

# Access to novel medicines in England

Delivering a transparent, inclusive and sustainable offer

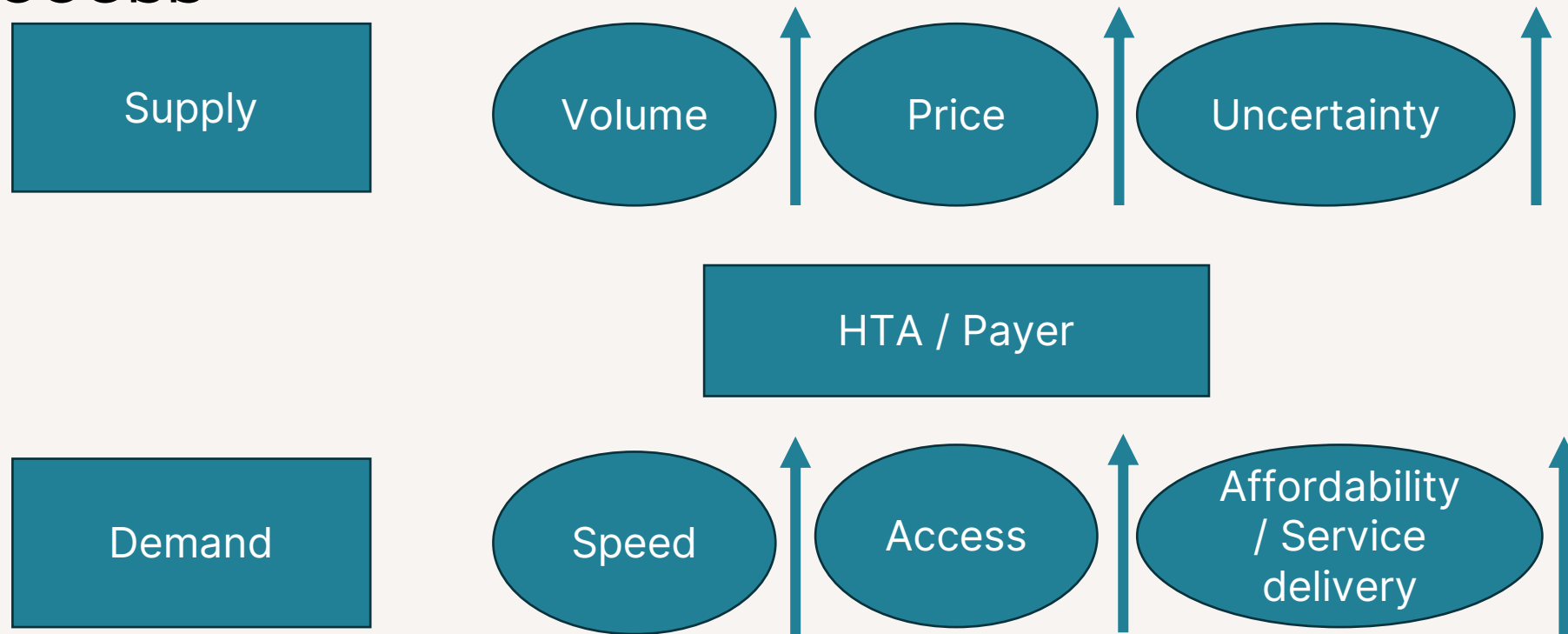
Meindert Boysen – head of international affairs

November 2023

**NICE** National Institute for  
Health and Care Excellence



# Novel medicines coming to market putting significant pressure on HTA and payer systems to support patient access



NICE



# Many complex, high impact, innovations are expected to come to market in next 3-4 years, with significant price tags.

31 ATMPs in  
39  
indications

49 ultra-  
orphan  
drugs

206 immuno-  
oncology  
records  
(pem/nivo/ate)

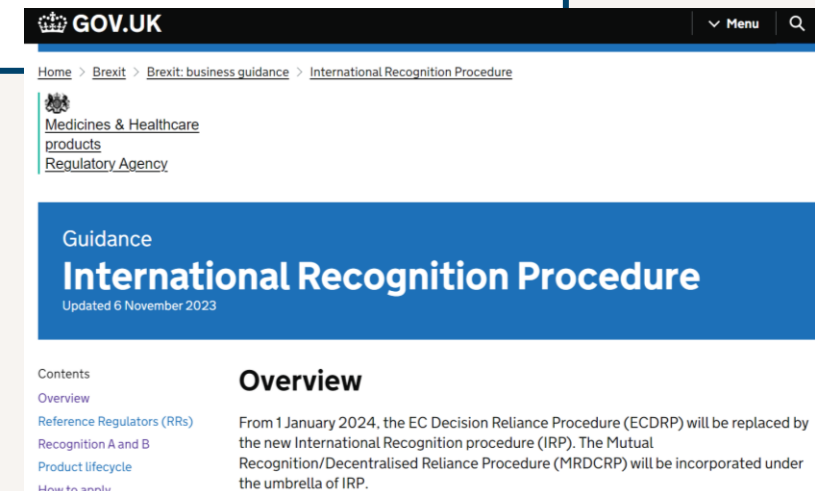
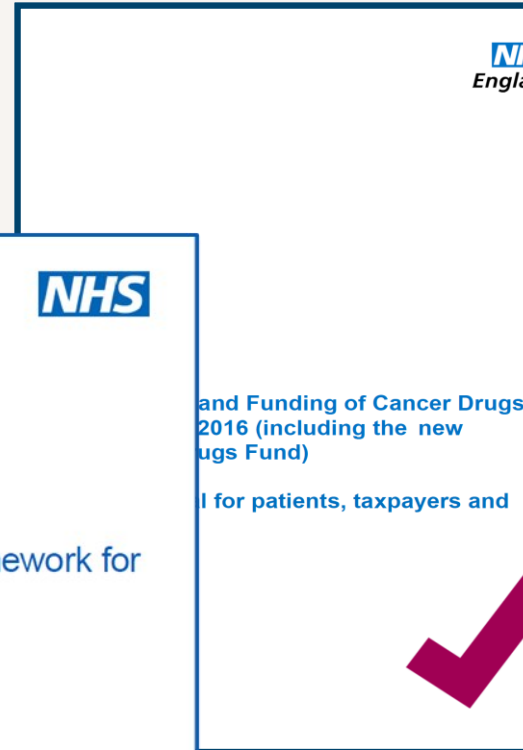
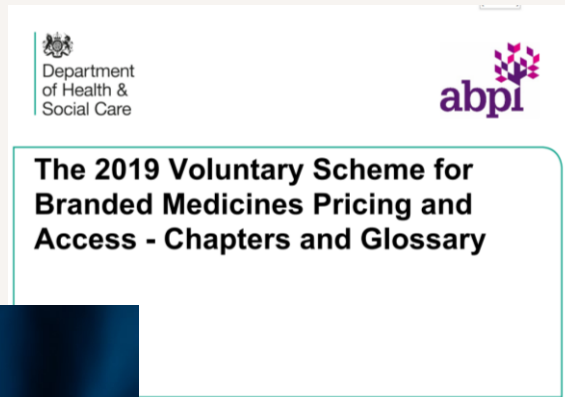
21 dementia  
drugs

12  
haemophilia  
drugs

Data on file NHS England – courtesy of John Spoons et al.  
Subject to change – different cut-off dates.



# UK has put in place several arrangements to stimulate and manage the introduction of (pharmaceutical) innovation



**In which NICE  
plays a central  
role ... with  
success (>80%  
of ATMPs  
recommended)**

**NICE helps practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer.**

We do this by:



Producing useful and useable guidance for health and care practitioners.



Focusing on what matters most by prioritising topics that are most important to the health and care system or address an unmet need.



Providing rigorous, independent assessment of complex evidence for new health technologies.



Encouraging the uptake of best practice to improve outcomes for everyone.

# To better serve people and the health and care system, NICE is evolving in 3 ways

We've listened to our stakeholders. While preserving our core values of transparency, rigour and independence, we need to change.

1

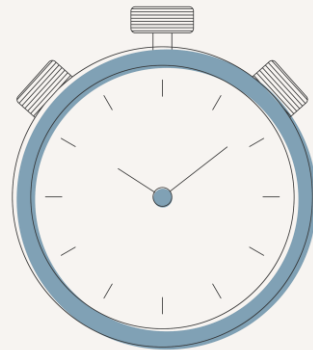
More relevant



...by focusing on what matters most

2

More timely and useable



...by providing useful and useable advice

3

Greater demonstrable impact

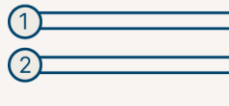


...by learning from data and implementation

# Impact of our changes in 2022-23

## Medicines access/timeliness

The UK is

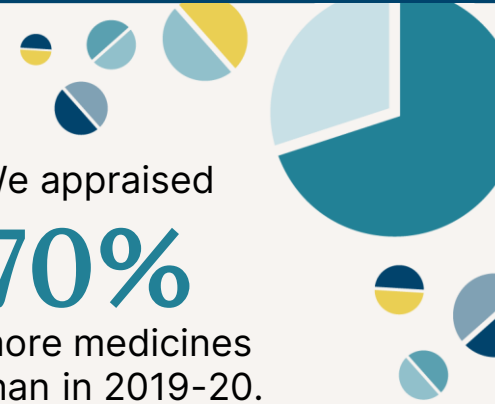


globally for the number of medicines commercialised within 1 year of regulatory approval.



We evaluated medicines on average **17% faster**, meaning thousands of patients can **access new treatments sooner**.

We appraised **70%** more medicines than in 2019-20.



We applied light-touch, proportionate evaluations to low-risk treatments, **up to 20 weeks faster** than our normal processes.



## Relevance

We recommended **20 digital technologies**



addressing key priorities including stroke diagnosis and mental health in children and adults.

We pioneered a world-leading evaluation and payment model for **antimicrobials**. This led to approval of the **first new antibiotics in a decade**.



## Use of real-world data

We recommended the **100th treatment** for the Cancer Drugs Fund, allowing patients to access promising medicines while real-world data is gathered.



We developed the first **real-world evidence framework** showing how real-world data can fill gaps in our knowledge and drive access to innovations for patients.

**20,000 views**

# What's next?

## Within the next 5 years we will:

- deliver integrated, living guidance
- offer agile evaluation of medicines and health tech, with recommendations automatically included in clinical guidelines
- contribute to a national learning healthcare system
- track uptake and impact of our guidance in the NHS.

NICE

## In 2023-24 we will:

### Ensure our relevance

- Develop a **NICE-wide prioritisation and topic selection function** underpinned by extensive stakeholder engagement.
- Establish a **single front door** for innovators and industry.

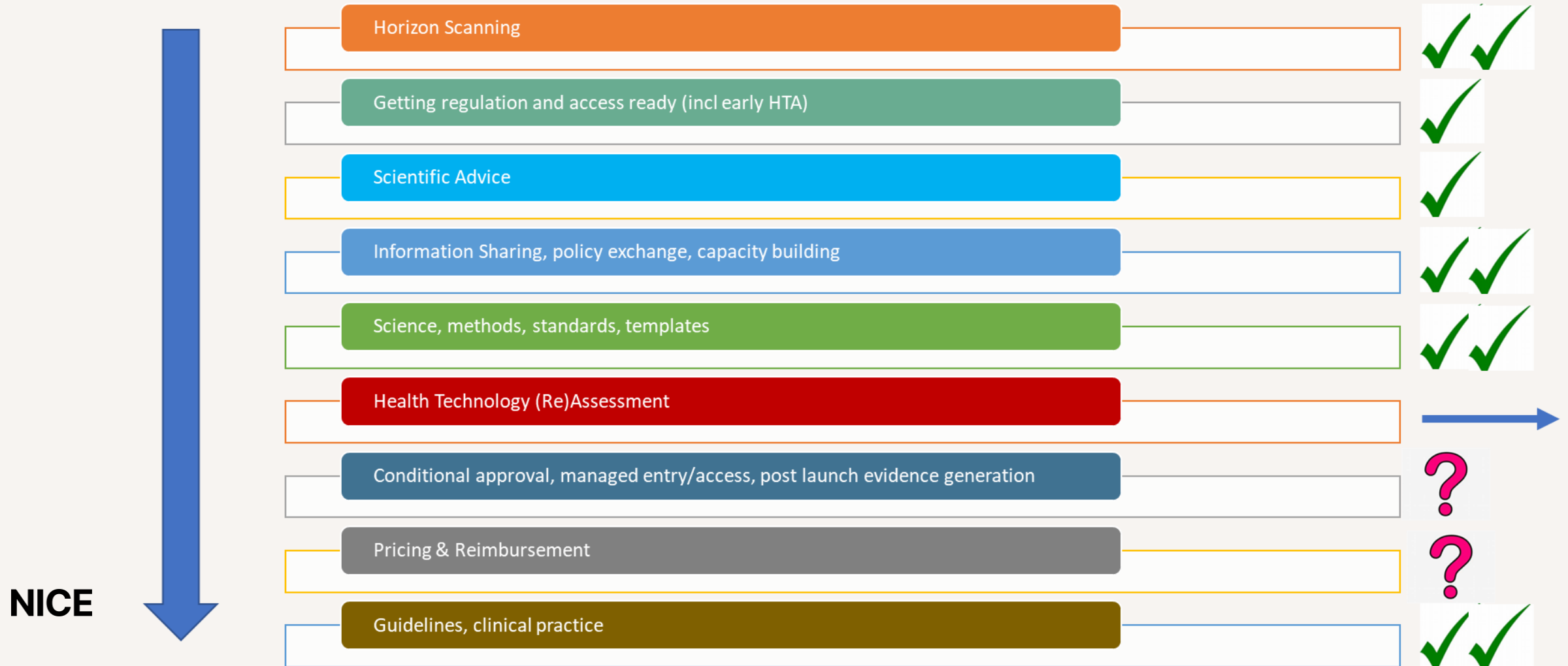
### Provide more timely and useable advice

- **Reduce the time taken to assess medicines and health tech by 15%** through streamlining processes.
- **Expand our health tech advice** by providing guidance on classes of technologies already in use and evaluating new digital technologies through our Early Value Assessment Programme.
- Pilot approaches to **automatically incorporate appraisals of medicines and health tech into guidelines.**

### Demonstrate our impact

- **Track uptake of NICE's guidance in key priority topics.**

# More can be done to make the system 'sustainable' through (international) collaboration.



# For example ... in the development and delivery of a managed access agreement

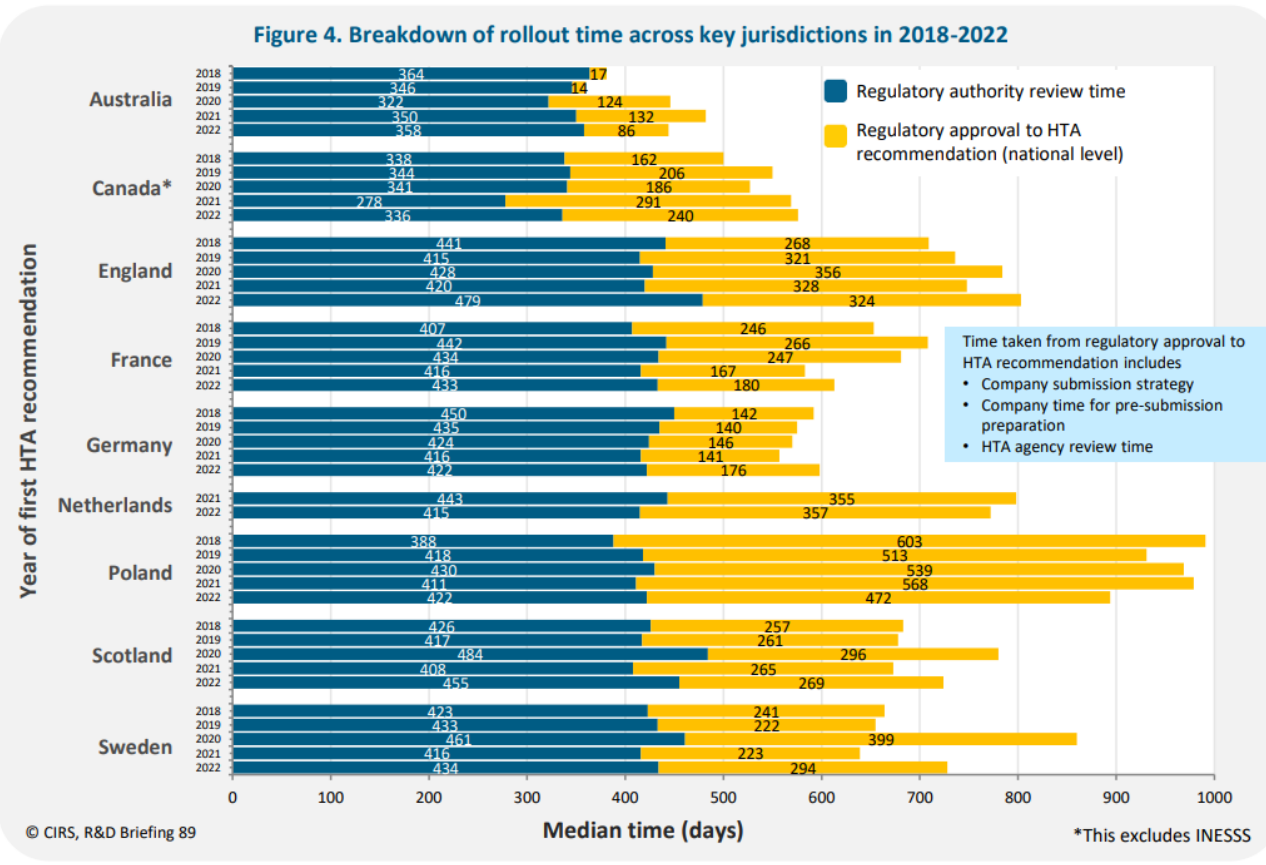


## UNDERLYING NICE-LED ACTIVITIES

Identify existing sources for data collection	Identification of potential topics for managed access	Company submission to NICE	Managed Access Oversight Group	NICE support for submissions from all stakeholders
Scientific advice	Managed access feasibility assessment	Data collection agreement working group (inc IG and data quality)	Methods statement (+/- ethics)	BAU data collection
ILAP & OMA engagement	NHSE&I commercial surgeries	Data Collection Agreement drafting	Funding arrangements for data collection and analysis	
REQueST Tool		Identify minimum dataset requirements	Standardised agreement templates for data access and funding	

# What will this picture look like in the coming years? What are we hoping to achieve?

## SYNCHRONISATION OF REGULATORY AND HTA RECOMMENDATIONS



- EU HTA
- EU Pharma Strategy
- AUSCANNZUK collaboration
- MHRA international recognition
- NICE proportionate approach
- HAS early access
- WHO NMP
- Etc