies? What products are being developed? When will the new products launch? Will the new products be priced competitively? Will the new products steal market share? If so, how much and from where?

In terms of regulation it is important to understand if the product will need to be reviewed by a regulatory body or go through a health technology assessment. Are there any other potential barriers to market access?

Understanding if there is an unmet need in the area and if this can be addressed by the new product will support development of the product.

Identifying these areas will provide an in-depth understanding of the target market. The research will drive the primary research techniques needed to estimate the potential product uptake.

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Summary: Primary Research

Define and size the market | Assess the market landscape | Primary research | Forecast

A good forecast will be supported by comprehensive primary and secondary research and expert knowledge in the market of interest. Understanding of the patient journey or pathway in more complex treatment areas, such as oncology, is vital when producing a forecast.

Asking the experts about the current trends in the market, drivers of epidemiological change, advances in technology and patient journeys provides an understanding of how the market will develop over the forecast period and how the new product will fit in. Primary research is used to build in different scenarios to test and assess how the product will stand-up to changes in the market place. Understanding the main drivers of physician choice and their preferences allows us to predict the future market share of the new product.

Combining forecasting with other methodologies, such as conjoint modelling and pricing methodologies, can provide insight into answering business questions to support development and launch of the product:

- What is the best price to launch at?
- How will share of market change with reimbursement vs without reimbursement?
- How will my market share change if I change product attribute x?
- What impact will the launch of competitor Product Y have on my brand?

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Summary: Forecasting

The final step in the forecasting process is to combine the market sizing information with the assumptions on future market and product uptake into a market.

If we turn back to sizing the stent market, we have estimated how many stent surgeries are performed each year. The next step is to estimate how this demand will change in the future:

- Will the number of stent surgeries increase or decrease over the next five years?
- What will drive this change? Increase in heart disease? Change in diagnosis rates?
- Will the capacity for performing stent operations change over the next 5 years?
- What other stents will enter the market in the next 5 years?
- How will they compete with the product?
- Will there be any changes in regulations that will impact the market and the use of the product?

Feeding all of these factors into the model helps to build the future landscape for the market and the product. Once the uptake has been estimated, additional considerations may have to be factored into the forecast, such as machine replacement rates, expansion of hospital/clinics, disposable components, if additional equipment is required and if the additional components will be available at the time of launch. These additional factors could impact the success of a launch if not accounted for in the forecast.

Building scenario planning into the forecast allows for different outcomes to be forecast – this is particularly helpful in areas where there is a degree of uncertainty. Scenarios could include, how will the product uptake change if the competitor launches six months later than planned? How will uptake vary at these two price points? If the competitor launches first, how will that impact uptake?

The final step in preparing a forecast is the validation. It is imperative that the results are pressure tested – do they make sense? Is the market share achievable? Does the market share make sense?

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Conclusion

Delivering the forecast

The delivery of the final forecast is as important as all of the research that feeds into it. The forecast will be meaningless unless delivered with a clear set of assumptions. Summarise the key assumptions used in defining and sizing the market, how the competitors will impact the brand, and how/if the product will grow the market. Highlight the growth, the key drivers and drivers/constraints. Be transparent. Most of all be prepared to be questioned on the forecast. A forecaster needs to be able to defend the numbers and tell the story behind them.

A key aspect to remember is that a forecast is based on the assumptions and market information made at the time of creating the forecast. External factors will change, and assumptions will need to be reviewed and updated. Tracking the forecast and understanding when and why the actual deviates from predicted will help inform stakeholders.

A forecast produced in early stage development should not be set in stone and used throughout product development. The external market will change, unforeseen disruptors can appear, and assumptions will need to be reviewed and updated to reflect the changing environment.

As the product moves through its lifecycle, initial forecasts should be revisited, amended, adapted and enhanced as the knowledge of the market grows and assumptions become clearer and confirmed or rejected.

Conclusion

Market sizing and forecasting are integral components of a business plan. The level of complexity involved in sizing and forecasting products/markets will vary in relation to the initial business question, the therapy area and the geography. Taking a step-by-step approach to sizing and forecasting and reviewing the wider picture will provide a solid base from which to start.

Contact Us

Dr Christophe Homer | Director of Medical Devices & Diagnostics: Christophe.Homer@Ipsos.com
Liz Bates | Director of Forecasting, Healthcare: Liz.Bates@Ipsos.com

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