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Round Table

What does the UK life sciences sector need to change in order to be prioritised more often by global firms as a leading market for new product launches?

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Agenda

- How is the UK market currently perceived as a place to launch?
- What are the most attractive features of our home market, and conversely, what are the inhibitors?
- How do VPAG and other pricing and reimbursement models impact upon the UK market?
- Does the European JCA provide an opportunity for the UK?
- Do the challenges differ for rare disease product launch? Are they the same, but amplified challenges?
- Are regulatory agencies attuned to industry's increased utilisation of RWE?
- What can we do to improve the situation?

Chair's Summary

The challenges of securing market access are complex and multi-faceted. This provided the context for our discussion, and I was delighted that as with our previous round tables, we benefitted from the experience, expertise, evidence-led debate and insights offered by our expert panel. We were joined by market access leaders from a range of biotechnology and pharmaceutical companies, corporate affairs and communications professionals, and leading experts from market access and Health Economics and Outcomes Research (HEOR) consultancy businesses.

While the central question of our discussion focused on what the UK life sciences sector needs to change to be prioritised more for new product launches, we did not want to limit ourselves to thinking about the UK market. Ours is a global industry, and we had the benefit of a rich mix of international experience around the room. Our panellists included people with experience and current responsibilities across Europe, the Asia Pacific region, and the North American market. We recognised that while we did not want to address the topic in a nationalistic fashion, we all have an interest in the UK being a successful location for product launches.

In a wide-ranging discussion, we considered issues relating to the launch of new drugs and treatments in the UK. Panel members also offered perspectives on current practices, issues, challenges, and trends in other markets. Perhaps reflecting the broad range of experience across the panel, we heard about the ups and downs, the challenges, and opportunities we face in the market. To enable a productive outcome, we focused on what actions we could take ourselves, and what we need from others to make the UK a more attractive place to launch. The discussion and conclusions are set out below.

I was pleased that our conversation covered the opportunities presented by improved utilisation of real-world evidence, the importance of hearing the patient's voice, and the value of taking a collaborative approach. This last point highlighted to us that while we had a broad and diverse panel of participants, we could further develop this conversation by hearing the voices of regulators. As an industry we want to see alignment across government departments in support of innovation and we will benefit from hearing the regulators' perspectives. We also noted the opportunity to broaden this dialogue to engage more with medical device, medical technology, and digital health experts, and to hear more about the patients' and medical practitioners' concerns.

Geoff Dobson
Discussion Chair

Discussion

Throughout our conversation, it was evident that while the UK market can be a tough environment for product launches with many challenges, there are significant advantages, and it is up to the industry and government to find ways to utilise these opportunities.

Life sciences industries and their affiliated businesses, and higher education are two of the UK's most important economic sectors. The UK has world-class universities, research institutions, medical charities, and patient advocacy groups. The UK's biotechnology and pharmaceutical industry works together with the research communities to generate significant discoveries and innovations. The rigours of our regulatory approval processes and institutions, while a challenge also act as an advantage. The credibility gained from the National Institute for Health and Care Excellence (NICE) approval should not be underestimated, even if the landscape is changing with the EU adoption of its Joint Clinical Assessment (JCA).

Pricing is still a challenge in the UK, with many life science companies preferring to invest and launch in the US or German markets, especially where randomised clinical trials may have been completed. The UK's relatively low spending per head on healthcare and medicines compared to countries such as Germany, the US, and Japan, is also seen as an important factor when companies are deciding where to launch.

We discussed how we can perceive other markets to be easier, and we may see the challenges of the UK market more clearly as we are close to them. While we can summarise some pros and cons, there is always nuance. The UK's NHS offers a fitting example of this conundrum. The NHS is a well-developed institution. It has advanced and credible approval processes, but the NHS is not always an easy place to conduct research. However, the use of Real-World Evidence (RWE) and Real-World Data (RWD) collection is increasing. It is also important to note that as well as being necessary for UK market access, UK NICE approval is still seen to be of value as an endorsement for launch in other markets.

The table opposite may help summarise and provide a framework to appreciate the issues highlighted by the participants in our round table.

Advantages	Challenges	Neutral factors and changing environment conditions
• World-class university research • World-leading medical research institutes • Active and vigorous medical charities and patient advocacy • The NHS as a (broadly) integrated healthcare system • Credibility of NICE and associated regulatory and approval work • Willingness to consider RWD and RWE and other innovative research methods	• Pricing challenges associated with NICE approval • Comparative lack of clinical trial activity in the UK compared to USA, Germany, and some other locations • Market size in relation to other important markets • Lack of joined-up thinking at policy level between Government, biopharma organisations, research institutes, charities and patient groups • EMA no longer based in the UK but in the Netherlands • VPAG	• The emergence of the EU JCA • Social and political change in Germany that has already and may continue to reduce the attractiveness of Germany as a location for clinical trials and product launch • Changes in political power and leadership in the UK, across Europe, and in the USA • The emergence of RWD collection capabilities and RWE analysis and interpretation • New and emerging digital health technologies that combine clinical treatment process, patient monitoring, and data collection

NHS

While the UK NHS is admired around the world, it would be a mistake to think of it as a fully cohesive and integrated organisation. It is a confederated model and, in many ways, not as ‘joined up’ as we may think, hope, or want it to be. It is not always an easy or the most desirable location for product launches. One must offset the benefits of a well-developed and credible regulatory approval process with the often-complex challenges associated with clinical research, launch, pricing and other factors.

More open-mindedness about methodologies, data collection and patient engagement

One panellist explained that the UK is now more willing to consider innovative research methodologies and forms of data collection. Furthermore, the role of patient advocacy groups, many of which are headquartered in the UK are advantageous and will be further developed in offering access to valuable Real-World Data for numerous conditions.

Long term returns versus lower initial pricing

While it was agreed that the UK was a tough market for a product launch over a five- to ten-year period, the UK may be a better place to do business than other European markets, where there is continuous price degradation both at a national and sub-national level. As one participant explained *“I have worked in global roles, and in my work if I took a longer-term view, I could often see advantages for the UK. It might not be the biggest market, or have the best margins, but longer term price stability is valuable.”*

In contrast, another panellist reported that their company had launched products in the UK, but they needed to break the floor price to get it across the line for approval from NICE.

“It might be quite interesting to see what would happen if they removed the confidential pitch access scheme. I think a lot of products just wouldn't be launched in the UK. The price in the UK is much lower than a lot of other European markets”.

In addition, the rate of adoption of new products in the UK is not at the level many of us would wish for. Even with a positive NICE recommendation, it's not guaranteed that the product will be successful in terms of patients accessing the medicine.

One participant shared a view that said the UK is not on a par with the rest of Europe or the US in terms of translating discovery and innovation into usable approved products despite the UK’s output in life sciences research. We also discussed perceptions of a lack of connected thinking at national political and policy levels to optimise the relationships between investment in life sciences research, new product development, approval and availability to patients.

Rare diseases - a need for more flexibility

The costs associated with regulatory approval in the UK were also raised. The UK is still using a Health Technology Assessment (HTA) model that was originally developed several decades ago to deal with single medicines. One participant suggested that smaller, innovative companies could struggle with the costs of submission for rare disease products.

We heard mixed views about the challenges and opportunities for innovations in the treatment and cure of rare diseases. One participant described how they have worked with regulators and companies to address initiatives designed to support managed entry agreements for rare disease drugs and for oncology patients. However, others felt that the supposed concessions were not material. Costs of regulatory submission remain significant and rare diseases may add complexity and not benefit from scale.

Another panellist also argued that the definition of a rare disease is simply too demanding to be effective. They went on to add that new products for symptomatic relief or the slowing of a degenerative disease don’t attract prices that compensate for the investment in research and development. HTA models that appropriately measure and calibrate the cost / benefit model for pricing do not generate feasible returns for non-curative treatments. Another round table member commented *“Sometimes it feels like the cost side of the cost / benefit equation is the only thing really calculated”.*

Why UK NICE Approval is still valued

The round table heard that NICE remains such an influential organisation outside of the UK, whereby companies are willing to accept a lower price, even breaking the floor price, to gain regulatory approval, as it would be worth the positive impact in other markets. However, this might change with the development of the JCA method of combined appraisal in Europe. One panellist said, *"I think the influence of NICE is going to go down, and a lot of companies will say 'I'm not going that low with my price, because NICE approval is not that important to us anymore'."*

However, others maintained that the EU JCA is still in its infancy and is relatively unproven. NICE remains credible and influential with other regulatory bodies and internationally based companies, as they see it as the benchmark standard for approval in their own markets.

The experience of working with NICE was a discussion topic that engaged the round table members and prompted a variety of comments.

One panellist saw differing aspects of their experience with NICE. They felt that in several ways NICE has operated as an innovator and an enabler, particularly in relation to the adoption of RWE.

Another contributor suggested that NICE is centre of excellence for HEOR, and they take pride in their methodology. However, this contributor felt many problems with market access in the UK lay with the lack of connection and smooth working between NHS England and the Department of Health.

A third person shared their observations that working with the UK NHS and NICE can offer excellence in research, pre-clinical and clinical development, but the NHS is a slow adopter of artificial intelligence technology. This panellist argued that there is too much of a culture of gentle, controlled evolution, and that a willingness to accept some revolutionary and disruptive steps could

enable much more rapid and far-reaching progress.

In a constructive contribution that led us on to our next theme, one round table member calmly but purposefully stated their view that collaboration is the way forward. They also highlighted that we as a group could feel connected and able to share our experiences, but we do need to engage with others including policy makers to explain ourselves and make our case for change.

A need for a more cohesive system and "joined up thinking"

The roundtable heard that, while there are still many advantages for life sciences product launches in the UK, the lack of alignment between the Department of Health and Social Care and innovation presents a large barrier. As one participant remarked *"Joined up thinking of the government is absolutely critical, because there's no point in having all these great innovations and rigorous approval processes in place if at the end of the day, patients are not getting access to the medicines."*

Another panellist explained that they felt the considerable HTA expertise across the UK academic sector and research institutions is not really being considered in terms of clinical outcomes and patient benefits in negotiations *"There is this huge rigidity. NHS England is just such a tough negotiator to deal with. They are not afraid to say no. It's all just about price and cost, not benefit."*

An idea mooted in the conversation suggested that the impact of a UK NICE evaluation was still highly regarded, and to encourage UK launches, one participant commented: *"As an industry we should watch for the opportunities to leverage collaboration possibilities with the rest of Europe. Patient needs are common*

across geographic boundaries, and the UK's research, innovation and approval infrastructure can be used as leverage for the benefit of many markets, across Europe and beyond."

Politics and Policy

NICE's reputation for excellence may be a strategic advantage, but there is only so much the regulator can do if the problem is the lack of joined up thinking between NHS England, the Department of Health and Social Care and the Treasury. As one panellist remarked: *"There is complete detachment from something like VPAG, NHS and individual hospital trust integrated care departments."*

It was suggested that the key to solving this disconnection can best come from positive collaboration. One participant who has recently engaged with NICE said they came away from the meeting with a genuine feeling that the NICE representatives are truly focused on the need to provide access to treatments that provide benefits to the widest population possible.

"There's no doubt that there are many solvable problems from a lack of cohesion. The way we solve that is to get everyone around the same table."

Skilled adoption of AI, RWD and RWE

An open-minded, positive approach to utilising the advantages of being a leading adopter of AI, Real-World Data, digital technology, and RWE analysis could be a significant opportunity to increase and improve the impact of UK product launches. The round table discussed how data collection and analysis is another global need and opportunity in life sciences. There is innovation, and a willingness – particularly from the USA – to invest in

data collection, management, and analysis. Data ownership rights and patient confidentiality are important aspects of this advancement, but these factors can be managed if the focus remains on patient benefits and the value of data is protected.

As one panellist remarked, *"A great thing about the NHS as one big, nationwide organisation is that however hard it may seem to us, data collection is much easier than in other markets."*

The roundtable heard that Wales has one of the world's biggest medical datasets, which is operated on a managed *"open access"* model, but cannot be traced back to any individual patient data set. Furthermore, the NHS Wales data is being analysed to link health outcomes to social determinants of health, income and various other things. *"That's one of the few life science and patient databases in the UK and Europe that allows you to do that end-to-end",* one participant explained.

Linking clinical trials and product launch

Demonstrable progress in the UK across the utilisation of AI, RWD and RWE at the clinical research stage should, the round table concluded, create new reasons to locate clinical trials in the UK. Historically the UK was seen as a favoured

location for clinical trials, and this feeds into product launches. In more recent years, the UK experienced a significant drop in the number of new clinical trial projects. Germany, Netherlands, France and the USA have been attracting more trial work. However, there has been some notable effort at the UK national policy level to regain credibility as a location for clinical trials, with strong links to our research infrastructure and our life science businesses. One person commented *"We must try to change the perceived advantages, and the anticipated reward structure to change behaviour. De-risking through AI data sets could be an interesting way to do that."*

Other issues considered by the round table included how US companies are prepared to pick up much of the costs of life science R&D, even to disproportionate levels, as it can enable market access. One participant remarked, *"if you don't have enough collective clinical experience, it's hard to get clinical advocates to the NICE committees and this exacerbates the problem."*

This panellist went on to say that in their experience, one of the keys to negotiating with the NHS was making sure a product fits in with its priorities. *"I think if you talk the language of what their priorities are, doors do open. NHS England has an excellent accelerated access collaborative unit, including the rapid uptake of products. I was lucky enough to be on one of those groups, that brings together NICE, NHS England, charities, patients, and the industry to work out how best to drive the adoption of medicines after a positive NICE review, and I think that's a really good way of doing it, and they should do more of that."*

The patients' voice and RWE in approval and product launch

So, what role should patients and their advocates take in this process? They do provide comments during the NICE process, something the other agencies across the world have tried to model, the roundtable heard. *"I think from that perspective, my opinion is that the UK is quite up there in terms of getting patient advocacy and patient input"*, one participant stated.

Despite this, some panellists questioned whether this input was making a difference and was seen by regulators as of actual value.

The round table broadly concluded that the UK's and other regulatory agencies' attitudes toward increased utilisation of patient voice and other RWE are evolving in a positive direction. Currently, there is, perhaps, more evidence collected than utilised in the decision-making process.

"There is a lot of acceptance of work being done", observed one round table member. *"It joins again back to our conversations of the general methodological and data treatment approaches that are well established and nicely done in the UK. Can it influence the other countries? Can it have an influence on the rest of Europe or other markets? Yes, this collaboration will have to. We must find a way to do that."*

Furthermore, the panel felt that NICE is willing to accept appraisals where an external control arm has been utilised, acknowledging at times that this is the best linkable data. There even seems to be an increasing acceptance of Flatiron data, the roundtable heard. There may also be opportunities to influence JCA approvals, but we heard that these can be heavily dominated by the process, rather than the data. One participant hoped that there will be more acceptance of research that confirms the patient and clinical benefit downstream, and more opportunity for reassessment of what provides value.

Another panellist, whose company had used Flatiron data sets, said that while NICE doesn't like beginning with Flatiron data, they will look at it and review it. However, it was suggested that using real-world evidence is not the issue. What is more of a problem is how to collect it, the resources needed and the cost.

One participant proposed that collecting real-world data could create opportunities for modulating prices as we would know more about how the products are used, the outcomes and patient impact, *"I think that's a real missed opportunity. And I think NICE should encourage more companies to be brave and go down the complex patient access scheme route."*

It was suggested in areas such as the MS space, multiple treatments could be joined up, but this is not currently happening.

Digital health is however bucking this trend, using real-world evidence to evolve and develop products, with companion apps having two releases per year. Further innovations are expected to come from other digital health innovations, some of which are attracting considerable investment. Advances in preventative medicine through devices such as wearable technology.

Can the life science industry support and enable change in the NHS to encourage product launches in the UK?

While there could be mutual interests and shared benefits from product innovation in the UK, achieving change in complex organisations is difficult, and the NHS is one of the most complex organisations in which to achieve change. One round table member suggested that the life science industry could facilitate and encourage change by demonstrating positive experiences of using real-world data in discussions with NICE and other regulatory bodies.

One barrier to this would be that the NHS uses multiple systems for prescribing medicine and the panel agreed that this is unlikely to change quickly. Local systems for prescribing are learned, embedded and would not be simple to change. Similarly, the NHS has not had sufficient investment in IT systems to make such change operationally manageable.

It was suggested that Health Secretary Wes Streeting's view that the NHS is broken could be an opportunity for the life sciences industry to put forward some radical ideas.

One panellist said that the Innovative Licensing and Access Pathway (ILAP) offers potential for early engagement between researchers and regulators in the UK to look at how to make clinical trials more efficient and fit-for-purpose. Furthermore, a joined-up process, where companies get their licence and reimbursement very close together, could also act as a catalyst for change to every party's benefit.

"The UK could become a real life sciences and healthcare economic powerhouse, for research and product launch if the UK retains its world-class discovery and translational medicines research" one panellist suggested.

To embed and retain this, it will also be important for the UK to benchmark itself against other comparable countries in an objective and impartial fashion. Another participant added, *"We need to elevate this to a more senior level in the political environment, calmly and objectively, and then get everybody around the table speaking to each other. We need to adopt a "level playing field" mindset to work together. We cannot just talk and operate as individual representatives of the parts of the system, like industry representatives, NHS representatives, the regulators, and so on. We need to become impartial, collaborative, and constructive in our assessment."*

The round table members concluded that effective collaboration is vital and schemes like the Accelerated Access Collaborative initiative (AAC) should be rolled out more widely and done for more NICE-approved products wherever possible. Increasing public understanding of what the life science industry does, and the efforts involved would also help. It is important to change public perceptions of the motivations and interests of the industry as it helps determine policy, and in turn, stimulates action to implement the measures that the life sciences industry must take to meet patients' and medical practitioners' needs. Parts of the mainstream and social media channels can portray the commercial elements of life sciences companies in a negative and unhelpful light. The panel members concurred that more could be done to constructively highlight the world-class research and development the industry delivers in conjunction with the medical professionals and other partners to fight diseases, improve patient lives and find cures for previously untreatable conditions.

Conclusion

Round table Chair's conclusions, next steps, and the voices we still need to listen to

A duty of the Chair is to manage the time during a round table discussion. It is also a sign of a good meeting to feel like we have not had enough time to explore all the issues raised. My thanks to all participants for investing their time in the meeting.

We set out to think constructively about what we – as active players in the industry – should be doing to make the UK a more positive environment for product launch. It is not surprising that with the depth of expertise around the table we had a lot to consider. It is also understandable that we could have become bogged down by complexity and worries about things seemingly beyond our control. However, I was delighted that we collectively demonstrated our interest, commitment, and ideas about how to achieve goals that focus on patient outcomes.

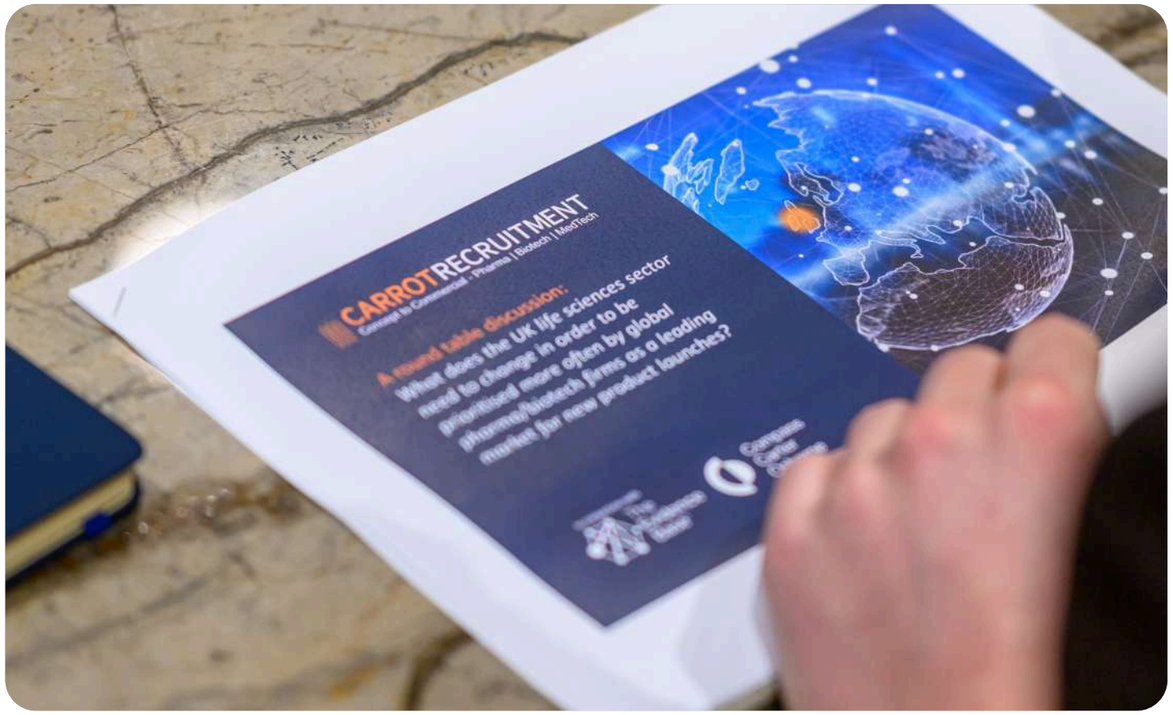
Without repeating every detail, some highlights for me include:

- Enthusiasm around the room to build the links across our ecosystem from discovery research, through translation, clinical development, product launch and medical surveillance.
- A fundamental belief that patients are the most important people in this endeavour.
- A willingness to learn from each other, across our part of the life science arena, and across our worldwide community.
- A drive to make the best use of real-world data and real-world evidence, not just to enhance and accelerate approvals and product launches, but to monitor patient outcomes.
- The desire to harness the benefits of digital health technology to enable better data collection and patient monitoring.

I hope that this report reflects the significant recognition that we reached about the need for joined up thinking to optimise discovery research, investment, clinical development, market access and product delivery; and to align all this with public policy, political commitment, and a more positive public perception of our industry. I am very grateful to two-panel members (unnamed, to prevent embarrassment, but they know who they are) who also reminded us that while our panel membership reflected an interesting mix of representatives from different companies, consulting firms and other advisors, we had not heard voices from patient advocates, from our colleagues in medical devices and medical technology, and crucially, we did not have panel members from regulatory organisations or the Department of Health.

It is a natural conclusion that we should make efforts to continue our dialogue and extend participation to cover these other voices. I look forward to reporting on our next steps in this regard.

Geoff Dobson
Non-Executive Advisor, Compass Carter Osborne



Glossary and useful background information

Accelerated Access Collective (AAC): *An NHS initiative and new organisation to bring together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking new treatments and diagnostics which can transform care. The AAC supports all types of innovations: medicines, diagnostics, devices, digital products, pathway changes and new workforce models.*

Health Technology Assessment (HTA): *HTA regulations were adopted by the European Parliament for EU states in December 2021. These countries measure the potential benefit of a new healthcare technology against its cost using HTAs. While the implementation of innovative technologies to improve the standard of care is essential, their affordability needs to align with the budget and goals of healthcare systems.*

The UK has three HTA bodies for its constituent countries: *the Scottish Medicines Consortium (SMC), NICE, and the All-Wales Medicines Strategy Group (AWMSG). These bodies assess health technologies using a cost-per-quality-adjusted life year (QALY) method. QALY is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One quality-adjusted life year (QALY) is equal to 1 year of life in perfect health.*

Innovative Licensing and Access Pathway (ILAP): *A new pathway from the Medicines & Healthcare products Regulatory Agency (MHRA) supporting innovative approaches to the safe, timely and efficient development of medicines to improve patient access. ILAP aims to accelerate the time to market, facilitating patient access to medicines. These medicines include new chemical entities, biological medicines, new indications, and repurposed medicines.*

The ILAP is open to both commercial and non-commercial developers of medicines (UK based and or global). It comprises an Innovation Passport designation, a target development profile (TDP) and provides applicants with access to a toolkit to support the design, development, and approvals process. The current pathway closed for new applications in November 2024, and the new, revised 2025 pathway will receive applications from March this year.

Joint Clinical Assessment (JCA): *The JCA is a collaborative initiative among EU member states to streamline clinical assessment of new health innovations. JCA has the potential to significantly improve the drug assessment process in the EU. By coordinating assessments across different regions and countries, the JCA could reduce regulatory barriers and streamline the assessment process, potentially speeding up drug approvals and improving access to new therapies for patients.*

National Institute for Health and Clinical Excellence (NICE): *The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care. NICE is a significant organisation that impacts upon the uptake of new drugs, medical devices, medical technology, and procedures in the UK. (See also the section above on HTAs.) The UK has robust measures in place to ensure that medicines and vaccines are both clinically and cost-effective before they can be used in the NHS. NICE is the body which advises the NHS on whether a new medicine is cost-effective; It does this by comparing how much it costs to give a patient an extra year of 'quality life' compared with the treatment already being used. Although a UK organisation, NICE approval or otherwise is taken into consideration in many other countries.*

National Institute for Health and Care Research (NIHR). The National Institute for Health and Care Research (NIHR) is the British government's major funder of clinical, public health, social care and translational research. With a budget of over £1 billion, its mission is to "improve the health and wealth of the nation through research". As a research funder and research partner of the NHS, public health, and social care, the NIHR complements the work of the Medical Research Council. NIHR focuses on translational research (translating discoveries from the laboratory to the clinic), clinical research and applied health and social care research. Although a UK organisation, NIHR is influential on the global stage and promotes access to and sharing of research data.

Real World Evidence (RWE): *Pharmaceutical Real-World Evidence (RWE) looks beyond clinical trial data. It can provide insight into how patient characteristics and behaviours affect clinical and patient outcomes. Thereby, it helps to predict the course and progress of the disease, a patient's response to therapies, or the risk of adverse events. Also, it makes research and development (R&D) investments more efficient and accelerates time-to-market. RWE has been in use for many years, but recent advances in digital health have increased and made more efficient the collection and analysis of data.*

2024 Voluntary Scheme for Branded Medicines Pricing and Access (VPAG): *This Voluntary Scheme is an agreement between the UK government, the NHS, and the pharmaceutical industry.*

It is one of the many longstanding policy tools used in the UK to ensure the NHS gets the best possible value from the medicines it uses. It operates alongside health technology assessments, the budget impact test, and all existing mechanisms to encourage market competition for medicines such as procurements and tenders.

The scheme ensures the NHS does not overspend its allocated branded medicine budget, even if it ends up using more medicines than forecast. To achieve this, the pharmaceutical industry commits to returning NHS overspend in the form of sales rebates.

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