Enhancing the role of UK medicine regulation

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Global Counsel RESEARCH PARTNER

Contents

"An internationally competitive regulatory framework is crucial for attracting investment and positioning the UK as a global leader for Life Sciences. By optimising and streamlining the regulatory framework we can attract increased investment, foster economic growth, and support the NHS. These changes will help improve UK patient access to innovative medicines, compared with other countries and support the Government's priority of improving the health and wealth of the nation."

Chris Stokes, President & General Manager, Lilly UK, Ireland and Northern Europe

"The UK's life sciences sector is renowned for its scientific innovation, and a strong, agile medicines regulator is critical if patients are to benefit from the latest treatments. The MHRA's expertise has long been globally recognised, and by enhancing its regulatory framework as outlined in this report, it can secure the UK's position as a leader in life sciences."

Peter Wickersham, General Manager for Gilead Sciences Ltd, UK and Ireland

"The MHRA plays a central role in safeguarding public health and incentivising investment in research and clinical trials for medicines in the UK.

For the UK is to compete internationally and ensure UK patients can access new, innovative medicines, we need an adaptable regulatory framework that provides even greater flexibility in the assessment process. This report highlights the importance of a robust and effective medicines regulator in the context of an increasingly competitive global marketplace for innovative medicines.

The MHRA has an opportunity to set itself apart and provide a unique, expert offer that supports the UK in becoming a global leader in medical innovation and medicines access. We welcome the findings of the report and look forward to working collaboratively to support the implementation of its recommendations."

Simon Newton, General Manager for UK & Ireland, Jazz Pharmaceuticals

"The UK is falling behind comparable countries as an early launch market for new medicines. We need a globally competitive regulatory system that works hand in hand with NICE to ensure accelerated assessments of new innovative medicines. This can be achieved by sufficiently resourcing the MHRA to be a regulator at full capacity.

The new Government has rightly identified the life sciences sector as a critical partner to deliver positive change and economic growth. A re-energized regulatory system in the UK would lead to faster patient access to new innovative medicines and a healthier population, as well as increased inward investment from Life Science companies."

Rippon Ubhi, Country Lead and General Manager for Specialty Care, Sanofi UK & Ireland

"In a rapidly evolving healthcare landscape, a flexible and responsive medicines regulator is crucial for ensuring that the UK remains a leader in unlocking the benefits of medical science for patients. By prioritising innovation and adaptability, we can build a healthcare system that not only drives medical progress but also protects the health of our communities."

Guy Oliver, General Manager for Bristol Myers Squibb UK and Ireland

"We welcome the ABPI's report and its emphasis on creating a globally competitive regulatory framework in the UK. As a company deeply invested in innovation, we chose the UK for its world-class science, research infrastructure, and strong public-private collaboration ecosystem. The report rightly highlights the importance of predictable, transparent regulation and robust resourcing to attract investment and accelerate patient access to new medicines. Initiatives such as the Regulatory Innovation Office and strengthened international partnerships are vital steps toward ensuring the UK remains a leader in life sciences and innovation, fostering transformative outcomes for patients and healthcare systems worldwide."

Darius Hughes, UK General Manager, Moderna

Foreword

The ABPI wants the UK to be the best place in the world to research, develop and use the medicines and vaccines of the future. Continued UK excellence in regulation is key to the success of our sector, as it underpins the high trust and regard patients have for our products, and enables us to rapidly bring new innovations to those who can benefit most.

As the Medicines and Healthcare products Regulatory Agency (MHRA) embarks on a new phase in its leadership, and the new government seeks to improve UK regulatory standards across the board, this report brings together our industry's contribution to shaping a globally leading UK regulatory framework for innovative medicines. Central to our recommendations is an ambition to rebuild the UK's world-class reputation in regulatory science, medicines' development and licensing, which has unfortunately seen a number of setbacks and challenges in recent years.

The MHRA has a critical role in the wider UK life sciences ecosystem. We continue to believe it can be among the best regulators in the world at both regulating innovation and innovating regulation, despite a period of recent challenge.

Our 12 detailed recommendations are found at the end of this report and are framed under these main themes:

- **Enhanced communications, transparency and accountability:** Pharmaceutical companies depend on finding regulatory and technical information quickly and easily and require access to performance metrics that inform the planning of product launches. Companies also need to have dedicated points of contact that provide relevant and timely information, particularly for scientific and technical advice and procedural queries, facilitated via stronger internal and external accountability mechanisms.
- **Resourcing and expertise:** Regulatory authorities need to provide expert opinion and consistency in approach, keeping up to date with evolving technological advances. A well-resourced regulatory authority should provide predicable and reliable services and ensure that the right capacity exists to focus delivery on key regulatory statutory functions.

- **Regulatory function and offers:** Growth in clinical trial activity depends on timely approvals and acceptability of innovative approaches. Regulatory reliance offers better use of resources and potential leadership in particular areas with horizontal agreements and positioning of the MHRA as a reference regulator. Early access flexibilities are crucial for patients with high unmet medical needs and these pathways need to be attractive to industry. Horizon scanning that feeds directly and measurably into resourcing and regular reviews of practice and future regulatory science challenges and opportunities are essential.

We believe that implementing these recommendations is essential for supporting the government's growth agenda, drive greater inward investment into UK life sciences, and facilitate earlier patient access to innovative medicines. Building confidence and predictability in the regulatory framework will help ensure that the ambitions of UK to be the best place in the world to research, develop and use the medicines and vaccines of the future can be fully realised.

Dr Richard Torbett MBE
Chief Executive
The Association of the British Pharmaceutical Industry (ABPI)

Executive summary

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has earned a global reputation for its expertise and leading role in elements of regulatory practice.

Since the UK's exit from the European Union, it has been necessary for the MHRA to reconsider and reconfigure its role as a sovereign regulator. This has occurred against the backdrop of the COVID-19 pandemic and an extensive organisational restructure. While the agency continues to be a key and respected player in a global landscape, these challenges have impacted aspects of its regulatory performance.

In an ever more competitive global life sciences marketplace, multinational pharmaceutical companies must make informed and often challenging decisions about where and when to locate their activity. As the 'front door' to a national life sciences ecosystem, it is vital that the MHRA offers an attractive and reliable service.

To help strengthen the regulatory framework for innovative medicines, the ABPI commissioned Global Counsel to conduct research and help develop a report focusing on areas of the MHRA's remit that are most pertinent to research and development, patient access, and the investment decisions of global companies: namely expedited and flexible licensing routes, clinical trial approvals and resources to conduct these functions. Our goal was to create a set of practical and practicable recommendations that can build regulatory excellence.

Our research included a stakeholder survey, which shows that the MHRA has gone through a period of strain regarding its operating and performance levels. This applies in areas such as predictability and delivery of statutory regulatory functions, as well as wider aims such as supporting innovation and the MHRA's own strategic planning. Performance varies but can be considered challenging in some areas from a UK competitiveness perspective. If the MHRA is to compete with the world's leading medicines regulators, capacity issues should continue to be addressed with a clearer narrative and focus on regulatory science and delivering statutory functions.

Based on our survey results, this report makes 12 recommendations to help deliver a world-class regulator that can play a leading role in the UK life sciences ecosystem, driving inward investment and facilitating patient access to innovative medicines.

Why worry about the MHRA and regulatory function?

Over the past five years, the MHRA has been subjected to a series of external and internal challenges. Externally, the agency has needed to adapt to the UK's exit from the European Union and the overarching regulatory framework of the European Medicines Agency (EMA). The COVID-19 pandemic placed unprecedented strains on the institution and left backlogs in some parts of its workflow. Internal restructuring, including the 'one agency' merger of the regulatory function with the National Institute for Biological Standards and Controls (NIBSC) and the Clinical Practice Research Data link (CPRD), coupled with budget constraints and staff reductions, have also been disruptive.

In some respects, the MHRA has emerged from this disruption well. In others, these shocks appear to have left more lasting challenges. The most impacted areas matter because they relate to the MHRA's statutory role as a regulator of clinical trials and approval routes for new medicines. These are the foundation for the UK's global reputation for enabling innovation and faster patient access, which in turn underpins the UK's capacity to attract global investment. While the MHRA has previously achieved world-first drug approvals – notably during the COVID-19 pandemic – these are currently more the exception than the rule.

Research methodology

The evidence base for this report comes from a multi-phase research programme. The first stage involved desk-based research of publicly available information relating to the performance of the MHRA, including key performance metrics and annual reports. This research also benchmarked the MHRA against its international peers – such as the Food and Drug Administration (FDA) in the US, the EMA, and the Health Sciences Authority (HSA) in Singapore – and compared levels of data reporting and transparency.

Following this, 20 in-depth interviews were conducted with senior individuals from industry (with either a global and UK perspective), patient associations and government organisations. Most of these interviews were conducted between May and June 2024, and covered clinical trials, scientific advice, licensing approvals, regulatory access pathways, and resourcing.

These interviews were also used to develop a framework for an online survey. The survey contained a mixture of quantitative questions and opportunities for qualitative feedback on a range of areas. Both have been drawn upon alongside the above evidence sources in forming this report's recommendations. The survey was distributed among interview respondents, ABPI members, trade associations, life sciences ecosystem organisations, patient associations and academia. Respondents were also invited to pass the survey to any contacts with regulatory expertise, a method known as 'snowball' sampling. Before answering the survey, respondents answered a screening question that established whether their role relates to and/or is impacted by the UK regulatory environment. In total, 168 individuals responded to the survey at least in part, with 75 per cent of these coming from industry.

Following the subsequent survey, interviewees were invited to attend one of a series of workshop roundtables to further discuss the research findings and their potential implications.

What makes a world-class regulator?

Over the past four decades, a huge amount of work has been done on best practice in regulatory policy – the practice of effective regulation. The themes of that work have often been distilled down into a set of core operational principles: transparency, predictability, independence, adaptability and accountability. Unsurprisingly, these themes come through strongly in this review and are often at the heart of areas where respondents feel MHRA performance could be further strengthened.

However, respondents also set a series of benchmarks for the MHRA that reflect the unique challenges of regulating the technological frontier in a fast-moving scientific area. A strong sense was evident among both interviewees and survey respondents that they want the MHRA to be seen as one of the world's best pharmaceutical regulators for innovation in regulation and in the regulation of innovation. While they support a regulator that uses reliance and deference pragmatically and as a way of following leading peers where they have set valuable precedents in trials, approvals or other areas, they do not want the MHRA to lose its appetite for establishing those precedents itself. They believe the MHRA had achieved this in the past and should again.

In neither case is this simply a question of size and resources – which is important. While survey metrics underscored the critical importance of resourcing constraints at the MHRA, comments also highlight a recognition that it is inevitable that the MHRA will never replicate the scale of the FDA or the European Union's aggregated medicines regulation resources. However, there is also a recognition that it does not need to, and that scale is not the ultimate determinant of a world-class regulatory reputation. The MHRA's challenge is ultimately to do more with less and to develop a lean regulatory model relentlessly focused on its statutory objectives and reputation for world-class ways of working.

One conclusion from this survey is that being an innovative regulator will go most of the way to making the MHRA a good regulator of innovation. Being world class is ultimately a question of doing the difficult but essential work of regulation well: predictability, transparency, adaptability and active and meaningful engagement with the market and technological and pharmacological pipeline to ensure that the regulator is ready to embrace innovation and change.

Key findings from the stakeholder survey

The survey presents a picture of a stakeholder community that sees scope to strengthen the MHRA's performance in key areas. In some cases, this is expressed through equivocation or uncertainty, and in some cases as a more emphatic critique of current performance in delivery, engagement and transparency. While this critique varies in intensity across the areas of activity considered here, it is a regulated community that sees and seeks opportunity for improvements.

Despite the MHRA's strengths, there is a need to more clearly and visibly demonstrate that it is operating at a level of excellence that makes it a peer or leader among the world's best medicines regulators. This applied both in areas such as expertise, transparency, predictability and accountability, and in areas linked to wider aims such as innovation and the MHRA's own strategic planning.

Performance vs Importance

% saying the MHRA exhibits exhibits characteristic completely/large extent vs % selecting characteristic as one of three most important for the MHRA

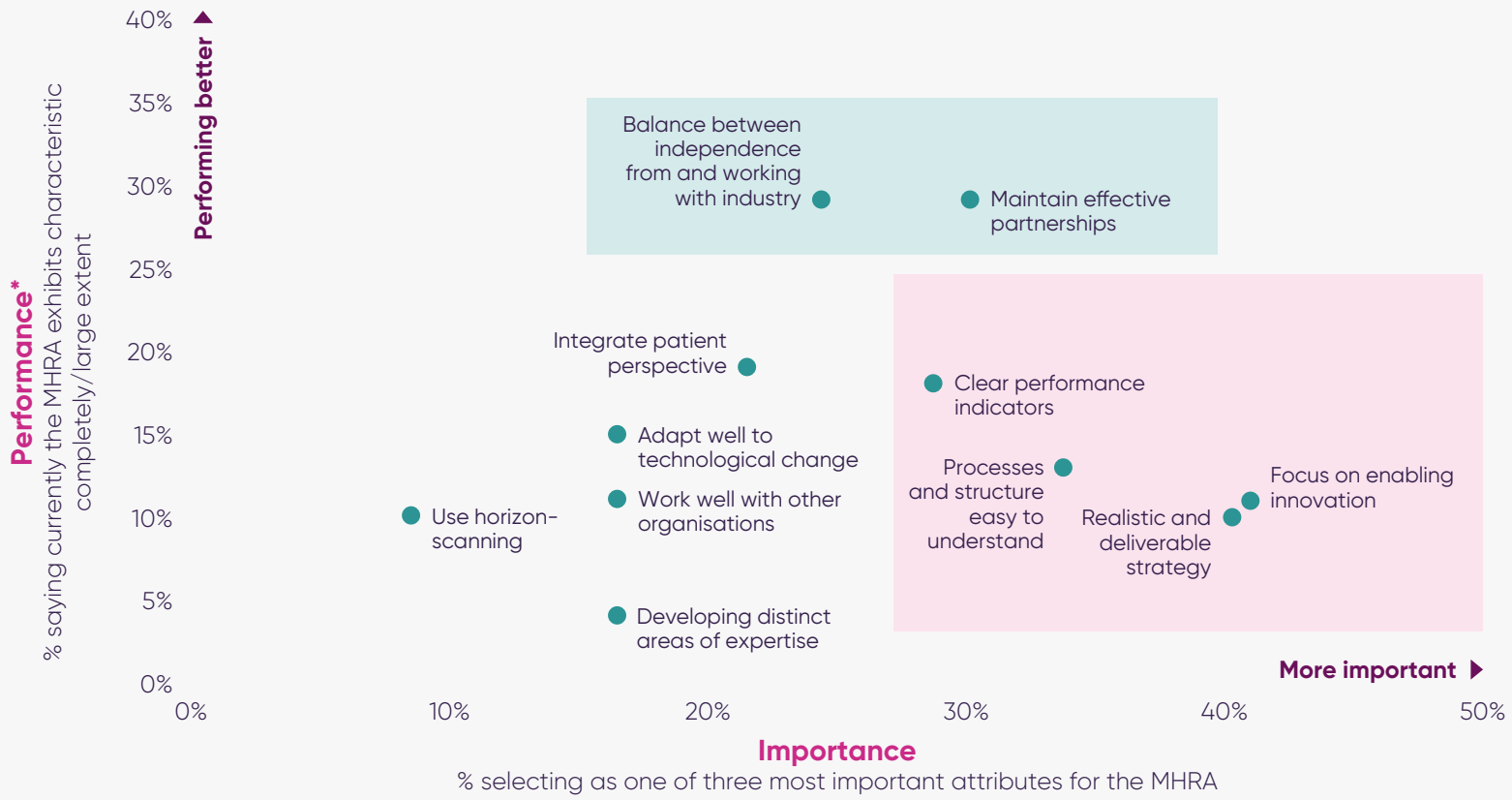


Figure 1: Performance vs Importance

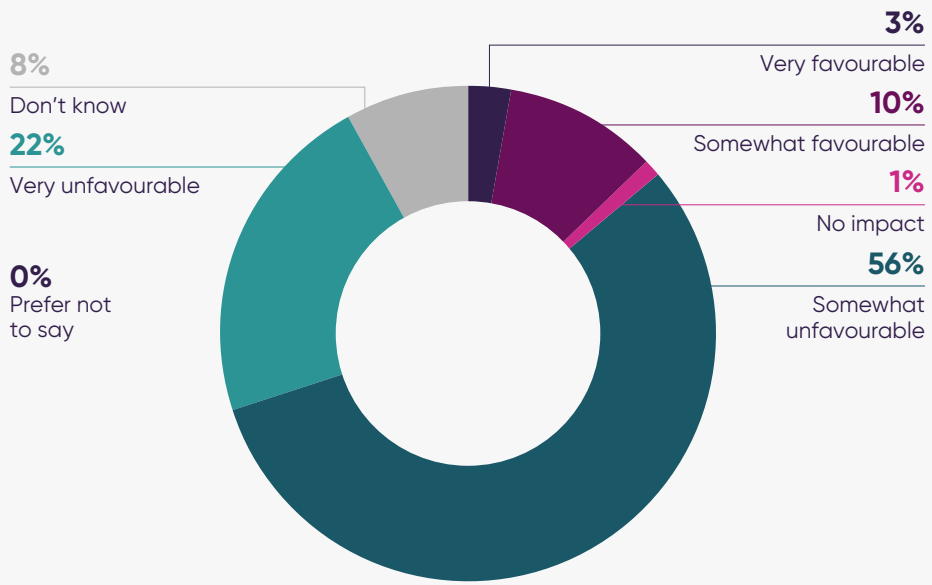
Survey respondents were asked to both assess MHRA performance and rate individual performance indicators in terms of their overall importance. A robust approach to the MHRA's independence and strong partnerships with peer regulators were areas judged as both effective and important. Recommendations here seek chiefly to buttress these strengths. Important areas of weaker performance included the need for revised performance indicators, clearer and more accessible processes, a greater focus on enabling innovation and a realistic and deliverable strategic approach. These are the areas where recommendations focus.

The role and importance of the MHRA

- **Regulatory performance is an important variable in decisions to invest or commit research and development resources to the UK.** However, many reported that this was currently working as a disincentive, with respondents noting that the UK's regulatory environment had an unfavourable impact, attributed to the capacity and predictability of the MHRA.

Impact of regulatory environment on consideration of UK

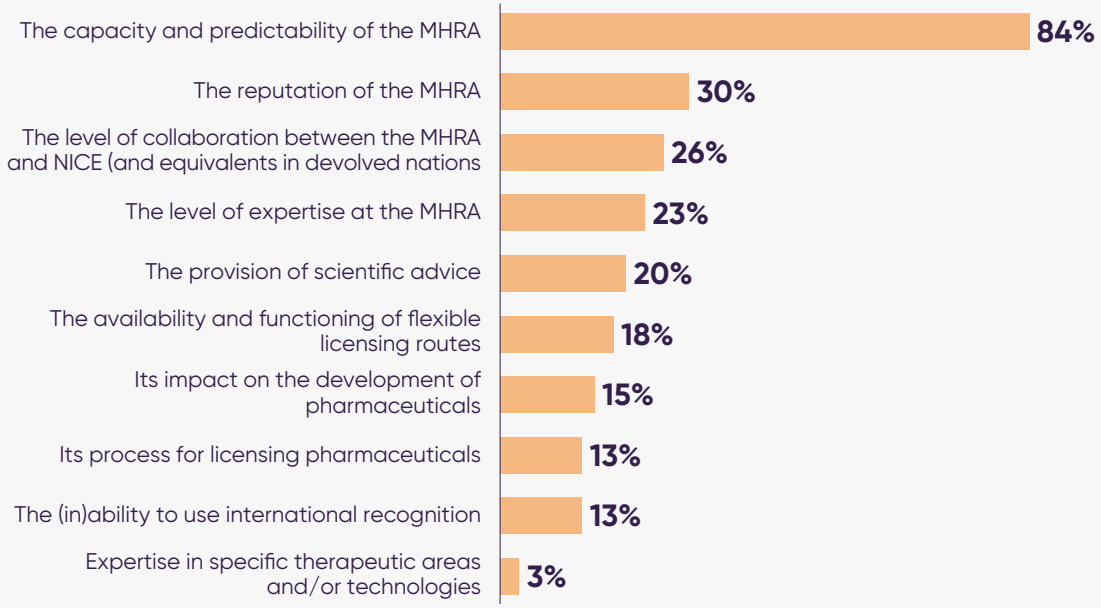
% of all private sector company respondents involved in investment decisions (n=80)



Q: You indicated that you have been involved in decisions around the countries in which to invest, prioritise, manufacture and/or conduct trials. Thinking about these, what impact has the regulatory environment had on your consideration of the UK?

Top reasons, unfavourable impact

% of all involved in investment decisions, saying regulatory environment has unfavourable impact (n=61)



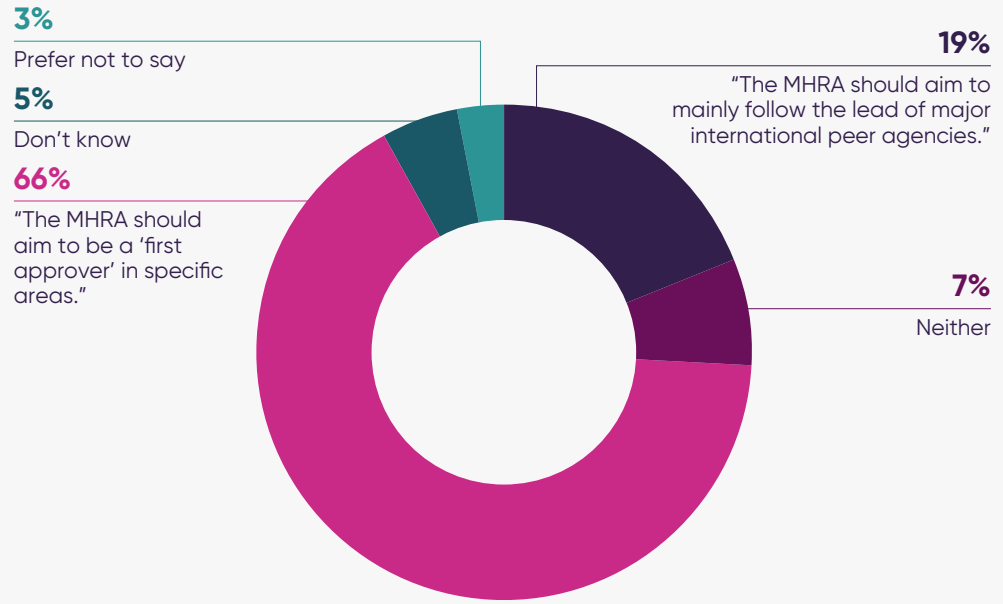
Q: What is it about the regulatory environment that has had a favourable/ unfavourable impact on your consideration of the UK?

Figure 2: Impact of regulatory environment on consideration of UK

- **Two-thirds of respondents want the MHRA to be ambitious in defining a global reputation and leadership role for itself.** In interviews and survey responses, stakeholders often emphasised the importance of not adopting a model of excessive deference to other international regulators, but instead of continuing to aim to set precedents in important areas. This was linked to challenges in current capacity for strategic planning, rationale for decisions to focus on particular technologies or therapeutic areas and ability to translate horizon scanning into resourcing and internal knowledge development.

Views on first approver vs follower model

% of respondents selecting each statement as closest to their view (n=167)



Q: Below are statements about what the MHRA should aim for. Please select which statement comes closer to your view.

Figure 3: Views on first approver vs follower model

Process, transparency and predictability

- **Very few respondents report finding the MHRA's processes and structures easy to understand.** Survey results highlight the need for improvements in transparency, both in general and concerning specific areas such as the sharing of information on approval times. In interviews, survey comments and workshops, it was often noted that the MHRA's internal reorganisation had not been well explained to stakeholders. Information on engagement points, key decision-makers or contacts and guidance for those seeking to engage with the regulatory process was often rudimentary or not available.
- **When asked specifically about the provision of the MHRA's scientific advice, many responded that more needs to be done to offer clear routes and predictable timeframes.** In interviews, survey comments and workshops it was clear that a lack of informal engagement routes such as information calls, emails and meetings was deterring companies from seeking advice. Companies report being referred to a formal advice route by default, often with delays, even when only seeking responses to a simple query. Clinical trials were cited elsewhere as an area where recent efforts to improve resource focus and delivery had helped, but this was perceived as coming at the cost of diverting resource away from other areas.
- **Many respondents believe that the MHRA needs to provide clearer and more useful performance indicators.** Stakeholder responses suggested that published performance data was often not accessible or informative to stakeholders seeking to build investment cases for the UK or to attract clinical trial sponsors. It is also notable that the MHRA reports fewer and less granular metrics than its global peers.
- **Many respondents expressed uncertainty over the MHRA's accountability frameworks for delivery.** Several comments indicated a belief that the MHRA is not held fully accountable for its performance, and that it needs clearer lines of escalation, and responsibility ensuring accountability for performance.

MHRA accountability

The MHRA's performance is critical to the businesses whose activities and products it regulates, not least because it supervises the licensing of medicines that can be placed on the UK market and authorisations for clinical trials. Accountability is harder to apply where data on performance is difficult to obtain. International benchmarking suggests that the MHRA publishes fewer and less detailed performance metrics compared to other regulators. For example, the EMA publishes comprehensive data on the provision of scientific advice, including by therapeutic area, advice by topic, and company type. In our interviews and survey comments, stakeholders also noted the lack of accessibility in the MHRA's published performance metrics. These are seen as often difficult to interpret for non-technical experts, with recent reporting changes making month-by-month comparisons more challenging.

There is therefore a need for an improved framework of accountability for the efficient, transparent, predictable conduct of MHRA regulatory obligations. This function needs to be adequately empowered to supervise, assess and issue recommendations on regulatory performance, holding senior MHRA leadership accountable for meeting set delivery targets and defining and publishing informative indicators on performance.

Resourcing and expertise

- **Only a small proportion of respondents considered that the MHRA is sufficiently funded to meet its obligations.** A potential reason attributed to the MHRA's lack of funding and resources is the removal its of trading fund status.
- **Respondents indicate concern that the MHRA is struggling to attract and retain high-quality expertise.** Additional open-ended responses suggested a clear negative feedback loop between failing to retain expertise and experienced personnel, and other aspects of regulatory performance such as high-quality interactions, capacity, responsiveness to scientific advice and meeting statutory targets. The underlying causes for this are multi-faceted. Many reported that experienced assessors had left the agency as the MHRA struggled to compete with higher salaries, delivered its programme of restructuring and faced staff and budget cuts following the UK's exit from the European Union . It was acknowledged that it will take time to build back the breadth and depth of knowledge.
- **Many respondents indicated potential for the MHRA to make better use of external expertise.** Doing so was further identified in open-ended comments as a way of remedying some of the issues caused by strained resources, experienced staff leaving and the agency struggling to retain them. The newly proposed Regulatory Science and Innovation Networks (RSINs) and increasing opportunities for secondments might help provide a solution.

The MHRA's Trading Fund Status

The Government Trading Funds Act 1973 established the legislative framework by which trading funds can be created by order. A trading fund provides a means of financing the revenue-generating operations of a government department. This means income from charges made via the provision of services – in this case, the MHRA's service fees – is retained and used to meet the agency's expenditure. The MHRA was established in 2003 with trading fund status. This status allowed for the MHRA to retain a certain amount of generated trading income as a surplus reserve to plan and reinvest against future activity.

In 2019 the Office for National Statistics (ONS) reviewed the sector classification of the MHRA and reclassified it from a trading fund to a market regulatory agency. This reclassification means that the MHRA is not able to retain and rely on cash reserves to manage areas of demand or invest in multi-year capability building as it has done previously.

Over the past five years, the potential implications of revoking the MHRA's trading fund status may have been significant, particularly in the wake of the external and internal shocks the agency experienced through the UK's exit from the European Union and COVID-19. Stakeholders raised concerns that the MHRA is not able to operate as a commercial entity despite providing revenue-generating services. Not being able to retain a surplus reserve prevented the MHRA from undertaking more comprehensive, long-term financial and commercial planning, and informed decisions regarding statutory fee and salary changes.

In 2022, the MHRA conducted a review of its statutory fees, which found that the MHRA was under-recovering. In 2024, the MHRA published another consultation on its statutory fees as part of ongoing cost-recovery work. Many stakeholders have argued that raising the MHRA's fees must be considered in the context of the wider question of whether the MHRA's operating model enables it to retain a surplus from its trading income. This raises the ultimate question as to whether the MHRA's trading fund status should be reinstated.

Talent and expertise

It was widely recognised by our survey respondents that retention of experienced and skilled staff is absolutely critical to a world-class regulator. Experienced MHRA experts and assessors bring immense value to the regulator through their knowledge, pragmatism and judgement. They are comfortable engaging in a more dynamic dialogue with companies where less experienced staff may be risk-averse and excessively procedural. Many respondents – across the survey, interviews and workshops – commented that the loss of a cohort of experienced staff from the MHRA over the past five years had had a profound impact on its culture and effectiveness.

It was also recognised that retention at the MHRA must reflect both the inevitable constraints of public sector pay scales and competition from the private sector for skilled staff. For these reasons, the MHRA must be able to pay competitive salaries for assessors and other experts. Retention also needs to be built around more than financial rewards, such as opportunities for career development and training.

A regulator performing again at the top of its game internationally, with an established reputation for regulatory innovation, will attract and retain talented staff. Similarly, strong mechanisms for institutional knowledge transfer and the mentoring of new staff by more experienced ones may help with retention. Respondents also felt that the MHRA could draw more on expertise from across the UK ecosystem of academics, researchers and industry.

- **Results highlight visible improvements in performance in clinical trials after a period of challenge, but many respondents argued more can be done to build the attractiveness of the offer in a globally competitive environment.** Areas to improve included better flexibility in processes for approving clinical trials and allowing changes to study design, and for specific provisions to support phase I trials (e.g. 14-day turnaround for healthy volunteer trials). Stakeholders highlighted the outcomes of the Lord O'Shaughnessy Review as a catalyst for speeding up the MHRA's trial approvals and improving commercial clinical trial activity. They also emphasised that any improvements in the MHRA's performance to approve clinicals trials needed to be matched by other ecosystem partners.
- **Respondents often reported that the MHRA's International Recognition Procedure (IRP) and international partnerships are functioning well.** Of those respondents with experience of the IRP, around half believed it is functioning well. A fifth said it is either too soon to say or did not know. Similarly, those with experience of the Access Consortium reported that it was functioning "quite well".
- **Of the MHRA's expedited national pathways, the Innovative Licensing and Access Pathway (ILAP) was commonly reported as not fulfilling its ambition compared to the Early Access to Medicines Scheme (EAMS), which is viewed more favourably.** Comments indicated that many respondents felt that ILAP was under-resourced and required an overhaul, though the principles of what it is trying to achieve are broadly welcomed by industry. EAMS was considered to have better performance but also to suffer from capacity issues.
- **For many respondents it is unclear what it means when the MHRA claims to have a focus on enabling innovation.** A clearer strategic narrative regarding the MHRA's ambition in the innovation space would be welcomed, linked to visible specific services, activities and outcomes that are measurable.

- **Some respondents noted that horizon scanning to anticipate future demands on MHRA services could be better utilised.** Respondents perceived that the MHRA could be using horizon scanning more effectively to help inform future strategic decisions and workforce planning. UK PharmaScan was highlighted as an under-utilised resource. The new proposed pipeline work from the MHRA could also provide a source of relevant actionable horizon-scanning signals but must be aligned with existing initiatives to reduce duplication.
- **Many respondents commented that better international comparisons were needed.** In particular, overall performance judged according to regulatory peers requires better contextualisation. Respondents were asked to rate the MHRA's performance against reference peers, (which comments indicate are generally held to be the FDA and the EMA). On balance, the MHRA was judged to be performing better than others in its expedited pathways, but worse in other areas, especially scientific advice and sufficiency of resourcing levels for statutory duties. Though clinical trials were currently seen as a standalone area of stronger performance for the MHRA, responses were less positive here once the international comparison was introduced. More judged the MHRA to be weaker relative to peer regulators than considered it stronger. This is important for the UK's relative international competitiveness.

Themes on performance

By seeking views on performance both in general and across specific areas of MHRA activity it is possible to identify more specific targets for focus. Some, especially clinical trials are perceived to be working relatively well. However, it should also be noted that when asked to compare MHRA performance with reference peers (generally the FDA and EMA) respondents may still judge the MHRA to be underperforming comparatively, even where performance is judged to be good. This is important from an international competitiveness perspective.

Strengths & weaknesses: common themes are timeframes, predictability, communication

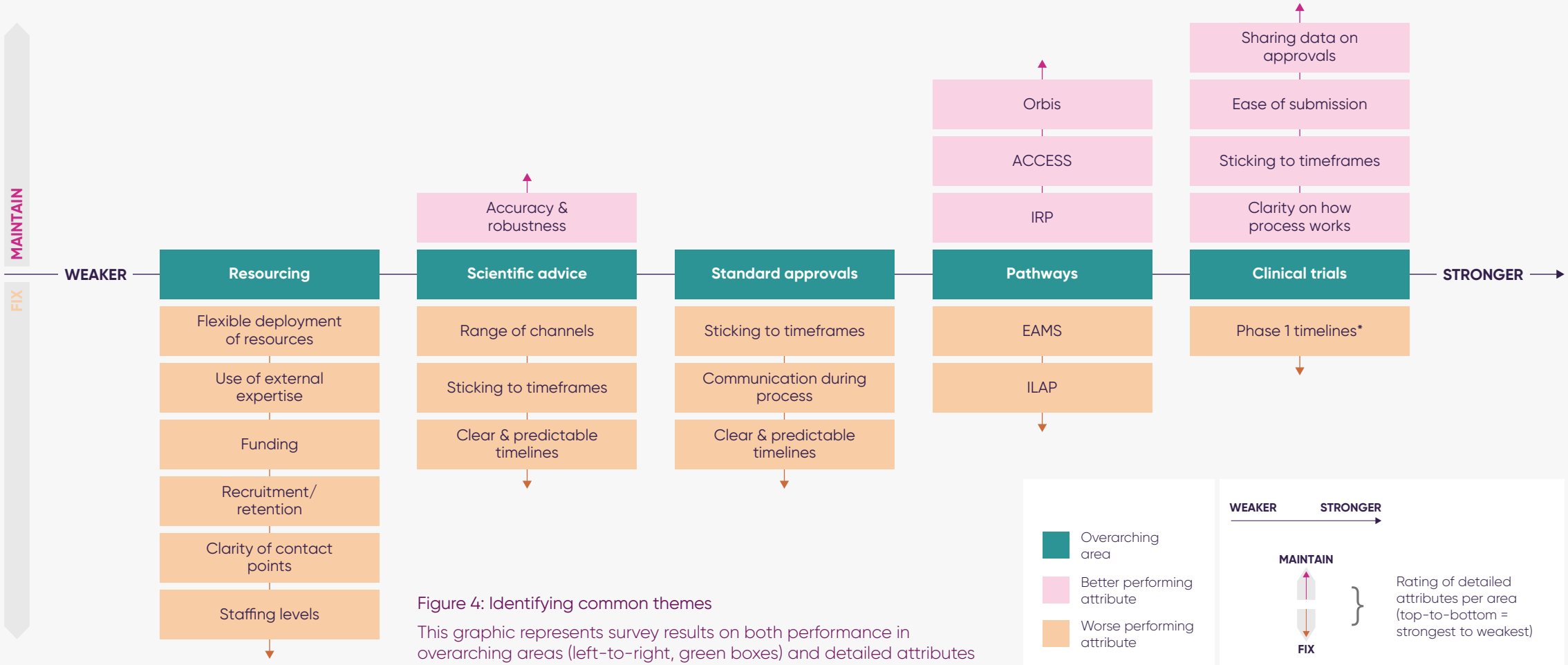


Figure 4: Identifying common themes

This graphic represents survey results on both performance in overarching areas (left-to-right, green boxes) and detailed attributes within those areas (additional boxes, top-to-bottom).

*Based on verbatim comments

Recommendations

The recommendations that follow are built directly on the evidence provided by our research and respond to the areas that could be strengthened and improved as suggested by stakeholders. They target the areas highlighted by respondents as both materially important to the future of the MHRA and most in need of action.

Most are actions that can be undertaken independently by the MHRA within its statutory authority. A small number involve changes in the governance of the MHRA and require action from government, although no recommendations would change the nature of the MHRA's statutory role. The recommendations are underpinned by four themes that run through the survey responses:

- improving the **transparency** of the MHRA in ways that make it easier for stakeholders to understand and engage with its structure and processes
- improving the **predictability and general delivery of the MHRA's statutory functions** for the provision of scientific advice, standard and expedited authorisation pathways and clinical trial approvals processes
- strengthening the MHRA's **internal resourcing capabilities**, development and retention of expertise and institutional knowledge base
- strengthening the MHRA's **engagement with its ecosystem of stakeholders**, including experts in regulatory innovation

The recommendations that follow sit beneath an overarching 'headline' recommendation that can be stated succinctly:

- The government and the MHRA should commit to establishing a world-class reputation in regulatory science, medicines development and licensing. The MHRA should play a critical facilitating role in leading the life sciences ecosystem and applying 21st-century technological advances. The MHRA needs to focus more on delivering its statutory regulatory duties and developing a culture of transparent, collaborative and predictable regulatory function. It must be among the best in the world at both regulating innovation and innovating regulation.

Resourcing and expertise

1.

The MHRA's operating model should be independently reviewed to assess the impact of the 'one agency restructuring model' and the removal of its trading fund status.

A well-resourced and well-functioning regulatory authority should provide predicable and reliable services and the MHRA has been challenged in recent times by capacity issues in a variety of key functions. As part of the assessment of capacity and predictability issues, a formal independent review of the functioning and operational success of the new one agency structure should be conducted as soon as feasible. This assessment should make recommendations on how to strengthen the current model including what are the key deliverables and remit that a regulatory authority must focus on in terms of prioritisation and resourcing.

Behind many of the challenges raised around resourcing, funding and capacity by our survey are fundamental questions of how the MHRA can legally operate and manage its income as an executive agency. A serious review of the MHRA commercial model should explore options for the MHRA to retain a cash surplus and could re-evaluate the ONS's 2019 sector reclassification of the MHRA. It could also involve an impact assessment of the decision to revoke the MHRA's trading fund status. This review should consider the MHRA's role as a fee-generating organisation that requires an ability to establish long-term business plans, and to build and allocate new expertise and resources in line with an evolving technological landscape.

2.

The MHRA should deepen its strategic engagement with external sources of expertise on regulatory innovation, including academia and sources of cross-sectoral insight, which should include enhanced opportunities for secondments.

Stakeholders were clear that the MHRA could do more to draw on external sources of expertise. The new RSINs or Centres for Excellence in Regulatory Science and Innovation, for which a discovery and implementation phase has been funded by Innovate UK, could provide the MHRA with extra external capacity and aid strategic direction. Subject to initial success, the RSINs should be prioritised and given ring-fenced funding to develop a dedicated workstream for supporting the MHRA's statutory functions and built into the MHRA's corporate key performance indicators. The MHRA should also consider two-way secondment opportunities or short-term 'exchange programmes' that provide MHRA staff and other stakeholders with an opportunity to learn from each other and reflect on how to align their ways of working.

3.

The MHRA should develop ways to improve and encourage the transfer of institutional knowledge between experienced and newer MHRA staff, and between industry and the MHRA.

Regulatory authorities need to provide expert opinion and consistency in approach, keeping up to date with evolving technological advances. The MHRA needs to develop a more targeted strategy for knowledge transfer and talent retention. This strategy should involve the development of new training programmes where former or current long-serving MHRA assessors teach and mentor less experienced assessors.

Regulatory function and offers

4.

The MHRA must strengthen internal and external accountability mechanisms for the performance of statutory duties and the development of innovative regulatory offers, helping to ensure consistent delivery of crucial regulatory functions.

The perception of a lack of accountability for external delivery was a persistent theme in survey responses, interviews and workshops. The MHRA's restructure in 2021 is often perceived to have contributed to this by displacing clear lines of accountability within a matrix structure. As a first step, an independent assessment should be made of the functioning of the organisational structure to evaluate its impact on regulatory performance.

5.

The government and the MHRA must ensure that the upcoming clinical trials legislation reinforces the strength of commercial clinical trial activity and keeps the UK globally competitive, maximising the unique attributes of the UK population and infrastructure, and opportunities for alignment of diagnostic regulatory framework.

Growth in clinical trial activity depends on timely approvals and acceptability of innovative approaches, particularly in the phase I setting and areas where the UK has strong expertise and attributes. While the backlog in trial approvals has been largely addressed, there are clear opportunities for the MHRA to move to a more effective, streamlined, and world-class trials regulation. The proposed legislative changes for clinical trials need to sustain the momentum generated by the O'Shaughnessy review to accelerate trial approvals, remove unnecessary burdens and speed up trial recruitment. This recommendation also hinges on other parts of the ecosystem, such as NHS trusts, being able to manage any increases in trial activity, should the MHRA be able to approve more trial applications more quickly.

6.

The government and the MHRA should continue to develop and champion international recognition and reliance protocols on a unilateral basis, and increasingly, a bilateral and plurilateral basis, with other countries across the globe, enhancing the reputation of the MHRA as a global leader.

Regulatory reliance offers better use of resources and leadership in particular areas. Stakeholders generally rated the MHRA's partnerships and collaboration with international reference regulators positively. As such, the MHRA should continue to champion its existing routes (IRP, Project Orbis, Access Consortium) and sustain a strong commitment to international regulatory diplomacy, convergence in key standards and reliance in appropriate contexts. Given stakeholder preferences for the MHRA to be a 'first approver' rather than 'fast follower' wherever it can, it should be emphasised that a proactive and pragmatic approach to recognition and deference should not come at the expense of ambition to be a first mover and precedent-setter in key areas, where the MHRA is the reference regulator.

7.

The MHRA should commit to enhancing the operation of EAMS, including creating an end-to-end access route for an EAMS marketing authorisation, removing duplication and replication of regulatory process.

Early access flexibilities are crucial for patients with high unmet medical needs and these pathways need to be attractive to industry. At present, data and documentation submissions made in the context of the EAMS process must be duplicated when ultimately applying for market authorisation. The MHRA should remove this duplication and enable EAMS applications to directly and formally support standard authorisation applications.

8.

The ILAP narrative should be strengthened and deliver the ambition with appropriate resourcing.

Collaboration on the development, evidence-generation and access routes through ILAP are welcomed. However, the ambitions and goals of ILAP have yet to be realised. A refreshed and enhanced ILAP with dedicated resources and strengthened cross-partner working should be implemented at the earliest opportunity alongside the publication of key success metrics.

9.

The MHRA should engage with national and international peers in a clearer framework for horizon scanning that feeds directly and measurably into resourcing and regular reviews of practice and future regulatory science challenges and opportunities.

Survey respondents frequently raised the importance of anticipating emerging technological and therapeutic trends to inform resourcing and strategic planning and for future-proofing regulatory protocols. The MHRA should integrate pipeline tools into its strategic planning but also aim to look wider at emerging technological trends and therapeutic opportunities and tapping into external expert networks to help it reflect on and adapt to incoming trends.

Enhanced communications transparency and accountability

10.

The MHRA should review and revise its published performance metrics to be more easily interpretable, allowing for stronger cross-market comparisons and reflecting the needs of the MHRA's stakeholders.

Industry needs predictability of the regulatory framework to effectively plan investment and product launches. Findings from our international benchmarking, interviews and stakeholder survey identified a relative lack of performance metrics reporting compared to the MHRA's international competitors and divergence from industry expectations of good practice. A revised set of performance metrics should be complemented by the reinstatement of service coordinator roles. These key administrative staff would be empowered to deliver an enhanced level of accountability across the organisation using accurate up-to-date performance data

11.

The MHRA should overhaul its web pages and web-based resources to provide clearer guidance on its internal structure and external contact points.

This should be coupled with improved engagement and utility of guidance for industry with opportunities to develop specific technical web page resources with an industry focus. Companies depend on finding regulatory and technical information quickly and easily. Many stakeholders viewed digital accessibility and website improvements to be easy fixes that the MHRA could start to implement immediately. Longer-term, the MHRA should consider creating a standalone website where users can quickly and easily find relevant technical resources, guidance documents and contact portals – something that has already been created for NICE.

12.

The MHRA should provide more channels for informal engagement with stakeholders, and widen a culture of collaborative access between assessors, experts and industry, building on the proposals for pipeline meetings and the Innovation Office offers.

Companies need to have dedicated points of contact that provide relevant and timely information, particularly for scientific and technical advice and procedural queries. Engaging with industry stakeholders and providing both formal and informal channels for engagement and advice is critical for a medicines regulator. Many stakeholders argued that the MHRA's necessary commitment to its independence should not encourage an arm's length culture from stakeholders or prevent expert staff from engaging in simple, bespoke advice requests quickly and pragmatically. Supporting recommendation two above, service coordinators could act as the accountable facilitators for such engagement. Encouraging this cultural change could also help the agency to better leverage independent assessments for clinical trial and market authorisation applications. As part of this, the MHRA may consider reviewing and reforming its Trusted Advisor Principles, under which it holds stakeholder discussions, to be more open and collaborative.

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