
***The Early Access to
Medicines Scheme
(EAMS)***

An independent review

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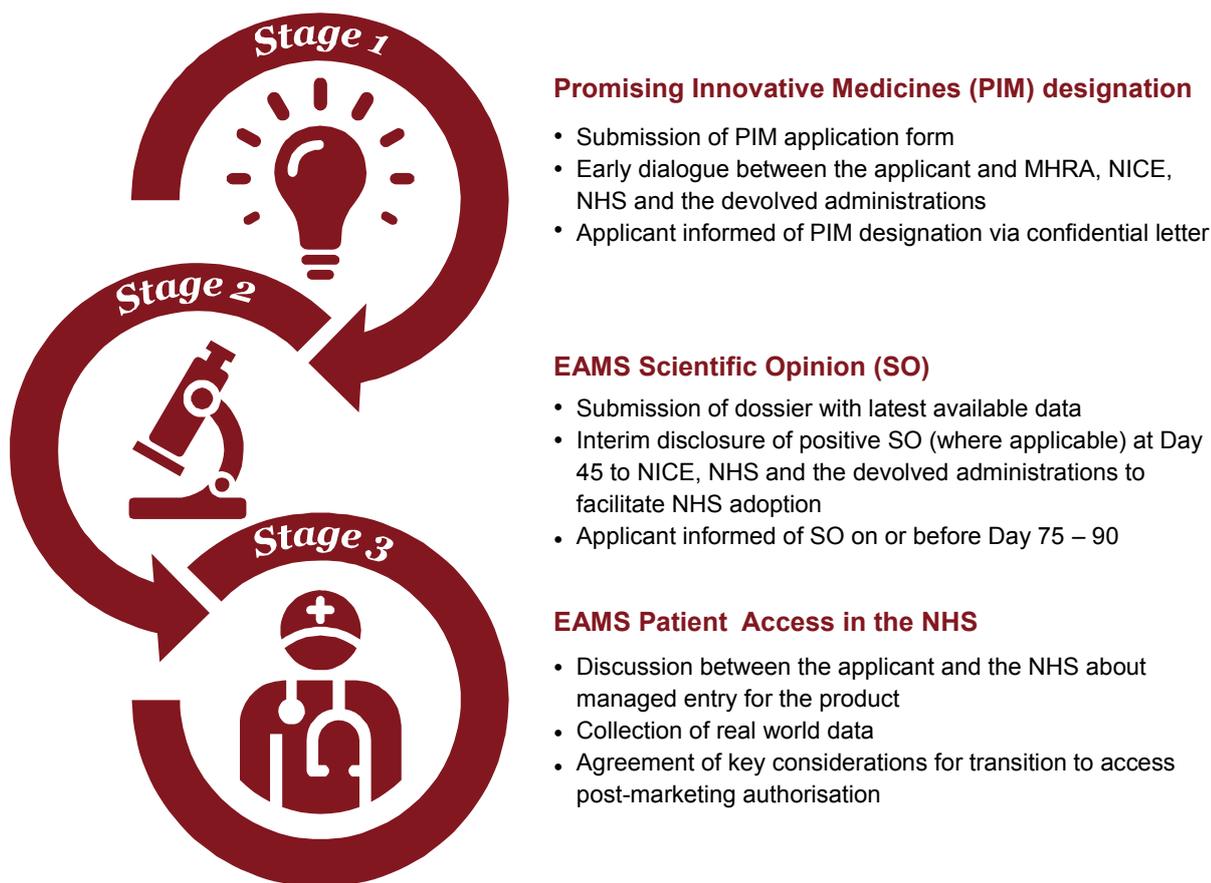
Executive summary

Background to the EAMS review

The UK's Early Access to Medicines Scheme (EAMS) aims to provide patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.

This independent review of the EAMS takes into consideration prior consultation documents in addition to over 50 in-depth interviews across 42 different stakeholders, an online survey, and three cross-stakeholder workshops with representation across industry, government, and arm's length bodies.

Exhibit 1: Key activities and milestones per EAMS stage



Our findings

Between launching in April 2014 and November 2015, the UK's Early Access to Medicines Scheme (EAMS) received 18 applications, approved 4 products, and provided early access to innovative medicines for over 500 patients across the UK.

From an industry perspective, the EAMS has offered a valuable opportunity for early dialogue with government and arm's length bodies about product uptake within the NHS. Further, applicants we interviewed also praised the introduction of the Promising Innovative Medicines designation, the support offered by the MHRA, and the role of the EAMS task group as key strengths of the current EAMS process.

Looking ahead, there is collective appetite from industry, government, and arm's length bodies to build on what the EAMS has achieved to date.

There are some potentially quick wins for the EAMS at the earlier stages of the process. They include a clearer articulation of the benefits of participation as well as clarification of the evidence requirements for entry.

Over the longer term, the greatest opportunity for change lies within the last stage of EAMS, patient access in the NHS, where there are three areas of focus:

- First, there is an opportunity to close the current patient access gap between EAMS and wider patient access by delivering an EAMS process which seamlessly transitions from the EAMS period to rapid uptake post-marketing authorisation
- Second, the UK could foster a more supportive environment for real world data collection and work in collaboration with industry to define and support their evidence generation
- Third, for selected companies where the lack of funding pre-marketing authorisation remains a major deterrent to entry, an affordable and negotiated funding mechanism via application could be considered

Our vision is for the EAMS is to offer a flexible, transparent, and smooth process that delivers rapid patient access to cost effective products pre- and post-marketing authorisation. We also recommend that the EAMS aligns with the proposed accelerated access pathways being developed as part of the UK's Accelerated Access Review as well as European-level developments such as the European Medicines Agency's Priority Medicines scheme.

Our vision is for the EAMS is to offer a flexible, transparent, and smooth process that delivers rapid patient access to cost effective products pre- and post-marketing authorisation

Background and methodology

Background to the UK's Early Access to Medicines Scheme

“The Early Access to Medicines Scheme (EAMS) aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.”

MHRA

The Early Access to Medicines Scheme was launched in April 2014 and aims to give patients access to innovative products that are not yet licensed.

Products eligible for the scheme are deemed to have the potential to deliver benefit to patients with a life threatening or seriously debilitating condition when other treatments are not available.

The scheme is coordinated by the Office for Life Sciences (OLS) and is supported by:

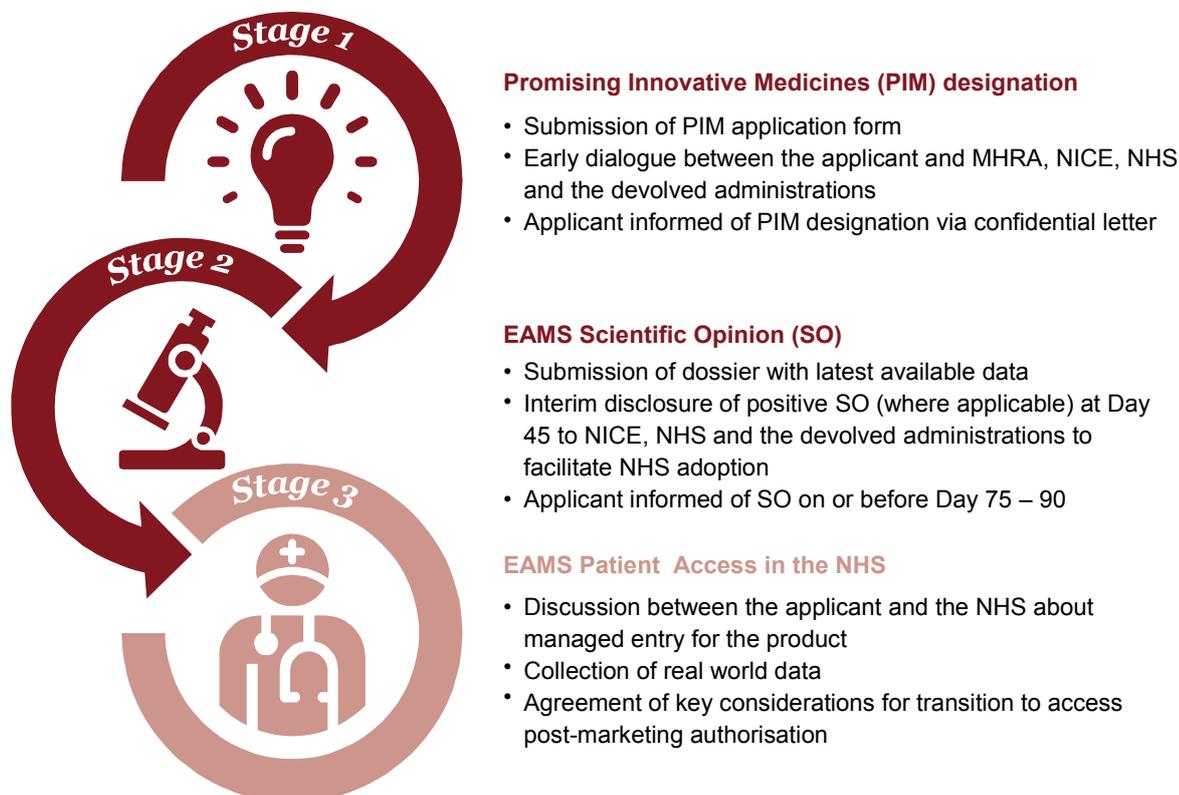
1. Department of Health
2. Medicines and Healthcare products Regulatory Agency (MHRA)
3. The National Institute for Health and Care Excellence (NICE), Scottish Medicines Consortium (SMC) and All Wales Therapeutics and Toxicology Centre (AWTTC)
4. National Health Service (NHS)
5. Devolved administrations (Scotland, Wales and Northern Ireland)
6. Industry, industry associations and patient association groups

The Early Access to Medicines Scheme was launched in April 2014 and aims to give patients access to innovative products that are not yet licensed

Summary of the EAMS process

The EAMS is a two-stage application process followed by a third stage which enables patient access across the NHS (see *Exhibit 2*).

Exhibit 2: The three-stage EAMS process



Objectives of the review

The OLS has commissioned Strategy& to conduct an independent review of the UK's EAMS.

The review meets the government's objective to assess the performance of the EAMS within two years of launch and aims to address three key questions:

1. What are the achievements and challenges of the current EAMS process?
2. How can EAMS be future proofed to be fit for purpose for new types of products and future patient needs?
3. What are the priority areas for change?

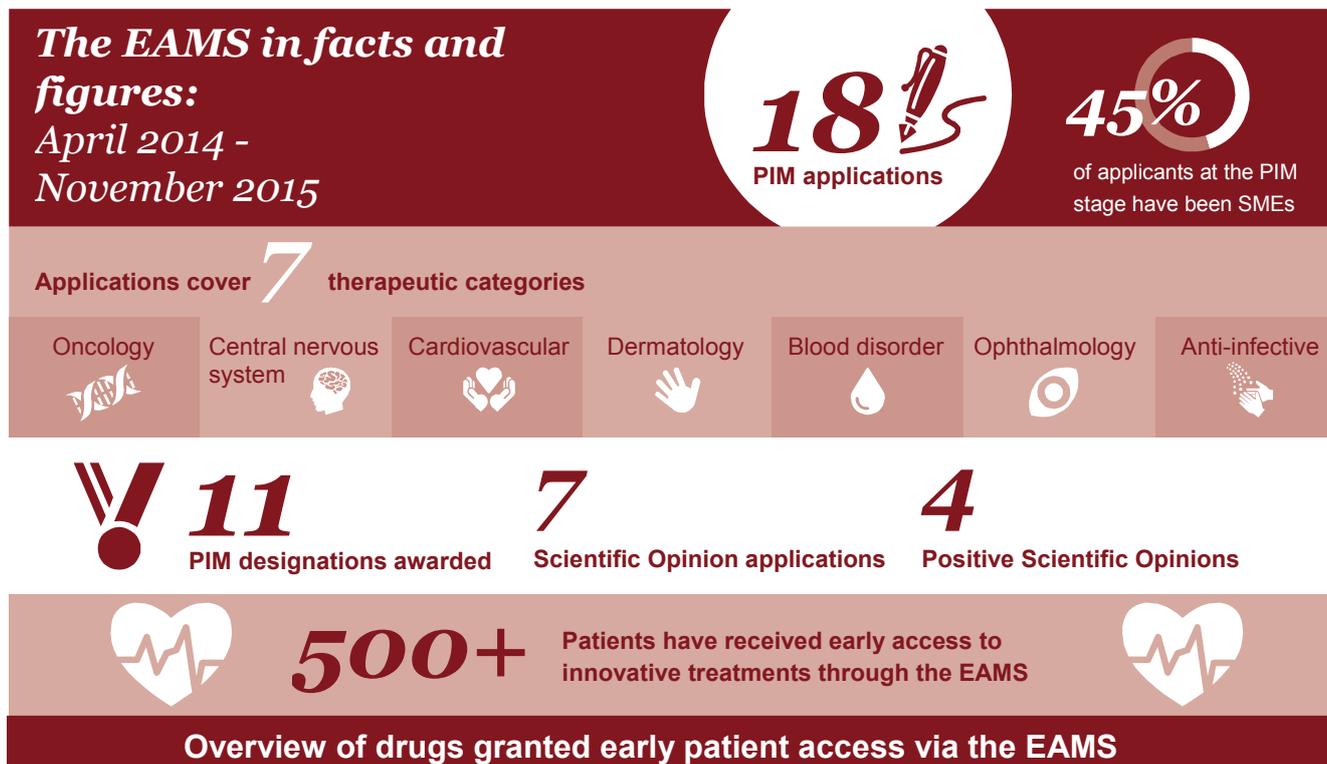
Methodology

The review has taken into consideration the public consultation in 2012, the government response in 2014, and written responses from the different industry groups. In addition, we have also conducted over 50 in-depth interviews across 42 different organisations, issued an online survey, and held three cross-stakeholder workshops. See *Appendices A and B* to further details of our stakeholder engagement.

The proposed recommendations have been shared with different stakeholders and the feedback received has been taken into consideration.

Whilst the EAMS review has been conducted on an independent basis, findings will also inform the UK's Accelerated Access Review (AAR).

Facts and figures: What has the EAMS achieved?



	Indication	Company	EAMS patient access period:
1	Pembrolizumab (Keytruda)	Melanoma MSD	131 days 09 March – 17 July 2015
2	Nivolumab (Opdivo)	Melanoma Bristol-Myers Squibb	22 days 29 May – 19 June 2015
3	Nivolumab (Opdivo)	Lung cancer Bristol-Myers Squibb	32 days 19 June – 20 July 2015
4	Sacubitril valsartan (Entresto)	Heart failure Novartis	80 days 01 September – 19 November 2015

Positive feedback on the current EAMS scheme

Introduction of the PIM step has been well received

The Promising Innovative Medicines (PIM) designation was introduced as the first step in the EAMS as part of the “Government response to the UK’s EAMS consultation” published in March 2014. PIM provides an early indication to the applicant that the medicinal product is a promising candidate for early patient access.

We’ve heard broad support for the introduction of this additional step to the EAMS application process and industry see the PIM designation as an early opportunity to engage with MHRA, NICE, NHS and the devolved administrations.

Although the MHRA does not publish PIM designations, four companies have chosen to publicise this information¹, indicating that they perceived the designation as a positive development for their products.

“We support the promising medicines designation which precedes the EAMS process. This is a welcome step in signalling that a therapy is likely to be of particular importance”

Trade association

“One of the successes of the EAMS is the PIM step – it allows companies to have an early discussion with the MHRA and also gives NICE/ NHS (national level) a heads up”

NHS England

¹ Company websites and public press releases

MHRA have provided good signposting of the EAMS application process

Applicants to the EAMS we have interviewed commented that they have found the application process to be simple, clear to understand, and relatively straightforward.

In particular, industry praised the MHRA for the guidance documentation provided on the EAMS webpage and for the accessibility of its staff to discuss the benefits and risks of entering the scheme.

“Our experiences with the MHRA have been extremely positive. They really helped us navigate our way through the stages of PIM and SO”

Large Pharma

“The MHRA had a face to face conversation with our global regulatory team pre-submission. They explained the benefits and risks of the scheme and gave us the confidence to apply”

Large Pharma

Applicants to the EAMS we have interviewed commented that they have found the application process to be simple, clear to understand, and relatively straightforward

The EAMS task group has been an effective forum for communication

Coordinated by the OLS, the EAMS task group brings stakeholders from industry, government and arm’s length bodies together on a regular basis. *See Appendix B for details of task group members.*

With an open invitation via trade associations to all companies interested in the EAMS, the task group has provided industry with a forum to raise questions and clarify concerns.

The task group has also developed a set of principles, operational guidelines, and a schematic of the end-to-end EAMS process that industry has found to be useful.

“Never before have I had the opportunity to sit around the table with DH, MHRA and NICE – the EAMS working group is a great forum to get everyone talking right from the get go.”

Large Pharma

“We have really benefitted from the opportunity to engage in early dialogue with NICE and the NHS early on in the process.”

Large Pharma

Going forward, there is collective appetite to build on the current EAMS process

Both government and industry stakeholders recognised that although the EAMS is still relatively new, it provided a welcome signal that the UK is recognising innovation.

Twenty months post-launch, there is now an appetite across these groups to consider how to further develop the scheme, particularly in the context of recent developments such as the European Medicines Agency's (EMA) announcement of the Priority Medicines (PRIME) scheme and the UK's Accelerated Access Review (see *Exhibit 3*).

Twenty months post-launch, there is now an appetite across these [government and industry stakeholder] groups to consider how to further develop the scheme

Exhibit 3: Overview of the PRIME scheme and the Accelerated Access Review



EMA's PRIME scheme

PRIME represents a new European scheme to be launched by the EMA in the first quarter of 2016. The proposed scheme seeks to strengthen support for priority medicines that have the potential to benefit patients with high unmet medical need. Key proposed features of PRIME include provision of multidisciplinary expert guidance and scientific advice at key development milestones.

UK's Accelerated Access Review

Announced by the Minister for Life Sciences in November 2014, the Accelerated Access Review aims to accelerate the speed at which 21st century innovations in medicines and medical technologies get to NHS patients and their families. An Interim Report of initial findings was published in October 2015 and the final report is due to be published in 2016.

"We have worked well in a partnership with the EAMS system so far but there is certainly room for improvement. I have a lot of ideas on what could be done..."

Large Pharma

"We are always open to hearing recommendations on how we could improve the EAMS process"

MHRA

"We are committed to conducting an earlier Health Technology Assessment (HTA) of EAMS approved products."

NICE

"EAMS approved products have delivered great benefits to patients so far and we will continue to work closely with all stakeholders to facilitate uptake."

NHS England

"The principles of EAMS are of great importance to patients, and as awareness of the scheme increases its impact and benefits will strengthen"

Patient group

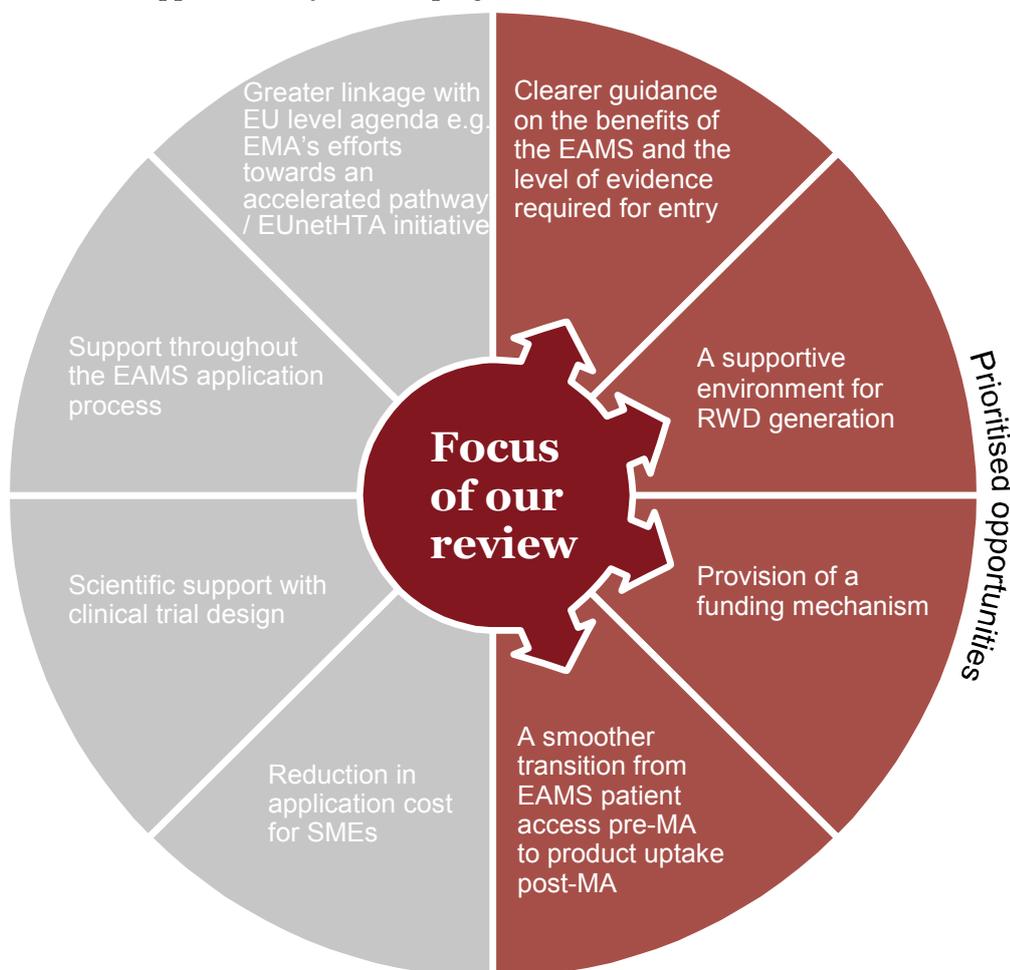
Opportunities for improvement

Following a review of position papers and written responses from government and industry on the EAMS, Strategy& identified a long-list of potential opportunities for improving the scheme. These options were refined and validated via interviews and an online survey to determine a short-list of prioritised opportunities for further consideration.

Four factors have been identified as offering the greatest potential to deliver a more attractive EAMS (see Exhibit 4). These opportunities take into consideration the perspectives of various stakeholder groups and capture the views of companies who have had first-hand experiences of the EAMS as well as those who have yet to apply. A breakdown of stakeholders we interviewed and further details on the survey can be found in Appendix A and Appendix C respectively.

Four factors have been identified as offering the greatest potential to deliver a more attractive EAMS

Exhibit 4: Opportunities for developing the EAMS



Source: Strategy& analysis based on primary research from survey and interviews conducted September – November 2015.

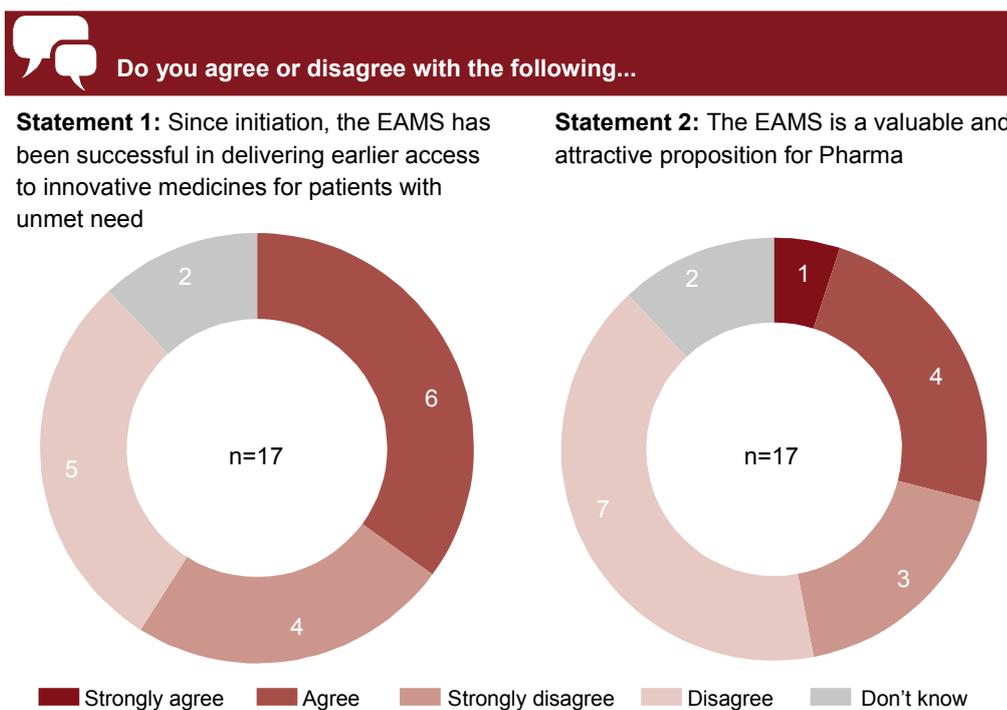
Clearer guidance on the benefits of the EAMS and the level of evidence required for entry

Whilst companies understand the benefits the EAMS could offer from a patient perspective, there is some uncertainty around its value for industry and the perceived success of the scheme to date.

For example, of the seventeen companies that participated in the online survey, ten respondents reported that the EAMS is not currently delivering an attractive proposition for industry and nine respondents believe that the scheme thus far has not been successful in delivering early patient access (see Exhibit 5). To contextualise this, it should be noted that the number of companies completing the survey was small compared to the total landscape and that many of the companies that responded had not been through the scheme (See Appendix C for further details of survey respondents).

Whilst companies understand the benefits the EAMS could offer from a patient perspective, there is some uncertainty around its value for industry and the perceived success of the scheme to date

Exhibit 5: Industry views captured by the survey on the perceived success and value of the EAMS



Nevertheless, it is important to recognise the request from industry for a more clearly articulated benefit of participating in the EAMS and we sought to understand the rationale behind these views via in-depth interviews and further analysis of the survey results.

Through this, we identified that the lack of clarity around the value of the EAMS are two-fold:

- First, companies are unclear of the advantage of the EAMS over existing named patient programmes and compassionate use schemes in the UK and in other markets. As such, these companies often did not feel equipped to provide a robust business case to advocate the scheme within their organisation, particularly where a UK affiliate puts forward a case to the global headquarters which may reside outside the UK
- Second, despite general perception that there is good support offered by the MHRA during the EAMS application process, companies remain unclear at what stage of development they can enter the scheme and the level of evidence required for entry. There is a perception from industry that applicants require a bespoke submission package rather than being able to repurpose existing submission packages

“I would like to put one of our products through the EAMS but, in order to do so, I would have to make a very strong business case to my US headquarters to outline why the benefits outweigh the risks”

UK affiliate, Large Pharma

“I am not clear what the EAMS brings – we already provide patient access pre-MA via clinical trials and compassionate use schemes”

Biotech

“Enhanced stakeholder communications with formalised engagement structures are needed to form a more streamlined process. If all stakeholders can work together to make this happen, then I believe that access to important new treatments in the UK will increase.”

Large Pharma

A supportive environment for real world data generation

To date, the patient access periods for EAMS-approved products have been short and there has been limited opportunity to collect real world data (RWD).

Companies with EAMS-approved products have told us that the data collected thus far has primarily been used to comply with pharmacovigilance requirements and to track the number of patients receiving treatment.

Although the RWD infrastructure exists or is developing for certain conditions, e.g. the SACT dataset for cancer, the amount of data currently captured is limited. For example, quality of life and patient reported outcome measures are not currently captured into the database. Also, for the most part, capture is usually by manual entry in addition to what is available in the electronic medical record.

Although the RWD infrastructure exists or is developing for certain conditions, e.g. the SACT dataset for cancer, the amount of data currently captured is limited

However, both industry and the NHS recognise the potential value of collecting detailed RWD and analysing this data to generate insights to support commissioning and funding discussions. Further, industry have also commented that they would contribute to creating robust databases coordinated by the NHS to which they could have access.

“We are collecting outcomes data to support ongoing commissioning as part of the Commissioning through Evaluation scheme. I see no reason why we can’t consider doing something similar for medicines”

NHS England

Provision of a funding mechanism

At the stage of patient access, the EAMS does not offer funding to manufacturers pre-marketing authorisation (pre-MA) and companies are expected to supply the product free of charge.

Whilst some companies have not considered this to be a significant barrier, others perceive the lack of funding to be a major barrier to entry. These selected companies have raised concerns about the impact of making products available as part of the EAMS given the high production cost some drugs, e.g. biologics, and the lack of guidance on an exit plan should the drug not receive a HTA recommendation.

Funding was considered as part of initial discussions about the EAMS and this was referenced in the Department of Business, Innovation and Skills’ UK Life Sciences Strategy report (published in 2011). The government clarified this issue in its response to the public consultation (published 2014). Due to a lack of consensus around how a funding mechanism which provides value for money could be implemented without linkage to a formal cost-effectiveness assessment, it concluded that a dedicated fund would not be established as part of the EAMS.

Industry have commented since that the scheme would be more attractive if the funding gap pre-MA and pre-HTA was addressed. Any funding mechanism introduced should be carefully considered. There was consensus amongst all companies we engaged with that funding during the EAMS should not reflect the price of the product post-MA but rather should serve as a recognition of the company’s commitment to early patient access. Furthermore, whilst desirable, funding was not deemed to be critical if the EAMS was able to offer rapid uptake post-MA decision and access to a robust infrastructure to collect real world data that they could apply to other markets.

Any funding mechanism introduced should be carefully considered. There was consensus amongst all companies we engaged with that funding during the EAMS should not reflect the price of the product post-MA but rather should serve as a recognition of the company’s commitment to early patient access

In France, via its Authorisation Temporaire d'Utilization (ATU) scheme, funding is offered for early access pre-MA. Considered by many in industry to be one of the best examples of a scheme with similar aims to the EAMS, the ATU has been in place for 21 years. It is useful to explore the experiences within the ATU, including the advantages and disadvantages of funding pre-MA and its applicability to the UK market (see next page for further details).

It is useful to explore the experiences within the ATU, including the advantages and disadvantages of funding pre-MA and its applicability to the UK market

“Small and medium sized companies will simply struggle to cover the cost of supplying some of their drugs during the EAMS period”

Trade Association

“I don't see a guarantee that participation will lead to earlier or faster product uptake post-MA...and unlike large companies we simply cannot afford to take the financial risk”

Biotech

“We should explore the ways industry and the NHS can share costs of the EAMS scheme”

Large Pharma

Learning from the ATU in France

The ATU scheme (Autorisation Temporaire d'Utilisation) in France makes medicines available to patients with high unmet need, typically 10 to 12 months pre-MA.

ATU is approved and controlled by the French ANSM (Agence Nationale de Sécurité du Médicament et des produits de santé).

ATU approval requires the manufacturer to submit data from clinical trials on efficacy and safety, information on the patient or the patient group to which the treatment will be provided, and justification for the treatment's use.

Key features

- **Offered pre-MA** for products treating rare or serious diseases with no effective alternative in France
- **Funded** with the price set by CEPS (Comité Economique des Produits de Santé) and the opportunity for clawback if the reimbursement exceeds a fixed ceiling
- **Available for a limited period of time**, typically no longer than 7 months after EMA approval
- **Two types** of ATU: Named Patient and Cohort, see below.



Delivered for one named patient at the request and responsibility of the physician

Product safety and efficacy presumed

Named Patient ATU

Cohort ATU



Delivered for a group of patients

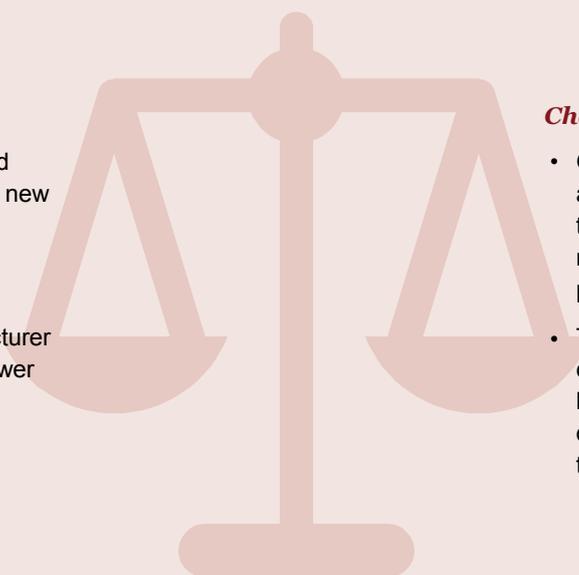
Product safety and efficacy strongly presumed with a commitment to submit an MA application

Benefits of the ATU

- Patients with unmet need receive earlier access to new medicines
- Government has the opportunity to request a rebate from the manufacturer if the price post-MA is lower than the ATU price

Challenges of the ATU

- Government needs to allocate a greater budget for transformative medicines to make the product available pre-MA
- The requirement for the company to set an early price benchmark for funding is difficult when value data on the drug is still being collected



Transition from EAMS patient access pre-MA to product uptake post-MA

The main concern for industry about the EAMS was the rate of uptake post-MA following the EAMS patient access period.

There is strong appetite for a smoother transition process from product uptake pre- and post- MA and industry has noted four areas as opportunities for improvement:

- Transition from managed access during the EAMS period to expanded access post-MA but pre-HTA decision
- Speed of HTA decision post-MA
- Application of the exit strategy post-MA and post-HTA for EAMS patients
- Speed of NHS uptake post-HTA decision

The main concern for industry about the EAMS was the rate of uptake post-MA following the EAMS patient access period

“There is currently a gap whereby access stops after marketing authorisation. We need a mechanism to sustain patient access”

Trade Association

“The main reason we’ve not considered the EAMS for our products to date is because we are concerned about how the early access period transitions to product uptake post-MA and post-HTA decision”

Large Pharma

“I like the idea of EAMS but I’m concerned whether the product will receive a positive HTA recommendation. As a result, I have limited prescription of these drugs to the most unwell cohort of patients.”

Clinician

Our recommendations

Based on our interviews and survey, industry felt that the greatest opportunity to improve the scheme was in achieving seamless uptake across the NHS following EAMS patient access. We recognise that solutions to address this will take some time to implement and have therefore also identified quicker wins that industry felt would deliver some more immediate benefits.

In the long term, we envisage that the EAMS will fit into the accelerated access pathways being developed as part of the Accelerated Access Review.

Short term recommendations

1. Provide updated guidance on the benefits and entry requirements of EAMS

Building on the procedural documentation currently available on the EAMS webpage, further clarification to summarise the entry requirements at each stage of the application process could be posted to ensure common misunderstandings are accurately addressed. This information could be published on a dedicated website which also includes the principles, operational guidance, and schematic of the EAMS.

In order to provide companies with a greater understanding of the value of the EAMS, there are several opportunities:

- Sharing the feedback from companies who have been successful in the EAMS process via case studies
- Statements from senior government stakeholders and arm's length bodies (MHRA, NICE, NHS and the devolved administrations) on their commitment to the scheme and the role they will play towards its success
- Highlighting the value of the commitment of the different stakeholders to the process pre- and post-MA

2. Provide easier industry access to MHRA, NICE, NHS and the devolved administrations

Industry has commented that one of the valued components of the EAMS is access to government and arm's length bodies. However, how they wanted to access these stakeholders differed.

As such, we recommend that companies are made better aware of the ways they could interact with the MHRA, NICE, NHS and the devolved administrations so that they are able to gain easier access to these stakeholders. These interactions could include:

- Upfront discussion with all the relevant stakeholders including the devolved administrations. This will aid a common understanding of the UK's evidence needs so that it can feed into their global development plan
- Advice throughout the process on study design and data collection to support patient access in the UK. This is likely to be particularly valuable for SMEs and biotech who may have limited experience of navigating the UK regulatory, HTA and local payer environment

Based on our interviews and survey, industry felt that the greatest opportunity to improve the scheme was in achieving seamless uptake across the NHS following EAMS patient access

We recommend that companies are made better aware of the ways they could interact with the MHRA, NICE, NHS and the devolved administrations

- Ad-hoc, via a directory of contacts who can be leveraged to support a successful EAMS process

In addition, we recommend that companies are encouraged to share the preliminary Scientific Opinion with local NHS stakeholders whether for specialised commissioning or CCG commissioned products so that the manufacturer and NHS can prepare for managed access.

3. Track patient access of approved products during the EAMS period

In order to better articulate the value of the EAMS, it is key to be able to track the level of patient access achieved during the EAMS period. Data could be collected by the company on a regular basis and reported back to the OLS on a national level for publication.

This can help to (a) incentivise uptake across the NHS and (b) demonstrate the UK's commitment to early access via the EAMS when the data is then shared at an aggregate level nationally.

The data could also be used by UK affiliates to demonstrate the value of the EAMS to their headquarters and likewise for CCGs and Trusts to assess their uptake of innovative products.

Medium term recommendations

1. Earlier HTA of EAMS-approved products

Earlier HTA by NICE will help to shorten the patient access gap which currently exists between MA and adoption in the NHS.

To deliver this, NICE have committed to start the HTA process in parallel with the MA review, which will allow draft guidance to be issued on the day the European Commission ratifies the MA. It also means that if the recommendation was positive, NICE's Final Appraisal Determination (FAD) could be issued within 6 weeks of this date if there was no appeal.

Achieving earlier HTA approval will require both the company and the HTA body to engage in earlier discussions. This is already occurring in some instances. For example, MSD was able to receive NICE draft guidance for its product pembrolizumab (Keytruda) within 5 weeks of its EU MA commission decision.

We recommend that the HTA bodies and companies continue to consider how they can accelerate the review of EAMS-approved products.

2. Rapid NHS uptake following a positive HTA to provide smooth transition to nationwide access

In England, for EAMS-approved products that undergo specialised commissioning, there is a commitment from the NHS to make funding for the product available within 30 days of NICE's final guidance. This allows patients to receive access to treatment up to 2-3 months earlier than other products which typically have a 90 day implementation mandate.

Building on this commitment, there are several other potential opportunities to close the patient access gap between MA and NHS uptake:

Achieving earlier HTA approval will require both the company and the HTA body to engage in earlier discussions. This is already occurring in some instances

- Providing interim funding for EAMS-approved products pre-HTA decision where data collected during the EAMS patient access period show positive outcomes. The company could set the price at the proposed price for HTA and, depending on the outcome of the HTA, would credit or debit the NHS post-HTA. This would be similar to the approach that is taken in Germany where free pricing is permitted until the HTA is completed
- Commissioning of EAMS-approved products following the publication of a positive draft HTA guidance rather than at the stage of final positive guidance
- Supporting faster uptake of all EAMS-approved products (specialised and CCG commissioned) across England and the devolved nations

Realising the benefit of these opportunities will require early dialogue between the manufacturer, MHRA, NICE, and the devolved administrations around a product's suitability for use during the EAMS period and also subsequently post-MA.

3. Offer funding via application

For the group of companies where the lack of funding pre-MA would preclude them from entering the scheme, we recommend the government considers whether funding could be made available. One potential approach could be:

- Enabling companies to apply for a fixed rate of funding per patient per pack
- For products with high manufacturing and distribution costs, the company could submit additional data as part of their application to request a higher level of payment, up to a fixed ceiling. We recognise that this may be difficult to implement and additional effort would be required to assess the information submitted and grant the funding
- A cap could also be introduced to limit how long the funding could be claimed for, should the MA take longer than a set time period

Companies should identify early on whether they intend to apply for this funding so that (a) patient access post-SO is not delayed and (b) the NHS could budget accordingly.

Long term recommendations

To support the drive towards adaptive licensing, we suggest that the EAMS provide companies with the relevant infrastructure to collect real world data. Consideration should be given to how this could be positioned within the UK's Accelerated Access Review.

1. Use existing databases to collect RWD

Whilst it is recognised that the EAMS patient access period would typically be less than a year, there is nevertheless an opportunity for companies to generate RWD to support funding and commissioning decisions.

The company should work in partnership with the NHS, MHRA and HTA bodies to realise the potential benefits of RWD. This builds on the existing experience of the NHS and NICE in facilitating RWD collection as part of the Commissioning through Evaluation scheme.

Key activities will include:

- Identifying what data is required from a UK perspective and how this could feed in to the overall global development plan

Realising the benefit of these opportunities will require early dialogue between the manufacturer, MHRA, NICE, and the devolved administrations around a product's suitability for use during the EAMS period and also subsequently post-MA

- Defining what infrastructure changes should be made to facilitate the collection of RWD during the EAMS patient access period and post-MA

This will not be easy to implement and there are some key questions that still need to be resolved as part of the Accelerated Access Review as well as wider government initiatives.

Conclusion

The EAMS is an important mechanism in securing early patient access to innovative medicines in areas of clear unmet medical need and with some changes could become an even more effective means to accelerate adoption of these products across the NHS.

Building on the strengths of the existing scheme, we believe that implementation of our short- and medium-term recommendations will help deliver an improved EAMS process.

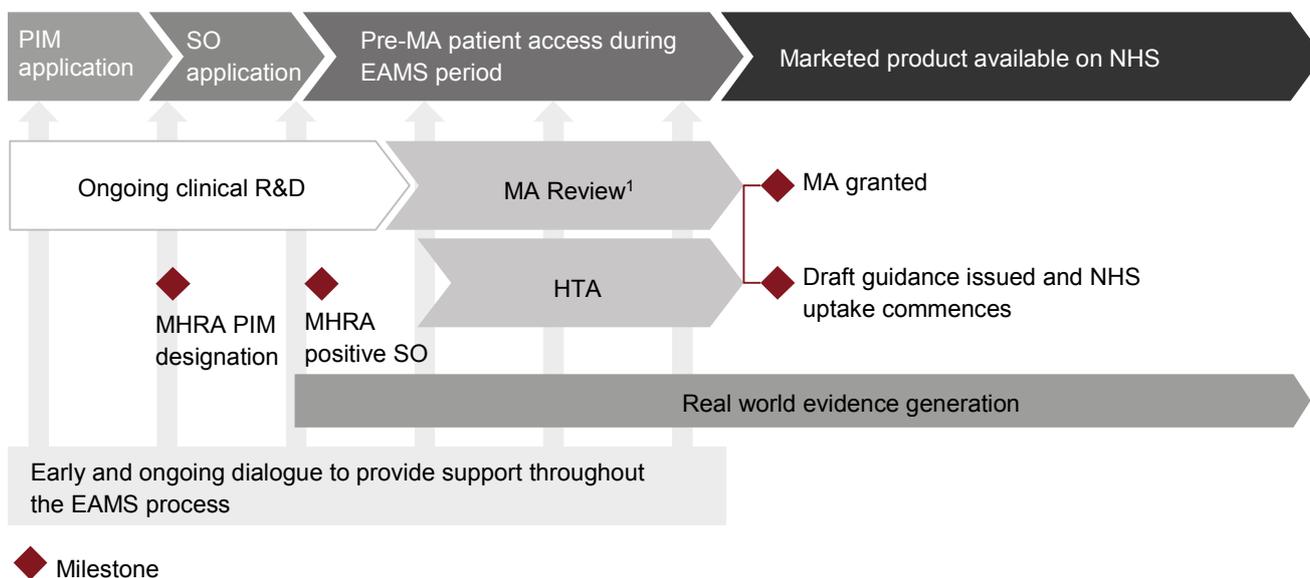
The key features of our vision for a future EAMS process include:

- A clear articulation of the benefits of EAMS and the level of evidence required for entry
- Consideration of funding pre-MA to support companies with cost of supply to the NHS
- A robust mechanism to support real world data generation during the EAMS patient access period and beyond
- A flexible, transparent and smooth process that delivers rapid patient access pre-MA
- A seamless and smooth transition to NHS adoption post-MA

Building on the strengths of the existing scheme, we believe that implementation of our short- and medium-term recommendations will help deliver an improved EAMS process

Exhibit 6: Our vision for a future EAMS process

c. 2 months, c. 2-3 months¹ (variable, until MA grant)



Note: ¹PIM and SO application lengths can vary

Over a longer time horizon, we recommend that the EAMS aligns with the proposed accelerated access pathways being developed as part of the UK's Accelerated Access Review as well as European-level developments such as the European Medicines Agency's PRIME scheme.

Appendix A: Interview and workshop stakeholders

Insight and viewpoints of the EAMS have been gathered through a series of interviews and workshops. In total, Strategy& have held discussions with 42 different organisations.

The full list of organisations contacted can be found below:

Industry

AbbVie
AstraZeneca
Atlantic Healthcare
Avillion
Bristol-Myers Squibb
Eisai
Eli Lilly
Gilead Sciences
GlaxoSmithKline
ImmunoCore
Janssen-Cilag
MSD
Novartis
Pfizer
Shire

Trade associations

Association of British Pharmaceutical Industry
BioIndustry Association
Ethical Medicines Industry Group

Innovation centres

Cell Therapy Catapult
Centre for the Advancement of Sustainable Medical Innovation
Precision Medicines Catapult

Patient advocacy groups

Cancer Research UK
Cystic Fibrosis

Duchenne Children's Trust
Myeloma UK
Pumping Marvellous

Government and AAR team

Department of Health
National Institute for Health Research
Office for Life Sciences
Scottish Government
Welsh Government

NHS organisations

Health Innovation Network (South London AHSN)
NHS England
NHS Foundation Trusts
NHS Northern Ireland
NHS Scotland
NHS Wales

Regulators

Medicines and Healthcare products Regulatory Agency

HTA bodies

All Wales Therapeutics and Toxicology Centre
National Institute for Health and Care Excellence
Scottish Medicines Consortium

Appendix B: Government and industry task group members

Government and arm's length bodies

All Wales Therapeutics and Toxicology Centre

Department of Health

Medicines and Healthcare products Regulatory Agency

National Institute for Health and Care Excellence

NHS England

NHS Northern Ireland

NHS Scotland

NHS Wales

Northern Ireland, Department of Health, Social Services and Public Safety

Office for Life Sciences

Scottish Government, Directorate General Health and Social Care

Scottish Medicines Consortium

Welsh Government, Department of Health and Social Services

Industry

Association of British Pharmaceutical Industry

BioIndustry Association

Ethical Medicines Industry Group

Representative companies as invited by trade associations:

- Abbvie
- BMS
- Janssen-Cilag
- MSD
- Novartis
- Pfizer

Other

Centre for the Advancement of Sustainable Medical Innovation

Appendix C: Survey respondents and selected results

To accompany the views captured via interviews, workshops, and desktop research, Strategy& also launched a survey to engage with a broader range of stakeholders.

The survey was open from Thursday 29th October and closed on Wednesday 2nd December 2015. A total of 17 responses were received.

There were 21 questions in total and all results have been taken into consideration as part of our review. A selection of these findings are exhibited below.

Exhibit 7: Survey respondents by organisational category

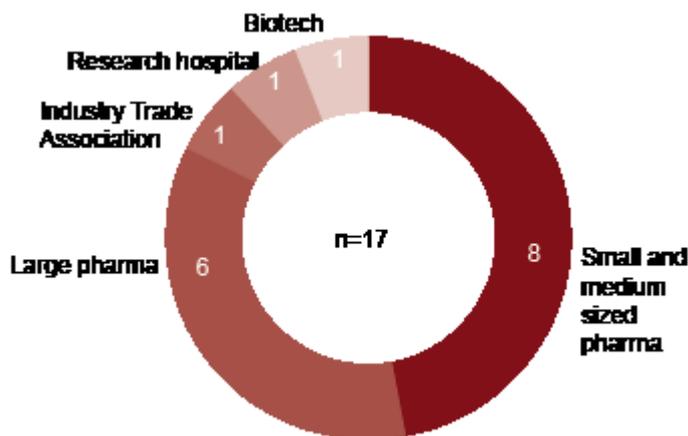


Exhibit 8: Survey respondents by experience of the UK's EAMS

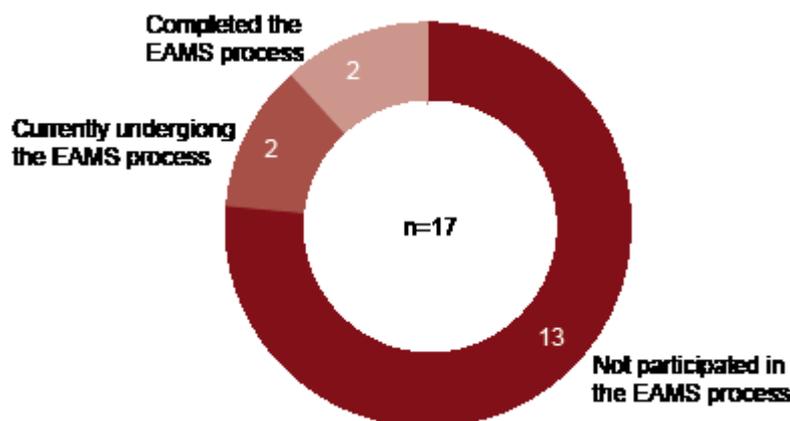
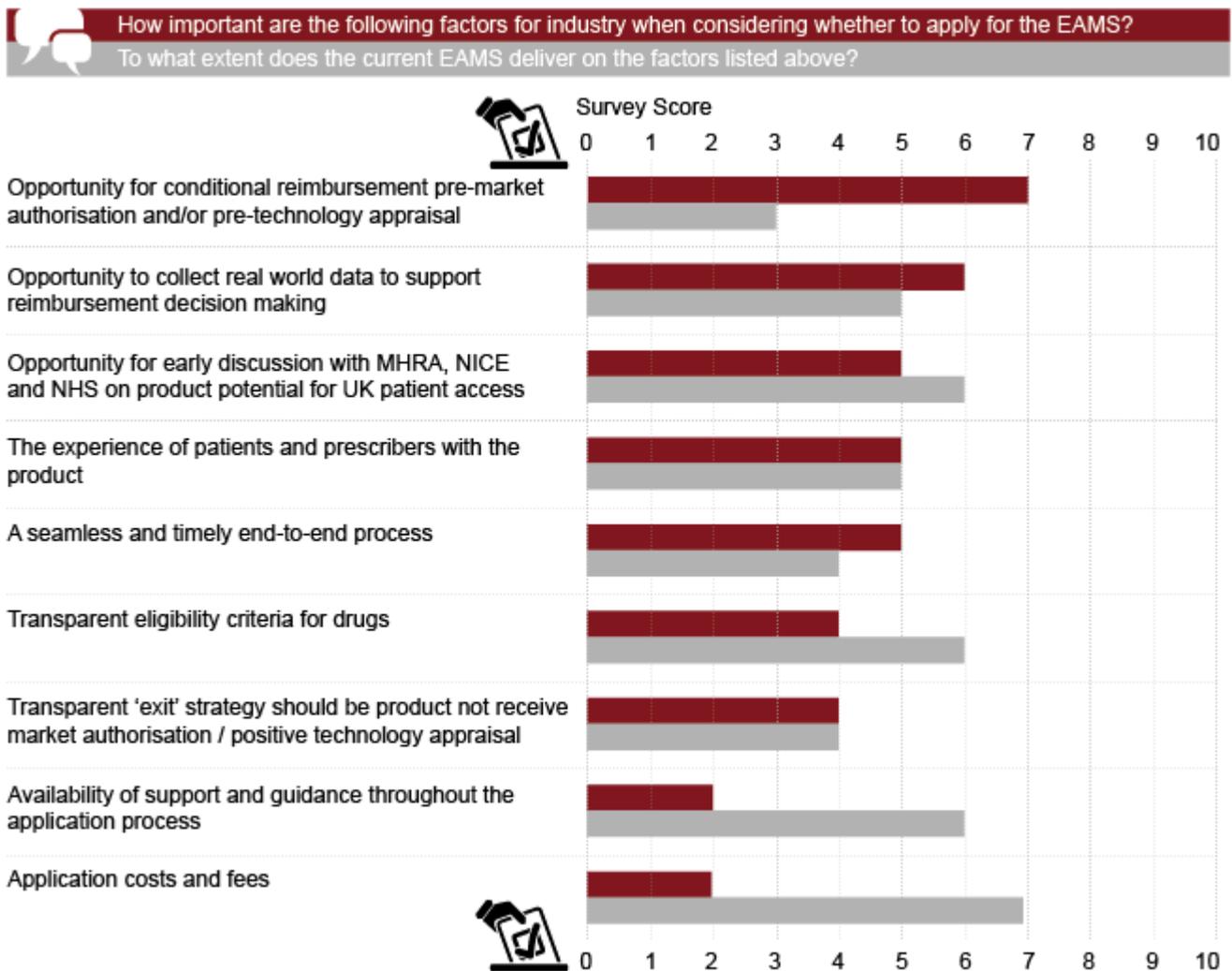


Exhibit 9: Survey participants scored their views on (a) how important factors are for industry when considering whether to apply for the EAMS and (b) to what extent are these factors currently delivered by the EAMS



Glossary of terms

Abbreviation	Term
ABPI	Association of the British Pharmaceutical Industry
AHSN	Academic Health Science Network
AWTTC	All Wales Therapeutics and Toxicology Centre
BIA	BioIndustry Association
CCG	Clinical Commissioning Group
CPRD	Clinical Practice Research Datalink
DH	Department of Health
EAMS	Early Access to Medicines Scheme
EMA	European Medicines Agency
EMIG	Ethical Medicines Industry Group
FAD	Final Appraisal Determination
HTA	Health Technology Assessment
MA	Marketing Authorisation
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OLS	Office for Life Sciences
PIM	Promising Innovative Medicine
PRIME	Priority Medicines
RWD	Real World Data
RWE	Real World Evidence
SACT	Systemic Anti-Cancer Therapy Dataset
SMC	Scottish Medicines Consortium
SME	Small and Medium Sized Enterprises
SO	Scientific Opinion

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