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White Paper

Maximising pharma launch success in challenging times

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As the pharma industry becomes more reliant on new products to fill the gap left by the patent cliff, ensuring effective launch for novel treatments is critical. Here, CSD presents the results of its recent survey of pharma marketers exploring the challenges faced when planning for a new product launch and data sources that are most important in this process. The results highlight some common themes around market access and data integration.

In the information age in which we now live, launching new pharmaceutical products should be made easier by the wealth of data available for planning and feedback. However, a number of challenges have arisen to counterbalance this, including changing local launch environments that are increasingly payer driven and variable by geography, plus the inherent issues of combining multiple data sets together to produce interpretable insights.

"Patient data also ranks highly as an important data asset during post-launch activities"

For pharma marketers, these factors mean that the strategic planning and tactical implementation processes for launching new medicines have had to adapt considerably over the last few years. In order to understand these challenges in more detail, we ran a survey to understand pharma launch challenges, with feedback provided by 59 participants in early June 2013. Respondents came from across different company types (pharma and service side) and with variable geographic responsibility, as shown in figure 1.

Good planning and market access shapes launch success

When asked to first consider the 'helicopter view' of pharmaceutical product launch and rank a number of factors in order of how challenging they were in relation to this process, a few areas emerged strongly, as shown in figure 2.

Pricing / market access and reimbursement were ranked in the top three most challenging factors by almost every respondent (95%). Arguably, this could be reflective of the heavy UK proportion of the survey panel and the increasingly cost-constrained environment within which pharma operates in this market due to the funding challenges of the NHS. However, the message is clear that the payer has become a key gatekeeper for successful product launch. As one respondent bluntly stated,
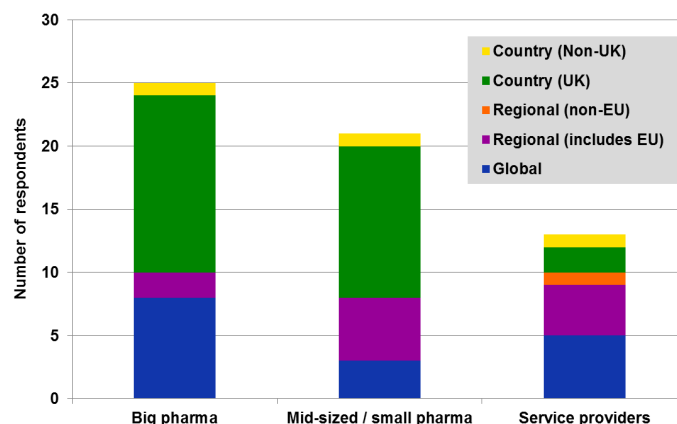

Figure 1: Split of survey respondents by company type (left) and geographic remit (right).

"without reimbursement for market access the product will fail to be prescribed", with another adding that "the level of market access you have will either make or break a product".

Two other factors were also consistently ranked within the top three most challenging aspects to product launch – market sizing / forecasting, with 75% including this in their top three, and segmentation / targeting, where just over half (54%) ranked this first, second or third most challenging. Some of the comments underlying these factors reveal a link back to the complexities of market access, with one respondent who ranked market sizing / forecasting as the most challenging factor commenting that "it is difficult to get right and has a large impact on resources made available at launch; changes in the market access environment and processes make it particularly difficult to forecast".

However, it is clear that knowing the market and putting in place the right planning is a key driver of launch success, with one respondent stating that "[market sizing / forecasting] is the most important aspect of a launch - without accurately assessing the
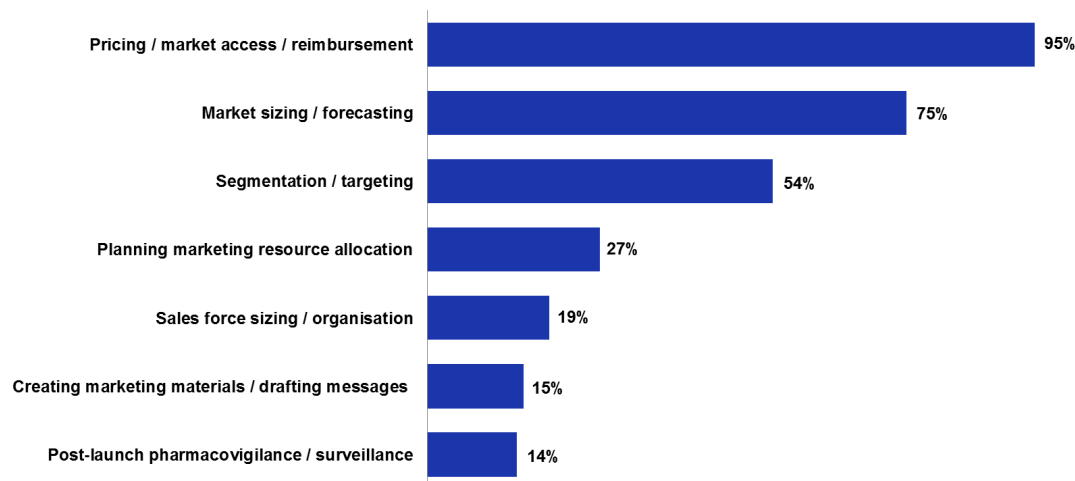

Figure 2: Proportion of respondents ranking pharmaceutical product launch considerations as the most challenging (ranked as 1-3 on a 7 point scale from 1 = most challenging to 7 = least challenging).

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market potential all other aspects of the launch will fail". Here, the problems around obtaining and collating accurate data start to surface, particularly in more complex disease areas, with another respondent adding that *"many new launches are now in specialist areas where readily available data is limited / lacking. This in turn makes it challenging to validate assumptions used in forecasting".*

The overall picture is clear – robust information that drives the right planning underpins everything else with launching new pharma products. In addition, this planning must factor in market access considerations as engaging with the right payers is as critical as interaction with the right prescribers.

Outcomes data leads sales and prescriptions

It is obviously impossible to make the right commercial decisions without the right data and insight underpinning them. In order to understand what the 'right data' looks like, respondents were next asked to rank various data sources by how important they were in optimising both pre- and, separately, post-launch activities, with the results shown in figure 3.

Whilst prescription and sales data remain key data sources in optimising post-launch activities, with 56% and 69% of respondents ranking them in the top three most important respectively, it is in the area of pre-launch data where market access again raises its head. Over two-thirds of respondents ranked health economic data and patient data, such as patient-reported outcomes (PROs) and real-world evidence as one of the three most important data assets during pre-launch activities. This ties in strongly with the need to either develop robust market access arguments to present to the payer, or face failure during product launch.

Patient data also ranks highly as an important data asset during post-launch activities, notably carrying the same weight as prescription data in terms of the

percentage of respondents ranking it in the top three (56%). This illustrates the fact that market access is rarely secured at the point of 'regulatory' launch, which instead serves merely as a starting point for such payer discussion.

Clearly, not all data is created equal and even within specific data types there is a multitude of options available to the pharma marketer. It was therefore interesting to see the feedback on what factors are defined as the biggest challenges in using data, to understand what 'good' data looks like, as shown in figure 4.

There is no surprise to see quality of data come out overwhelmingly on top, with 76% of respondents ranking it in their top three factors. In fact, it is almost surprising to see this figure is not even higher. However, looking beyond that three other factors came
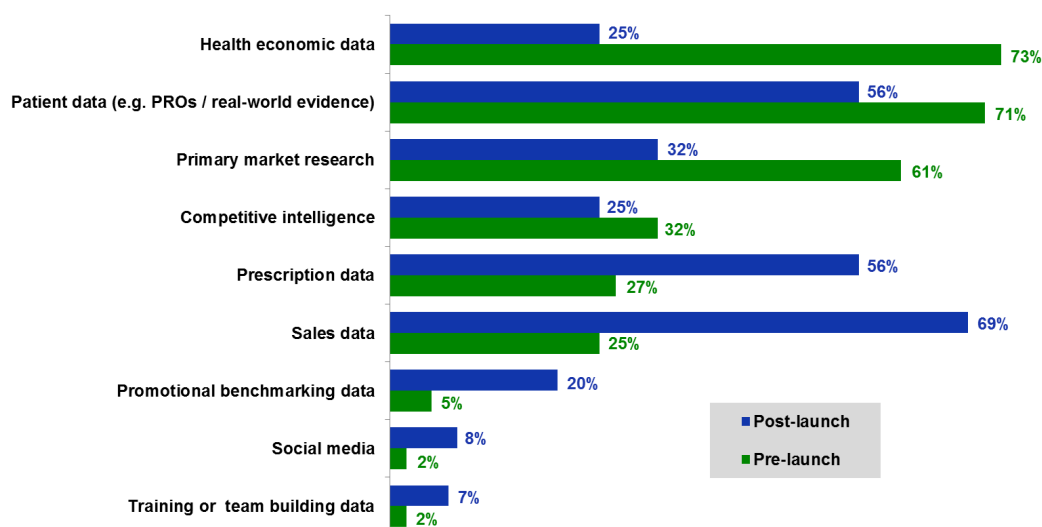
Figure 3: Proportion of respondents ranking pharmaceutical product launch data sources as the most important for pre-launch and post-launch activities for (ranked as 1-3 on a 9 point scale from 1 = most important to 9 = least important).
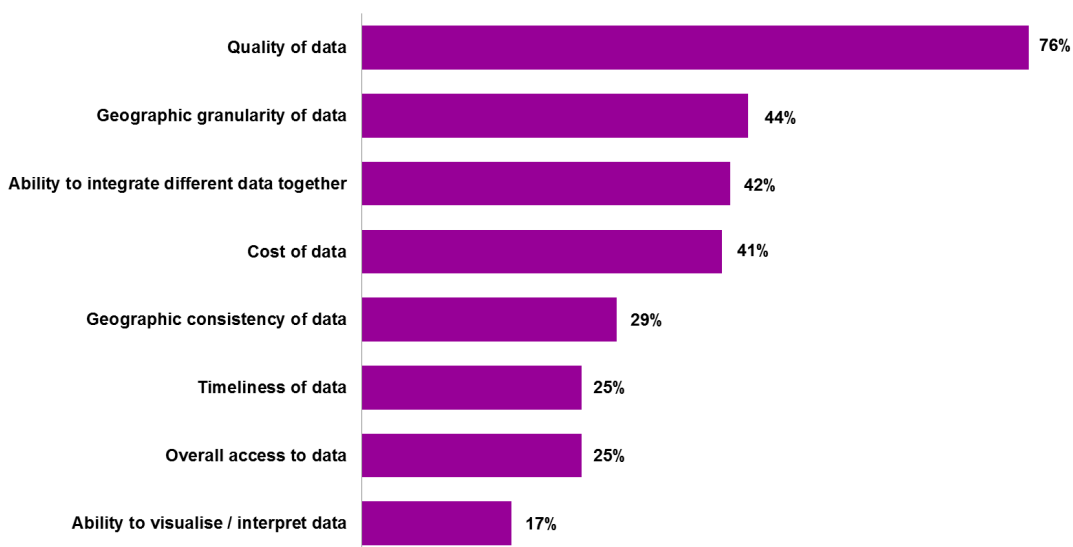
Figure 4: Proportion of respondents ranking data considerations as the most challenging when launching new pharmaceutical products (ranked as 1-3 on an 8 point scale from 1 = most challenging to 8 = least challenging).

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out consistently towards the top end of the rankings – geographic granularity of data, ability to integrate different data together and the cost of data. Ignoring cost for a moment, as it is always important, the previous two factors show that 'usability' of data is the key issue beyond quality. Without being able to utilise data down to a good subnational level and integrate multiple data sources together efficiently, it becomes much less useful in directing effective implementation.

> ## "We are using info from lots of different sources, in different formats that needs to be interpreted in a way that gives us meaningful results"

As one respondent who ranked the ability to integrate different data together as their number one challenge here said, "*we are using info from lots of different sources, in different formats that needs to be interpreted in a way that gives us meaningful results*". There is also the challenge of different data sources providing different views of 'reality', with another respondent commenting on the same aspect with their concerns over "*so many different data sources using different methodologies and often providing conflicting information*".

Structural change in the UK hinders market access

The UK has always presented unique challenges to pharma due to the cost-sensitivity of working with the NHS, but the recent changes to the NHS structure, implemented in April 2013, have presented new problems when it comes to pharma launch planning. In view of this, respondents were asked to rate how difficult it is to now implement a pan-European or global launch plan in the UK, with their response being on a five point scale from very difficult to very easy. The results, shown in figure 5, demonstrate clearly that over half (52%) see UK launch implementation as very difficult or difficult. A mere 5% categorise this as very easy or easy!

Diving beneath the surface of this overall picture, by asking respondents to rank particular factors in terms of how challenging they are for UK launch, again brings us back to the market access theme, as illustrated in figure 6.
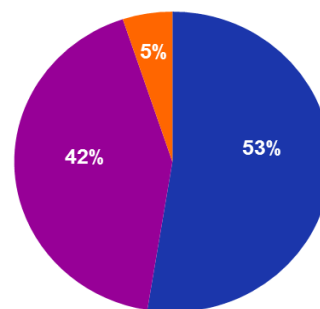
Figure 5: Split of survey respondents by how difficult is it to implement a pan-European or global pharmaceutical product launch plan in the UK market In view of the NHS changes in England.

The relative rankings of the six factors here can almost be viewed as a cascade of the pharma engagement process in the UK over time during a product launch. This starts with gaining national reimbursement approval, which was placed in the top three factors by 75% of respondents, with one adding for clarity that "*local payers will lack interest if national reimbursement has not been achieved*".

The downstream flow then continues into gaining positive local formulary status (63%) and identifying key local payers (53%), interspersed with 54% of respondents also ranking understanding new NHS structures, roles and responsibilities in their top three UK launch challenges. Notably, the traditional customers of the pharma industry – key opinion leaders and prescribers – come much lower down the list. Comments made here include observation that "*under NHS reform, identifying the right payer (who has the decision making authority) is increasingly difficult*," and "*in today's NHS, no formulary inclusion equals no sales*".
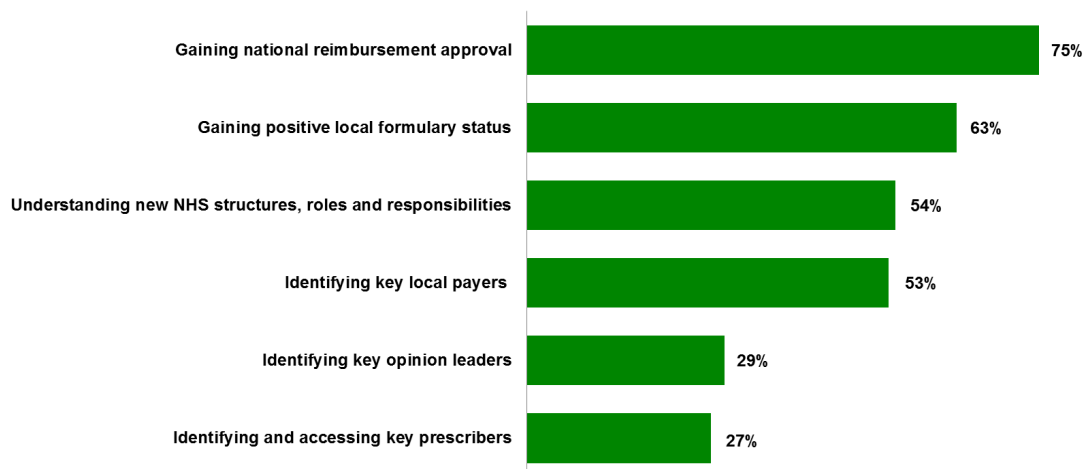

Figure 6: Proportion of respondents ranking UK specific market activities / processes as the most challenging when launching new pharmaceutical products (ranked as 1-3 on a 6 point scale from 1 = most challenging to 6 = least challenging).

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So understanding the new NHS structure and the decision makers within it is critical. It is also something that pharma cannot solely rely on field force feedback for, as one respondent wryly stating that *"before we can do anything we need to know our customers…even the NHS doesn't always know!"*.

Can the 'big data' project of releasing NHS information into the public domain help here? Well, on a four point scale from 'very interested' through to 'not at all interested', two-thirds of respondents (65%) were 'very interested' in such data becoming more accessible and user-friendly. However, the value of discrete NHS datasets is only fully realised when they are integrated with other public domain information, and relevant national and sub-national patient, prescribing and promotional intelligence.

Effective data integration and decision maker identification drive success

Overall, some key themes emerge from this survey around the challenges faced by the pharma industry in launching new products. Availability of information is no longer the major issue, with the

"Under NHS reform, identifying the right payer (who has the decision making authority) is increasingly difficult"

focus now moving onto data quality and how best to seamlessly integrate data together from different sources. Market access is driving the agenda here, with health economic and outcomes data being the new currency of success, alongside the ability to accurately identify the right decision makers. Increasingly, the core initial stakeholder is the payer, with the 'clinical' customer being more important only once this hurdle has been jumped.

The UK market also presents some unique challenges, with a new structure for the key 'customer' of the NHS and the prospect of freely available new data sources coming online. However, the challenges this presents of identifying new payer decision-makers and conducting 'big data' integrated analysis are global issues. Forward-thinking pharma companies will focus on addressing these points, if they are to shape the successful launch of the future.

About Cegedim Strategic Data (CSD):

Cegedim Strategic Data (CSD) is a leading market research company dedicated to the healthcare industry and operating worldwide.

With over 40 years' experience in the pharmaceutical industry, Cegedim Strategic Data offers a comprehensive range of primary and secondary market research services and solutions to its customers, which include more than 50 global and 500 local pharmaceutical companies.

CSD is one agency that has made newly available NHS prescribing data easily accessible to its customers and, by combining these data with its leading syndicated patient and promotional databases, offers valuable additional insights into practice potential, patient profiles and treatment and the impact of sales and marketing campaigns. To learn more, please visit our website: **www.cegedimstrategicdata.com**, email: **infocsd@cegedim.com** and follow Cegedim Strategic Data on Twitter **@CSDCegedim**.

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