Small and Medium-Sized Enterprises: How Do They Fare in the UK Medical Technologies Evaluation Programme (MTEP)?

PMD118

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Objective

- To assess the performance of small SMEs, in comparison to large MDMs, in the UK NICE MTEP.

Background

- Health technology assessment (HTA) of medical devices is rarer than pharmaceuticals, due to limited clinical evidence, shorter lifespan and variable pricing.[1]
- In contrast to pharmaceuticals, the majority of medical device manufacturers (MDMs) are small- and medium-sized enterprises (SMEs).
- The Medical Technologies Evaluation Programme (MTEP), developed in 2010 by the United Kingdom (UK) National Institute for Health and Care Excellence (NICE), promotes the development and market access of new medical technologies.[2]
- Barriers to entry into the MTEP for SMEs include costs, high clinical evidence requirements and a lack of awareness of the programme.[3,4]

Methods

- The 33 published medical technology guidances (MTGs) from the NICE MTEP and their corresponding manufacturer submissions were reviewed.
- Estimates of company size were generated from the number of employees listed on the MDM's LinkedIn page.
- The proportion of MTGs from small versus large MDMs (defined as <250 and >250 employees, respectively), and trends in submissions (guidance output over time, frequency of positive recommendation and time to publication) were assessed.

Results

SMEs are Under-Represented in Published MTGs

- In the UK, 98% of MDMs have <250 employees **(Figure 1)**, whilst only 60% of MTEP sponsors have <500 employees **(Figure 2)**.

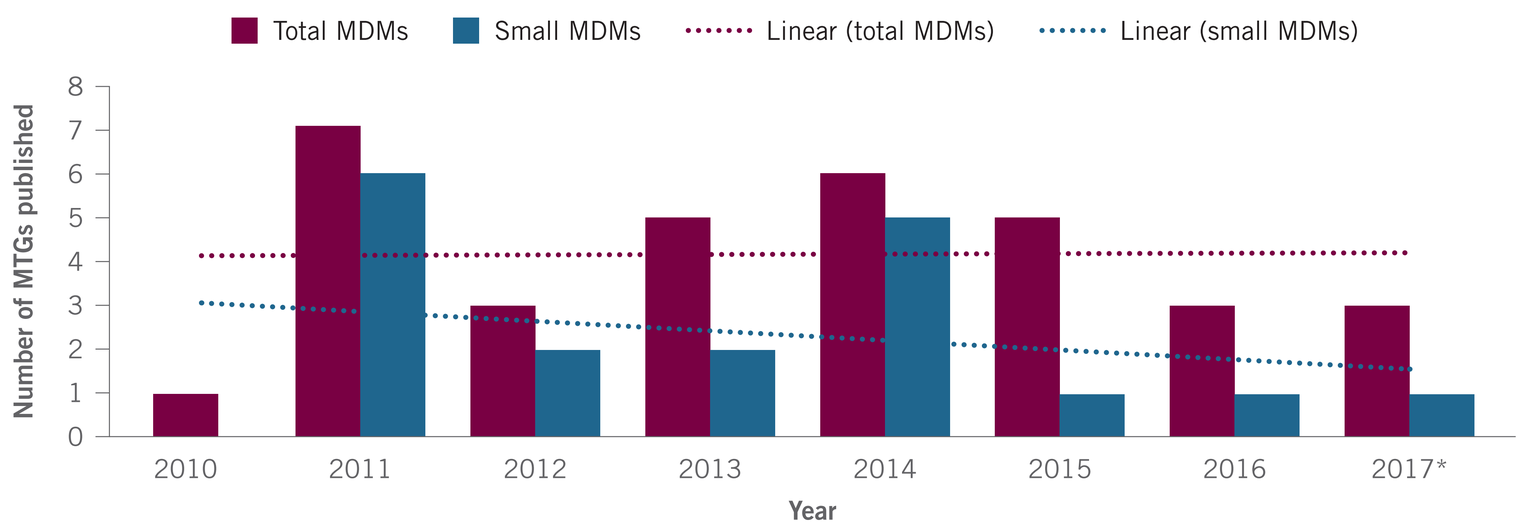
Small MDMs May Represent a Shrinking Proportion of MTGs

- The annual number of MTGs fluctuates, but has remained relatively constant over the past 8 years.
- Considering only submissions from small MDMs, the number of MTGs published each year appears to be diminishing **(Figure 3)**.

Large MDMs Receive Overwhelmingly Positive MTG Recommendations

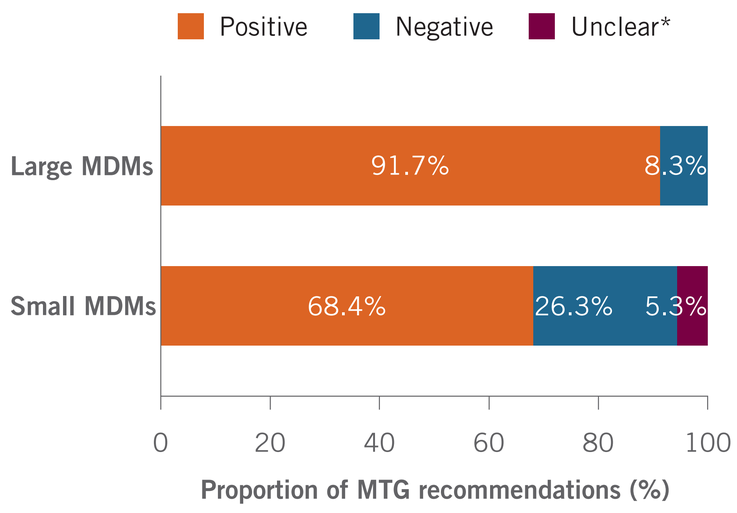
- In total, 75.8% of MTGs provided a positive recommendation.
- However, the proportion of positive guidance recommendations was substantially skewed towards large MDMs **(Figure 4)**; a lack of clinical evidence was cited as the primary reason for a negative recommendation in 100% of cases.

Figure 3 | Trend in annual MTGs published for all and small MDMs



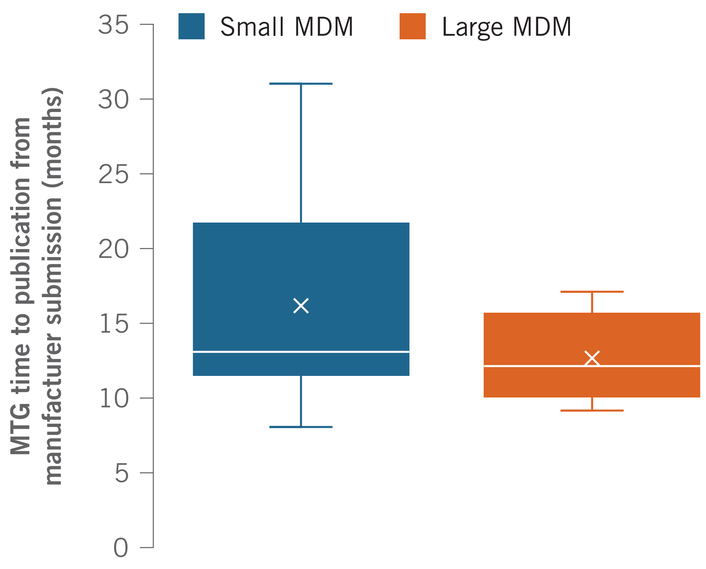
The dotted lines represent linear regressions, displaying the trend in the number of MTGs published annually across all MDMs (purple) and small MDMs (blue).
*Data for 2017 included all MTGs published up to April 2017. MDM: Medical Device Manufacturer; MTG: Medical Technology Guidance.

Figure 4 | MTG recommendations for small and large MDMs



*One MTG provided an unclear recommendation that was not categorised as positive or negative.[7] MDM: Medical Device Manufacturer; MTG: Medical Technology Guidance.

Figure 5 | Time to MTG publication for small and large MDMs



MDM: Medical Device Manufacturer; MTG: Medical Technology Guidance.

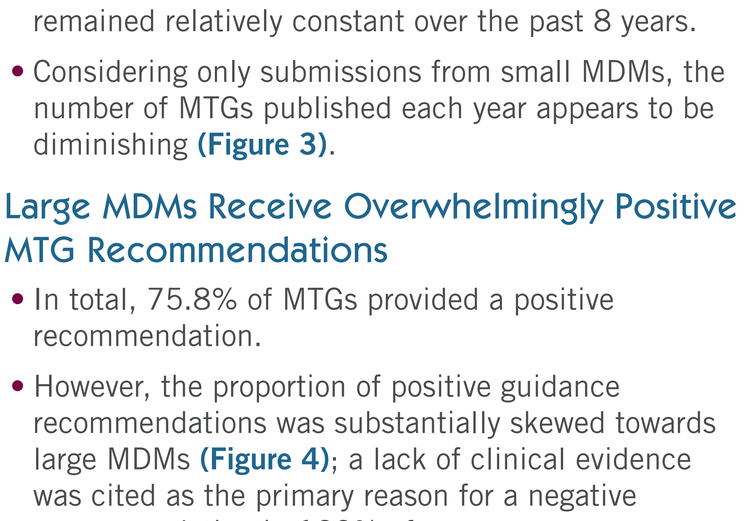
Recommendations to NICE to Improve SME Access to the MTEP

- Provide additional guidance for small companies to clearly establish the clinical evidence required to support a submission.
- Explore and illustrate how different forms of clinical evidence, such as real-world evidence or expert opinion, could be used formally to support the HTA process for medical devices.
- Emphasise the benefits of MTEP guidance and provide evidence of improved device reimbursement after MTG publication, in order to attract small MDMs to the programme.

SME Sponsored Submissions May Experience Substantial Delays

- The length of time from the manufacturer's evidence submission to NICE to the publication of guidance varied according to the size of the sponsor; SMEs experienced a numerically longer mean time to publication versus large MDMs (16.5 versus 12.6 months, respectively; p=0.13; **Figure 5**), likely driven by a number of substantially delayed submissions.

Figure 1 | Size of UK MDMs according to number of employees



Adapted from Strength and Opportunity 2015: the landscape of the medical technology and biopharmaceutical sectors in the UK.[5] MDM: Medical Device Manufacturer; UK: United Kingdom.

Figure 2 | Proportion of MTGs according to the size of MDMs

MDM: Medical Device Manufacturer; MTG: Medical Technology Guidance.

Conclusions

- The NICE MTEP is an important step towards improving HTA for medical devices in the UK. However, our analyses suggest that SMEs are under-represented in the MTEP.
- The overall positive recommendation rate for MTGs is comparable to the 78% positive recommendation rate for the NICE Single Technology Appraisal process for pharmaceuticals in the UK.[6]
- The skew towards positive recommendations and shorter appraisal time for large MDMs may reflect the inability of SMEs to provide sufficient clinical evidence to support their submissions.

References

1. World Health Organization. Health Technology Assessment of Medical Devices. WHO Medical Device Technical Series, 2012; **2.** National Institute for Health and Care Excellence. Medical Technologies Evaluation Programme: Process Guide, 2011; **3.** Sprange K, Clift M. The NICE Medical Technologies Evaluation Programme (MTEP): manufacturer submission challenges. Journal of the Royal Society of Medicine 2012;105:S4–S11; **4.** Panciera D, Satherley A, Entwistle J. The benefits and challenges of submitting to the NICE Medical Technologies Evaluation Programme: manufacturer perceptions and experiences. 2014; **5.** Department for Business Innovation & Skills. Strength and Opportunity 2015: the landscape of the medical technology and biopharmaceutical sectors in the UK, 2015; **6.** National Institute for Health and Care Excellence. NICE Technology Appraisal Guidance: Summary of Decisions, 2017; **7.** National Institute for Health and Care Excellence. Mega Soft Patient Return Electrode for use during monopolar electrosurgery, 2012.

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