Medicines & Healthcare products Regulatory Agency

Working together:

Accelerating access to breakthrough technologies

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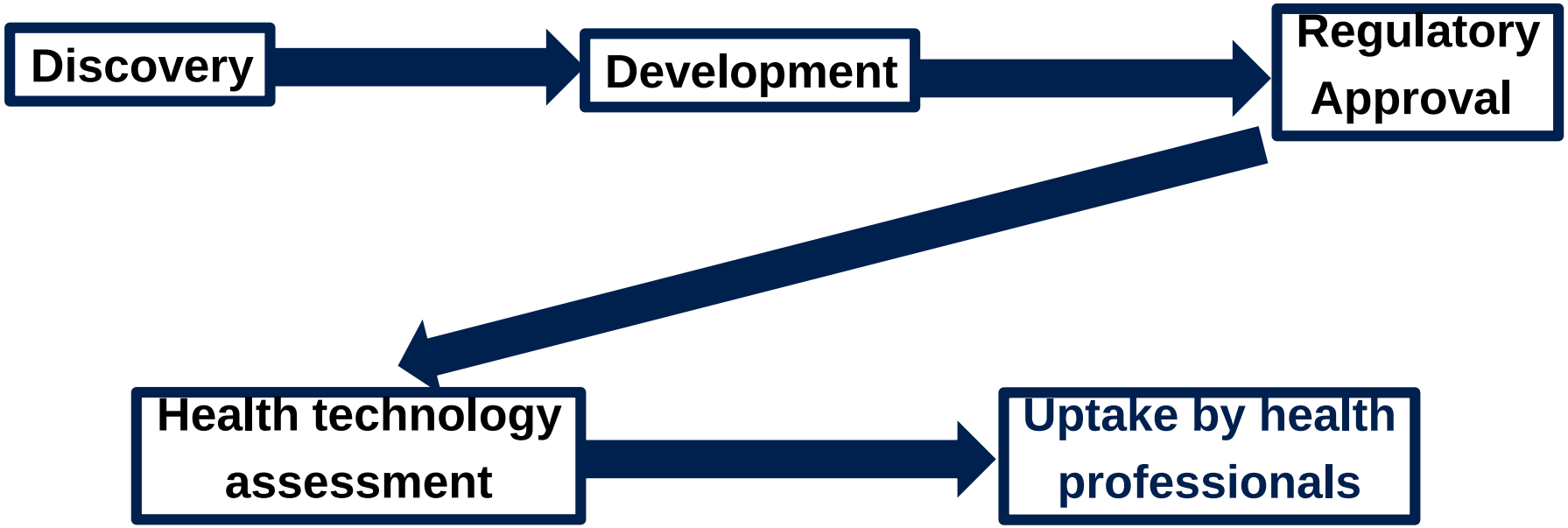
CPRD NIBSC MHRA

Pathway


Discovery
Development
Regulatory Approval
Health technology assessment
Uptake by health professionals

Accelerated Access Review

The AAR made a series of recommendations to enable the NHS to:

- Improve patient outcomes
- Use the UK's strong biosciences research and life sciences industrial base
- Enhance the international competitiveness of our life sciences industry

The roles of the AAC

These will include:

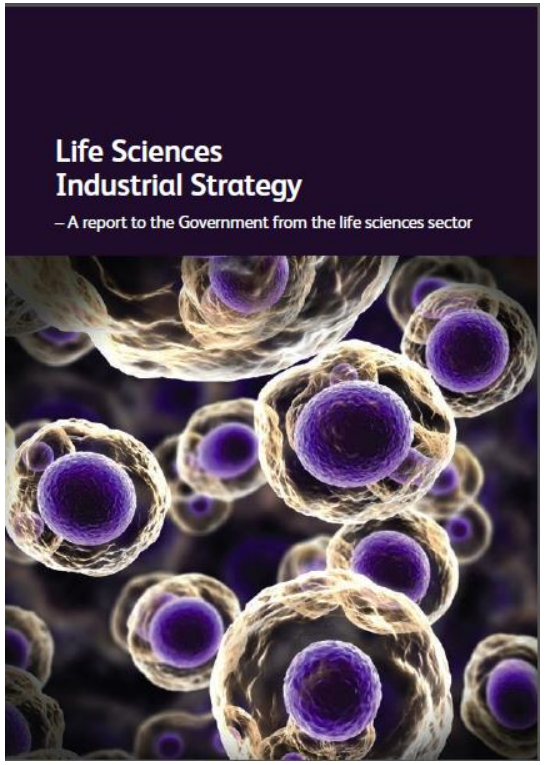
- Horizon scanning for breakthrough products
- Streamlining the development pathway
- Encouraging the use of “real world data”
- Encouraging the adoption of flexible pricing arrangements
- Supporting adoption and diffusion through the Academic Health Science Networks

Identifying transformative innovations

The horizon scanning process will consider:

- Improvements to patient outcomes
- Increasing efficiencies in the system
- Potential barriers to uptake

Life Sciences Industrial Strategy



Cross cutting themes

Those with special relevance for the MHRA include

- Novel clinical trial methodologies
- New “managed access pathway”
- Early Access to Medicines Scheme
- New transformative designation
- Innovation partnership/concordat - closer working with other regulators
- Development of regulatory science
- Commitment to closer working with other parts of the system to create end-to-end pathway

Clinical trials

1. Novel trial designs including:
   - Umbrella trials
   - Basket trials
   - Adaptive designs
   - Step-wedge trials
2. Greater use of Bayesian statistics
3. Development and use of novel biomarkers/surrogate endpoints
4. Use of “real world data”

Early Access to Medicines Scheme

Step 1: Promising Innovative Medicine (PIM) Designation

Step 2: Early Access to Medicines (EAMs) Scientific Opinion

A sponsor is then able to provide the NHS with the product despite the lack of Marketing Authorisation

Conclusions

1. Supporting innovation is a key priority for the MHRA and the government

2. MHRA will work closely with government to implement the recommendations of both the AAR through the LSISB

3. MHRA will continue to work with industry, academia and patient groups to facilitate patient access to innovative treatments and therapies