Barts and The London
School of Medicine and Dentistry

MSc Clinical Drug Development

WHRM910: Pharmaceutical and Healthcare Marketing Module

Day Three: Market Access

24 May 2023

Objectives

1. **To gain an understanding of ‘market access’ as a component of the marketing mix**

   - using the UK as an example, understand the key organisations and processes involved, and the implications for the pharmaceutical industry

2. **To understand how market access integrates with the marketing mix and impacts the product lifecycle and success**

Timetable for today

Timing	Activity
10.00 - 13.00	**Introduction to 'market access'** - positioning within the marketing mix and the impact on product potential - HTA outside the UK
	Group debate with active online student participation
	Health Technology Assessment (HTA): the UK experience
	Individual work: students to present their thoughts to the group
13.00 - 14.00	**Lunch**
14.00 - 16.45	**HTA requirements** - process for review and appeals - student debate - dossier development - individual work with students chosen to share their considerations
	Impact of guidance on prescribing and funding
	Group discussion
	Managing communication pre and post product launch - who, what, when to communicate - integrating communications across the marketing mix
16.45 - 17.00	**Summary of the day and final questions**

Introduction to ‘market access’

Some terminology & definitions

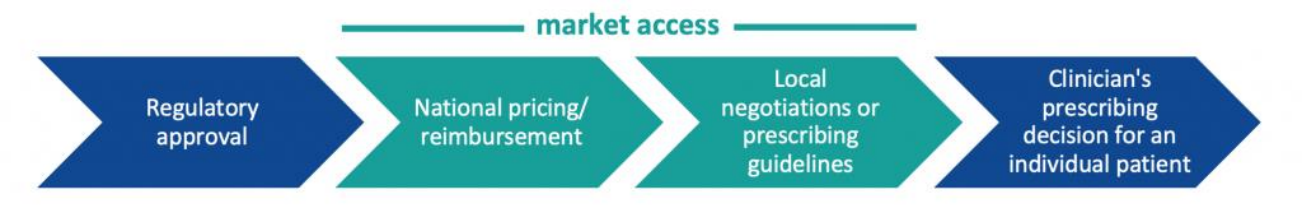
A variety of terms used .. historically; ‘managed entry’, ‘fourth hurdle’

Definitions….wide variety exists across the healthcare industry with no real consensus;

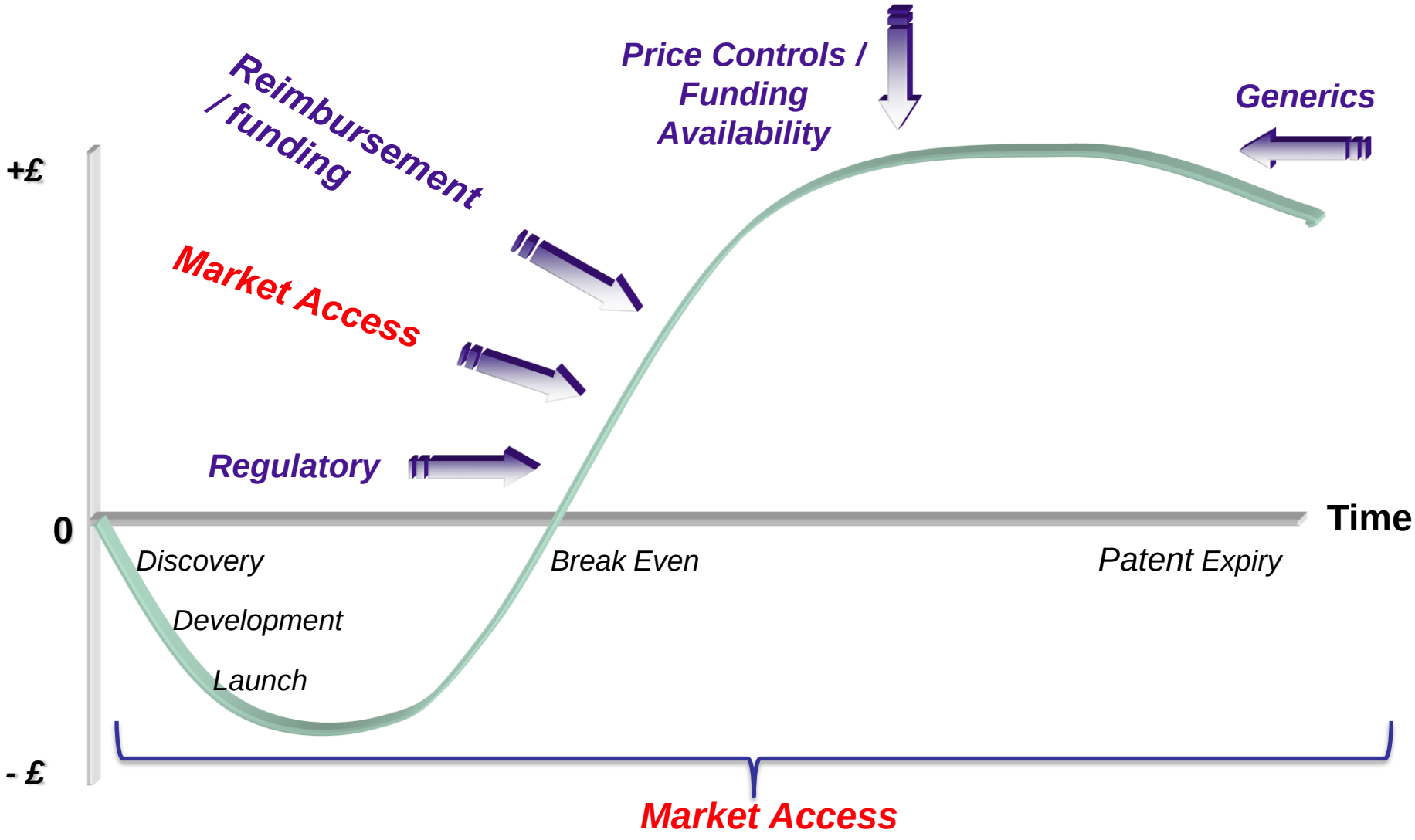
- “focusing on non-clinical barriers to the use of a product (usually involving financial hurdles)”
- “the process which prepares a positive healthcare environment with minimal barriers to access and use of a product”
- “creating the best conditions for developing, manufacturing and marketing new products”
- “considering the implications your product may have on the wider healthcare market and, in turn, the impact the changing healthcare market will have on your product”
- “to ensure that eligible patients in need have rapid, consistent and sustained access to (new) treatments”
- “making sure products and services are fairly priced and reimbursed”

Market Access Defined

Market Access is a strategic process that ensures the development and commercial availability of pharmaceutical products with appropriate value propositions, leading to their prescribing and to successful uptake decisions by payers and patients, with the ultimate goal of achieving best patient outcomes and profitability.



‘Market access’ will influence brand performance throughout the lifecycle



Why is Market Access so important?

Increasing costs, advances in treatments, aging populations and reduced budgets.....

Centralised guidance with localised decisions covering an increasingly complex array of stakeholders and influencers

Increasing demand for health economic data to prove value for money

Increasing potential for MEA's (managed entry agreements) to support drug funding

Why is Market Access so important?

Source: Proctor and Silvey Principles of Pharma Market Access in Europe

...so what is Health Technology Assessment (HTA) and how does it relate to Market Access?

Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of a health technology.

It is a multidisciplinary process to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology.

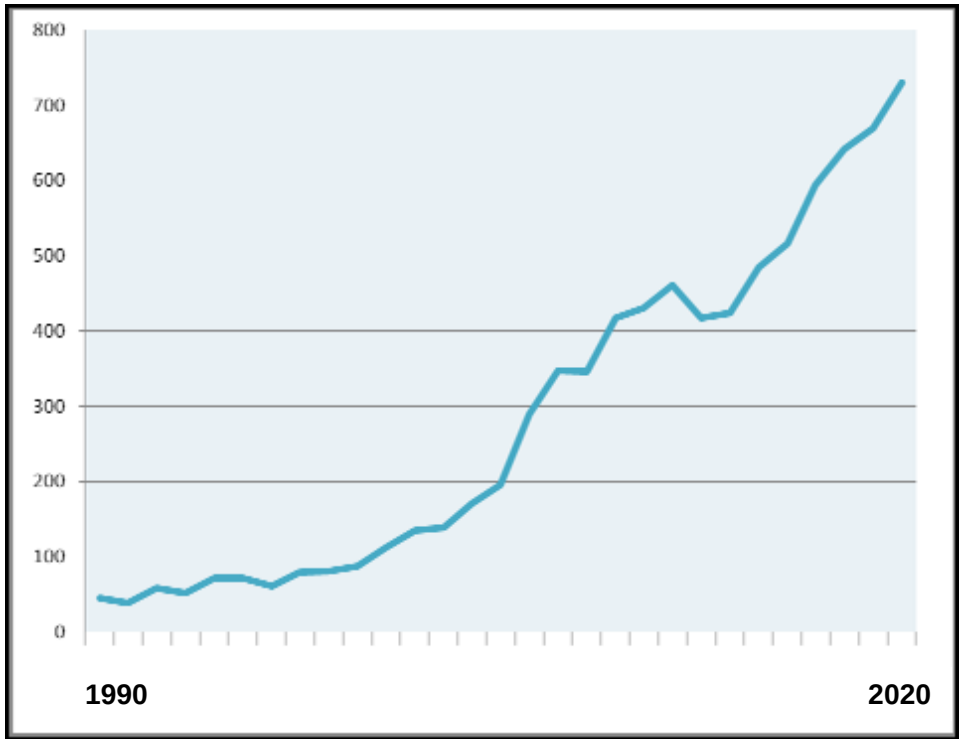
The main purpose of conducting an assessment is to inform a policy decision making in a transparent unbiased robust manner.

HTA seeks to achieve ***best value*** and ***best outcome*** *and d*espite its policy goals, HTA must always be firmly rooted in research and scientific method.

"Knowledge of HTA processes is essential to optimise market access"

Source: Adapted from EUPATI, European Patients Academy 2018 (www.eupati.eu)

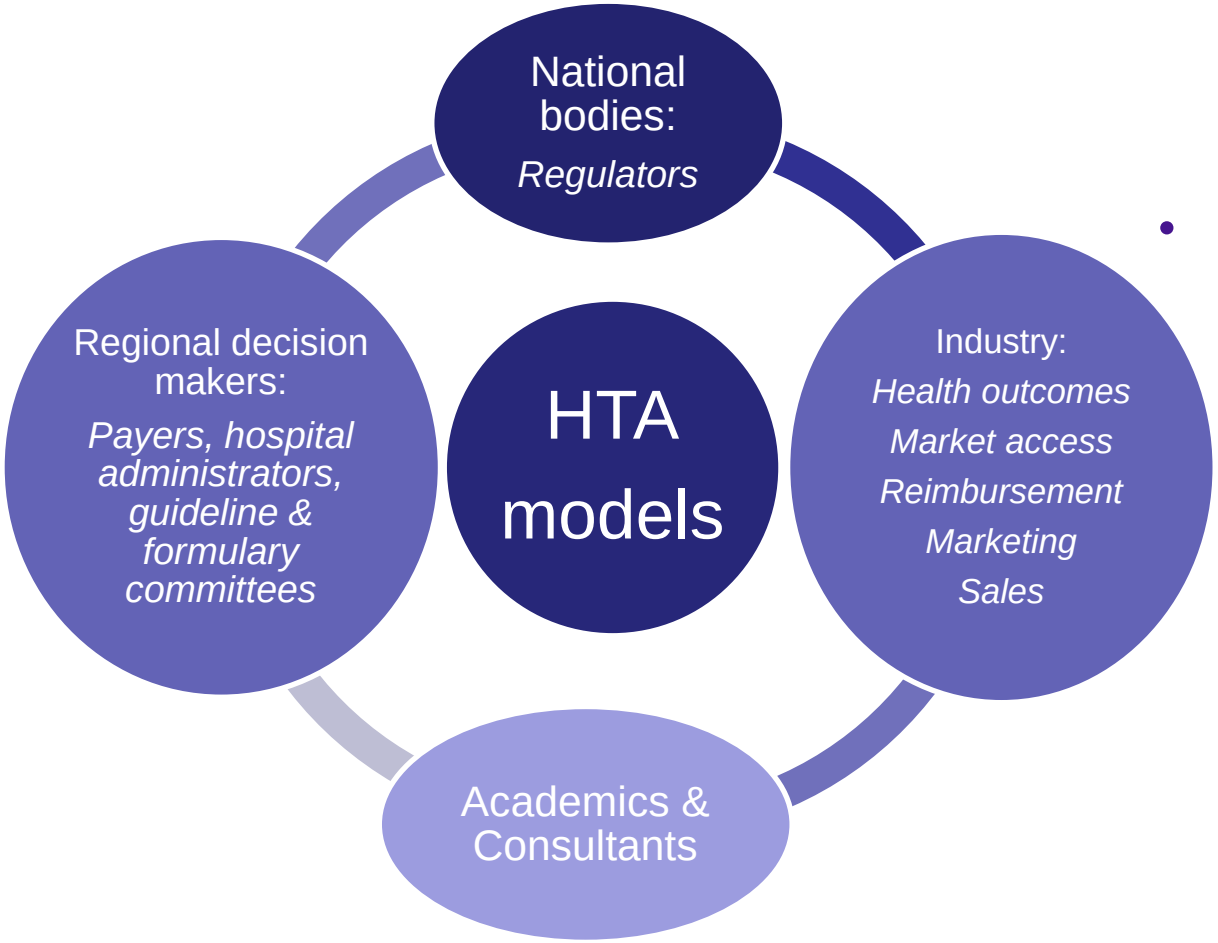
Spectacular increase in HTA studies...



... make economic modelling and the area of health outcome measurement of increasing importance in healthcare

Source: Adapted from the increasing number of publications with ‚cost-effectiveness‘ in the title on PubMed over the past 3 decades.

...and many people now have to deal with HTA models



- Who is the audience?
  - Not necessarily experts in HTA
  - Not familiar with modelling technology
  - Geographically distributed
  - Different priorities

... including the pharmaceutical marketer

- Health technology assessment is a critical tool increasingly used by health agencies across the globe in order to assess the **efficiency** of new pharmaceutical products by linking the drugs impact to **defined outcomes**.

- It has become the single most important appraisal in order to achieve market access and reimbursement status (and in the UK, funding).

- ***There is a disjoint between evidence required for registration and that required for reimbursement – often one where the marketer has to bridge the gap.***

- Failure to plan for and execute a high-quality market access strategy can cost a company millions/billions … and without it, a drug may not gain approval and never realise its full commercial and clinical potential.

... post Covid-19 challenges and opportunities

- Funding is becoming increasingly challenging given the expenditure surrounding Covid-19 and required catch up for healthcare systems
- Covid-19 has been used as a catalyst for change, and the disruption has been used to facilitate change in healthcare – notably in the short term, a digital revolution
- Media reporting has started to look at quality of life, the explanation of QALY, and the impact of Covid-19 on general health states
- Pharma companies that embrace ***value*** at the heart of their business will accelerate their positioning and success in the future
- ***"Manufacturers need to be able to tell a good story to drive utilisation and inspire coverage. To do that, they first must develop an amazing product, wrap the right distribution and patient support services around it, craft a story that will resonate with the market, and then use the right channels to tell that story to the right people"***

https://www.pharmexec.com/view/10-market-access-trends-to-watch-for-in-2023

HTA outside the UK

European HTA agencies

• Countries spend approx. 10% of GDP on pharmaceuticals

• Significant differences exist between countries in the recommendation of products to be used

• Differences driven by;
  - methods of assessment
  - which evidence is included
  - comparator choices etc.

INAHTA

eunethta

• Increasing case for data sharing and collaboration – pan EU groups emerged (EUnetHTA, The SEED Consortium: Shaping EU Early Dialogues for health technologies)
  - Public consultation on future working/guideline for comparators etc

European Commission

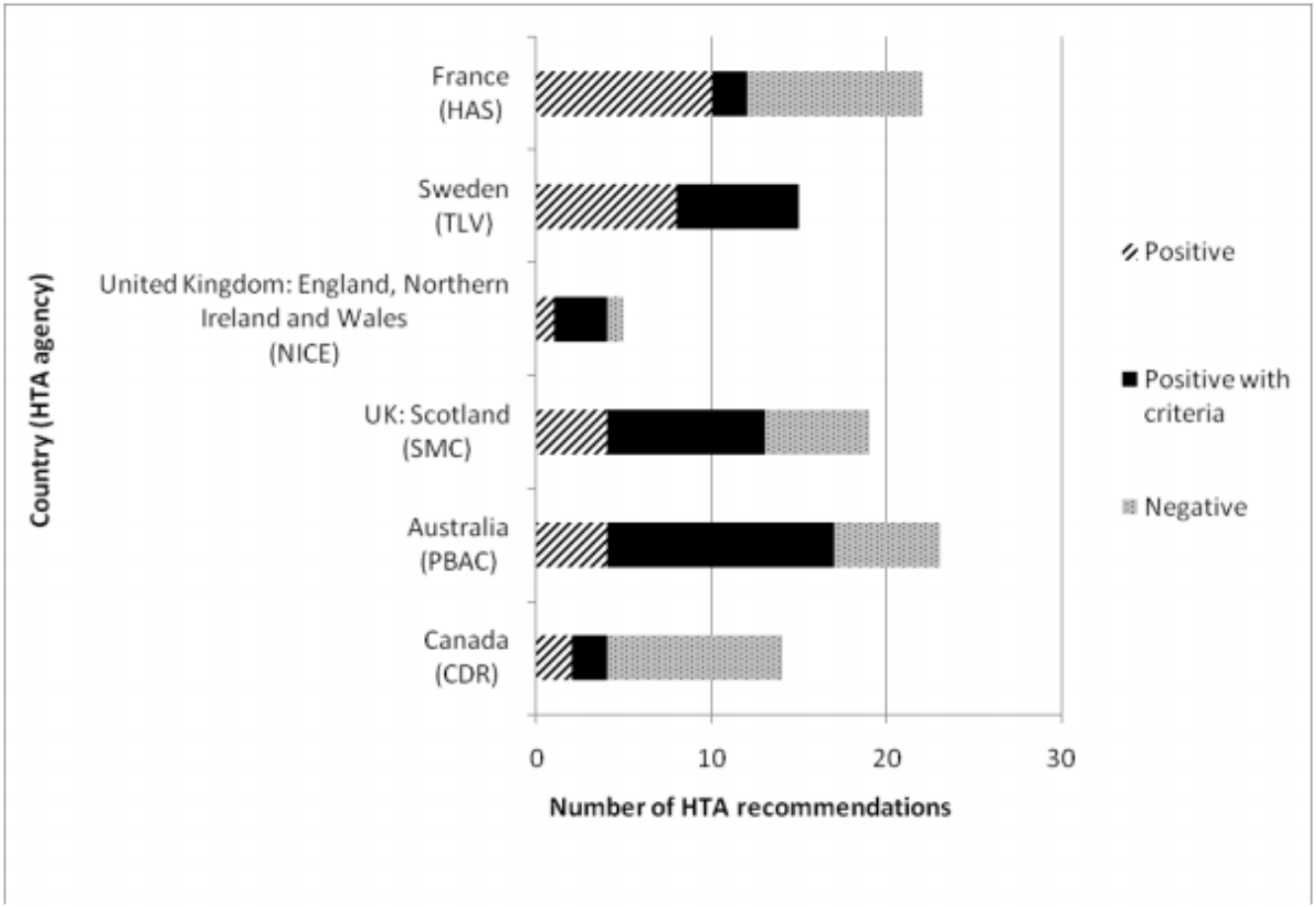
• European Commission in 2022 released legislation to build regulation of HTA (HTAR). Divergency of views with now until 2025 to agree detail.

•EUnetHTA will become official in 2025, creating one system to evaluate drugs across the EU

Source: Organisation for Economic Co-operation and Development www.stats.oecd.org

Variability within therapy classes:

An example of the differences in ***HTA outcomes*** between countries of 25 central nervous system (CNS) drugs

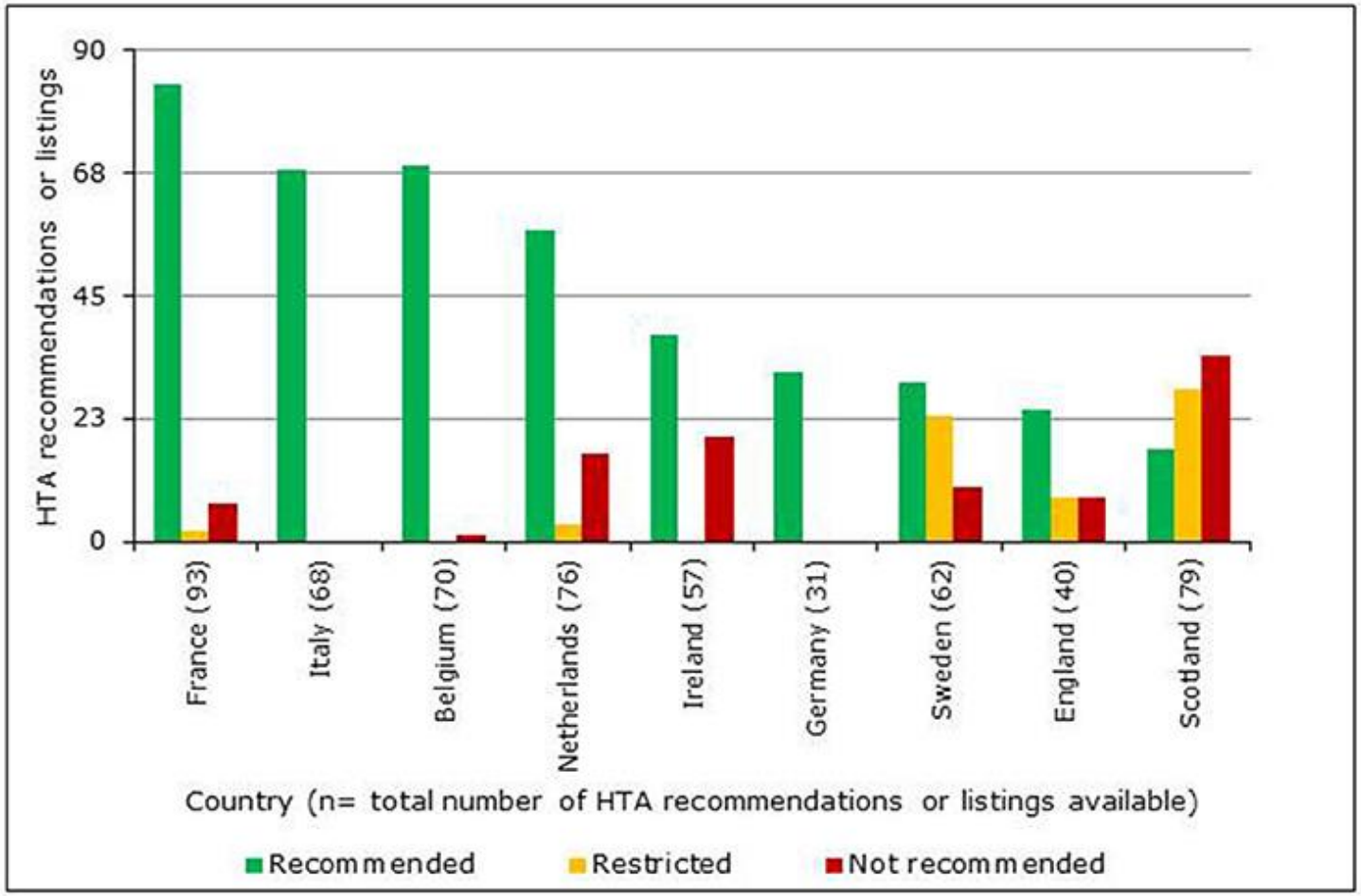


Note: In the case of France, a negative recommendation is ASMR V, which essentially says that the drug has no *additional* therapeutic benefit in relation to comparators.

Source: Differences in prices of and access to pharmaceuticals in the EU, Policy department EP, 2011

Variability between countries:

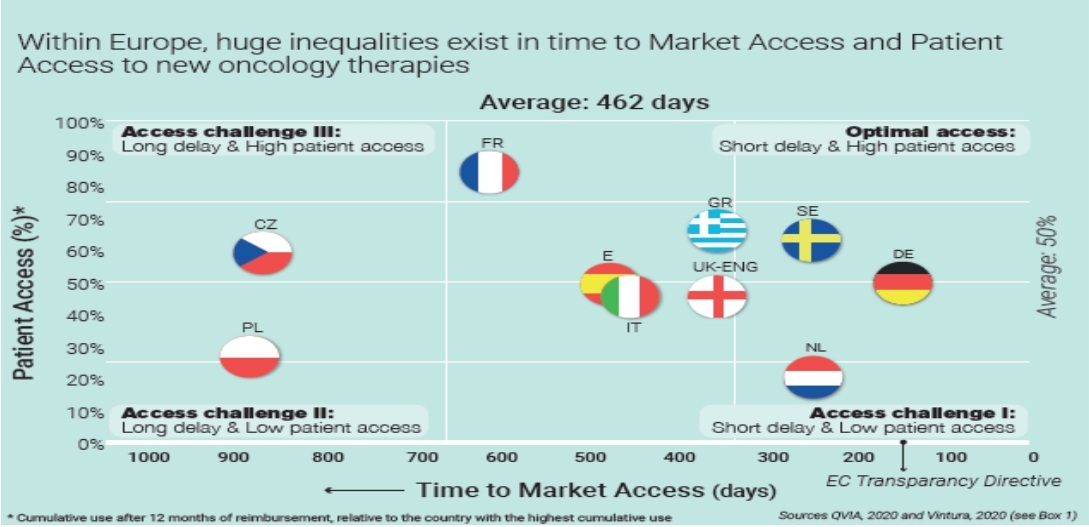
Number of ***HTA reimbursement recommendations*** for 9 EU countries classified according to recommendation category



A total of 102 new active substances (NAS's) received a central marketing authorisation in accordance between January 1, 2008 and December 31, 2012. Decision pathways varied across all 9 countries.

Source: A Comparison of Reimbursement Recommendations by European HTA Agencies: Is There Opportunity for Further Alignment? Allen et al 2017

Despite this acknowledgement, disparity still exists…will JCA be the solution?



JCA (Joint Clinical Assessment): The central pillar of the new EU-HTA regulation

- The JCA will be organised and coordinated by the "Member State Coordination Group on Health Technology Assessment" (Coordination Group) that will be composed of representatives of all EU member states.
- Similar to the scientific evaluation of marketing authorisation applications by the EMA, the JCA will be conducted by an assessor and co-assessor. These assessors will be from different member states and will carry out the clinical assessment, prepare a draft report, and consult relevant stakeholders.
- The Coordination Group will thereafter approve the reports, which will then be published by the European Commission. The timing of JCA for medicinal products will be coordinated with the central marketing authorisation procedure (i.e., EU Commission granting marketing authorisation), ensuring its timeliness for supporting member states' decision making at the time of launch.
- It is of particular importance that the JCA at EU level is strictly separate from value judgments, especially in terms of medical added benefit, which will continue to be made exclusively at the national level.

Source: https://www.xcenda.com/insights/htaq-spring-2022-joint-clinical-assessment-eu#:~:text=With%20the%20new%20European%20Union,from%20January%202025%E2%80%94was%20initiated

Source: White Paper: Every Day Counts by Vintura, July 2020

Development of HTA in Germany

- 1995: HTA initiative by Ministry of Health
- 1997 start of evidence-based decision making with HTA part of health care reform laws
- 2001 DAHTA (German Agency for Health Technology Assessment) established
  - The German Agency for HTA at DIMDI - DAHTA@DIMDI (German Institute for Medical Documentation and Information) runs the HTA information system and a programme for the production of HTA reports.
- 2004 IQWiG (Institute for Quality and Efficiency in Healthcare) to support G-BA*
  - Similar to the structure and role of NICE in the UK, IQWiG as a national assessment entity, provides research and support for evidence-based assessments.
- **2011 AMNOG** legislation saw introduction of **price controls** for new products, abolishing free pricing.

**The G-BA is the main decision-making body in German health care (statutory health insurance only)*
•established in 2004, reorganised 2008, but predecessor committees dating back to the 1920s
•represents physicians, hospitals, sickness funds and patients

Current status of HTA in Germany

- Rather than imposing a cost-benefit threshold, such as the QALY formula used by the UK's NICE, the provisions under AMNOG draw a **direct line between therapeutic benefit and price**.

- The system that took effect on 1 January 2011, allowed new drugs 12 months of 'free' pricing from launch. From 2023 this is reduced to 6 months.

- During that time, Germany's Institute for Quality and Efficiency in Healthcare (IQWiG) conducts an early benefit assessment versus a comparator specified by the Federal Joint Committee (G-BA) and scores the drug on a six-part scale.
  - This scale has four **added therapeutic benefit** categories (the highest being a major added benefit) and two scores denoting either no added benefit proven or a benefit inferior to the selected comparator.

- Only medicines given a score of 1-4 can go forward to negotiate a premium price with the National Association of Health Insurance Funds. Otherwise, they are subject to therapeutic reference pricing; in other words, the maximum price that will be paid by Germany's statutory health insurers (SHIs).
  - 58% of medications were labelled as no added benefit between 2011 and 2017

HTA in France

HAUTE AUTORITÉ DE SANTÉ

- As the second largest EU Pharma market after Germany, France has high strategic importance for any pharmaceutical company with the world's highest consumption of medicines per capita. 65 million population, of which 11 million are over 65 years.
- Marketing authorisation in France is obtained at a national (ANSM) or EU level (EMA).
- New pharmaceutical products in France must show a **significant improvement in therapeutic value** to achieve a premium price and are compared to products in the same therapeutic class.
  - Unique to the French market, regulators look beyond the drug's clinical trial endpoints and consider whether a given drug represents an improvement in medical services or whether it is cheaper than similar existing drugs.
  - Therapeutic effect (not just clinical value) expands the definition of "value" in France.
- "Haute Autorite en Sante" (HAS, High Authority for Health), was established in 2005.
  - With an HTA budget of €1m, 17 permanent staff and 225 consultants, like NICE, they review existing as well as new therapies and issue HTA guidance on the usefulness and appropriate use.
  - They look for medical benefit (SMR), and more importantly improvement of medical benefit (ASMR) and determine these ratings.
  - HAS will play a prominent new role with new EU cooperation (HAS president heading up bring national agencies together)
- Drug price setting is established by the Economic Committee for Healthcare Products (CEPS) after negotiation with the drug company. ASMR is one of the key items taken into account during price setting.
  - Different SMR levels define the level of reimbursement
  - CEESP (Economic and Public Health Assessment Committee) established since 2013
    - Influence in France is growing fast with dossiers of the quality submitted to NICE expected
    - Has resulted in growth of HTA agencies and health economic expertise in France
    - BUT often a delay in publishing opinions, and lack of ICER resulting in lack of clear recommendations diminishes international impact of CEESP

Source: Journal of Market Access & Health Policy "…understanding philosophy of CEESP…" 2017, updated 2023

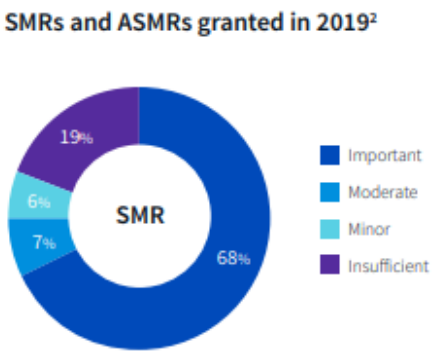
HTA and pricing in France

What determines the level of SMR (medical benefit)?

- Severity of the disease
- Clinical efficacy / effectiveness, and safety of the medicine
- Aim of treatment (preventive, curative, or symptomatic)
- Position of the medicine in the treatment strategy, and the existence or absence of therapeutic alternatives?
- Public health impact (burden of disease, impact at community level)

Level of SMR	Level of reimbursement (%)
Major	100*
Major or important	65
Moderate	30
Weak	15
Insufficient	0

*for medicines recognised as irreplaceable and particularly expensive



HTA and pricing in France

But ASMR (improvement in medical benefit) plays a key role in drug pricing so how is it defined?

Level of ASMR	Criteria
I	**Major innovation**: innovative product with substantial therapeutic benefit
II	**Important improvement** in terms of therapeutic efficacy and/or reducing side effects
III	**Moderate improvement** in terms of therapeutic efficacy and/or utility
IV	**Minor improvement** in terms of therapeutic efficacy and/or reducing side effects
V	**No improvement** over existing options but still can be recommended for reimbursement (e.g. generic drugs and me-too drugs)

- HTA is mandatory prior to pricing and reimbursement application
- For new drugs data is provided by pharmaceutical companies
- Since 2016, HAS reported that fewer new drugs were showing an additional benefit
- Early access schemes (known as ATU's) popular for drugs who have not yet undergone assessment (only given to drugs with a new indication)

Source: Journal of Market Access & Health Policy 2013, updated 2021

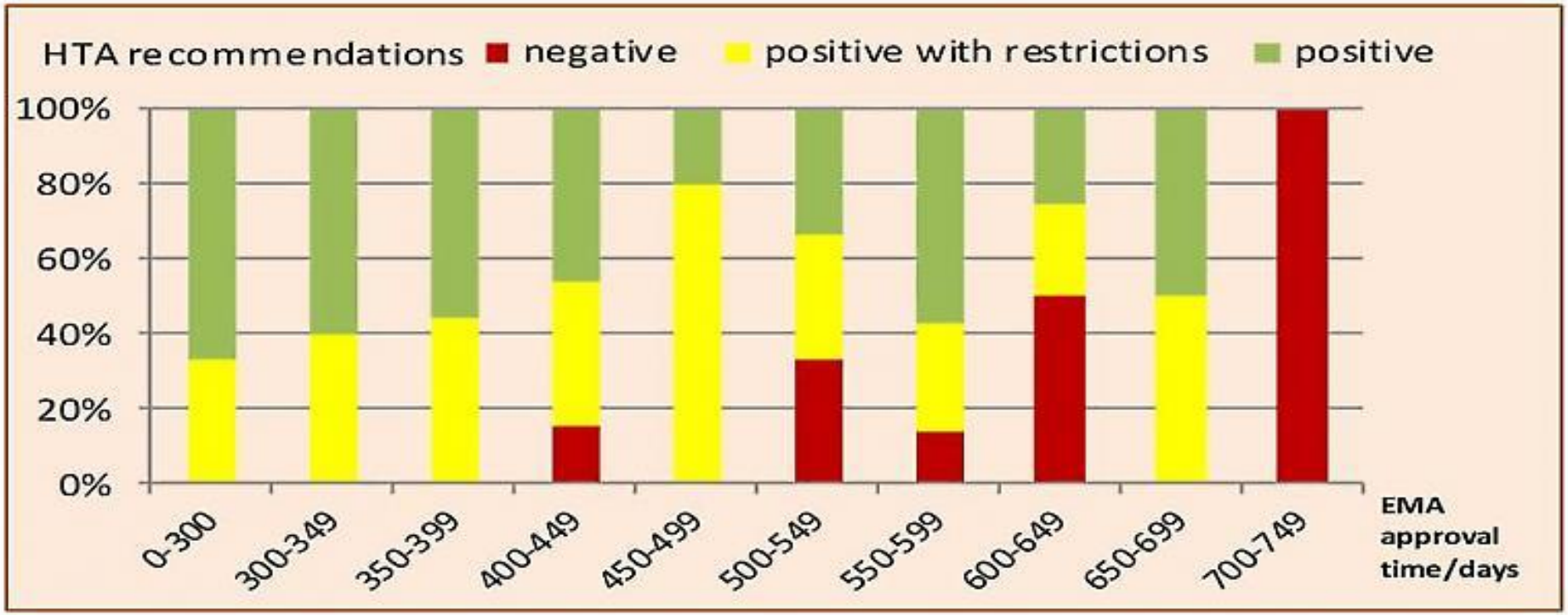
HTA in the Netherlands

College voor zorgverzekeringen
CVZ
Zorginstituut Nederland

- With a population of approx. 17m, and healthcare spend 10% GDP, the principle is access to care for all and affordable healthcare services
- EMA or Medicines Evaluation Board (known as the CBG) deliver marketing authorisation
- Ministry of Health, Welfare and Sport (VWS) makes the decision on reimbursement status, and sets the maximum drug price based on advice from the assessment and appraisal body the National Health Care Institute, Zorginstitut (ZIN)
- Health Insurance Board (CVZ) co-ordinates reimbursement and funding
  - Appraisal processes include factors such as the severity and rarity of disease, budget impact, life-style and cost-effectiveness as well as societal costs that help bring down ICER*
    **ICER incremental cost-effectiveness ratio*
- International Horizon Scanning Initiative (IHSI), chaired by ZIN, aims to bring together HTA alignment between Netherlands, Austria, Belgium and Ireland to increase access for patients

Source: International strategic agenda 2022-2023 National Health Care Institute

HTA recommendations in the Netherlands



Based on research between the association between European Medicines Agency approval and Health Technology Assessment recommendations.

The conclusion was that a longer EMA approval process is associated with a less beneficial HTA recommendation in the Netherlands.

Source: http://www.cirsci.org accessed May 2017, updated 2023

HTA in Italy

- Centralised process for pricing and reimbursement is governed by AIFA (Italian Medicines Agency), under the supervision of the Ministry of Health

- Agenas (restructured after 2018 financial law) to act as a link between central, regional and local bodies providing HTA research projects.

- Despite posing straightforward questions to determine price (Who has an urgent need for the new treatment? How many patients? Does this fit within our budget? Who can be treated later down the line?) they often dictate low drug prices.

- ...but strong political pressures have led to regionalising healthcare provision
  - 20 regions each develop own legal healthcare system
  - all regions use different tools – different HTA agencies at a local level
    - what is cost effectiveness in one region may not be in another i.e. different evaluation criteria

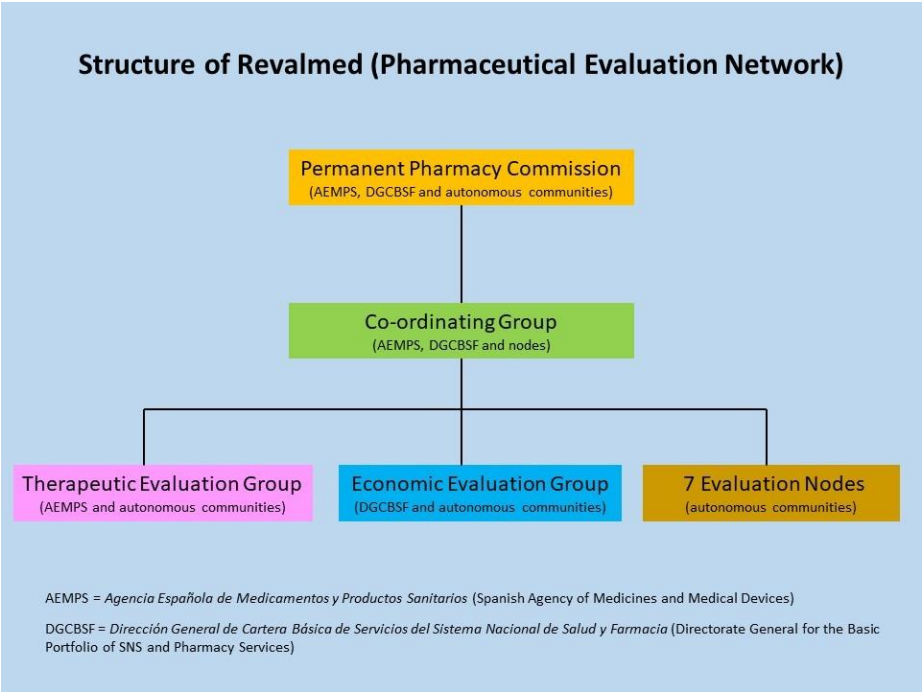
"It is essential to provide data on the population that may benefit with the new treatment, the price difference with existing treatments and the possible savings for the health care system" *Italian payer*

"…a drug that is more expensive but reduces the need for specific expensive monitoring may become more convenient for the health care system than a new drug that is not too expensive but is an add on to an existing therapy" Giuseppe Rosano, Expert Member of AIFA & EMA

HTA in Spain: history

- Spain has universal healthcare coverage funded through general tax funds at a national level.
- Decentralised healthcare system with increasing collaboration:
  - Regional HTA at a sub-national level across 17 autonomous communities provide healthcare and set their own budget:
- Potential to increase the time delay to access for patients, and to increase costs for industry
- It's no secret that Spain needs healthcare reforms to help enable patient access
- Spain is regularly criticised for its slow reimbursement times for innovative medicines, particularly orphan drugs.
- Of the key markets in Europe, Spain continues to have the weakest grasp on ways to fund and create access to vital medicines.

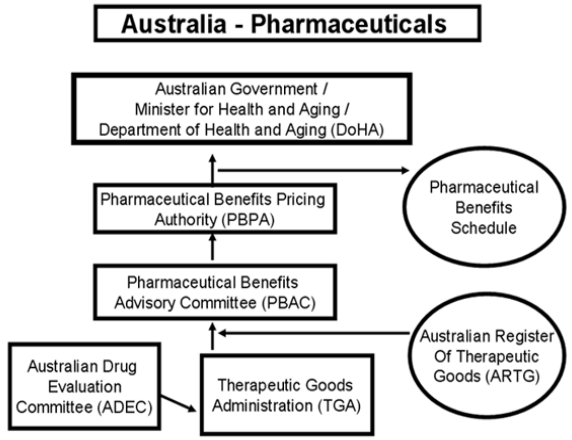
HTA in Spain: 2023 overhaul

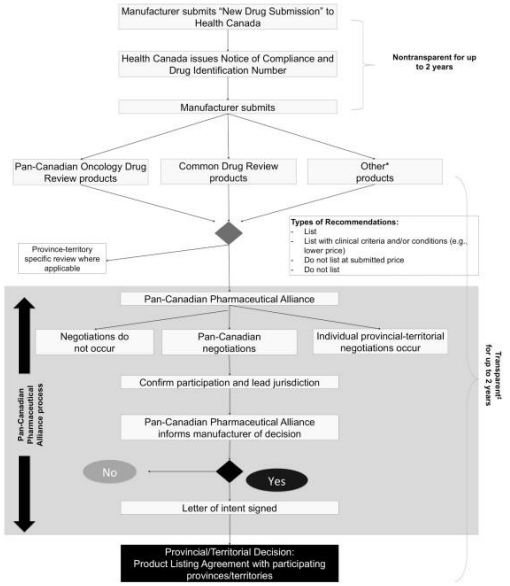


- New HTA network to produce therapeutic positioning reports
- New process the responsibility of REvalMED (formed in 2021)
- Seeking to copy NICE to develop a transparent HTA system (‘HispaNICE’)
- 12 step process taking a max of 90-95 days
- Many questions unanswered, and still falling short of international standards according to many…watch this space!

HTA in Australia & Canada

- **Australia** led the world in 1993 when it introduced economic evaluation into the approvals process for drugs
- Key stakeholder: The Pharmaceutical Benefits Advisory Committee (PBAC) recommends to the Minister which drugs should be made available / reimbursed.
- In contrast to most other countries, HTA in Australia has been woven into the fabric of health services funding, giving it greater impact on the introduction of new treatments. ***Without a PBAC submission and successful reimbursement, products do not launch in Australia (does result in quick decisions at/post launch with regulatory & HTA done in parallel)***
- Since 1988 **Canada** has had HTA programmes at national, provincial and local levels – and like Australia can have regulatory and HTA completed in parallel at launch
- HTA in Canada is used to inform decisions on which drugs to use that deliver the best value for money, through the activity of the national body, the Pan-Canadian Pharmaceutical Alliance

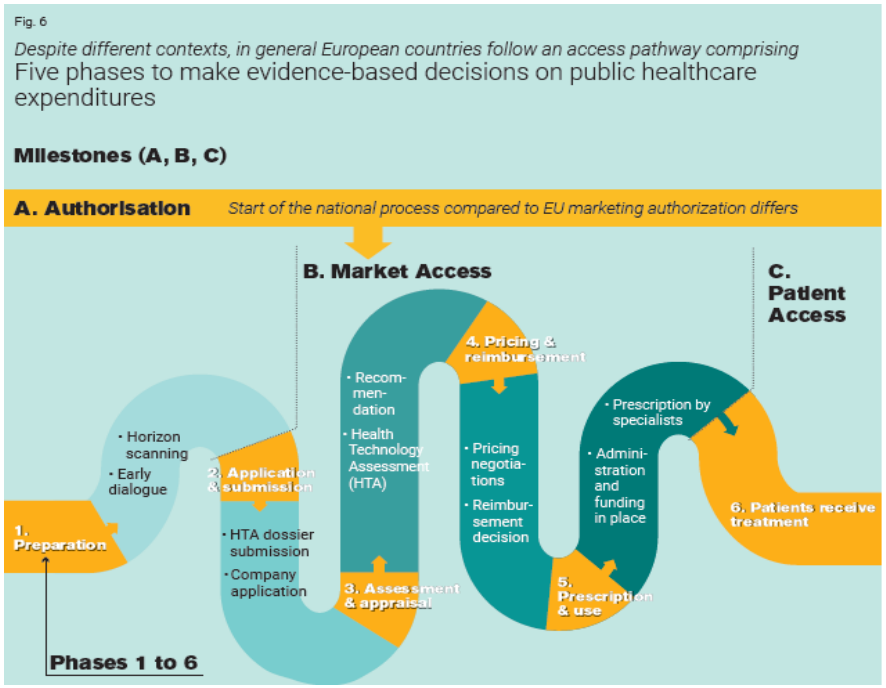




In summary, despite the access pathway being broadly similar, the criteria for reimbursement varies significantly resulting in different decisions

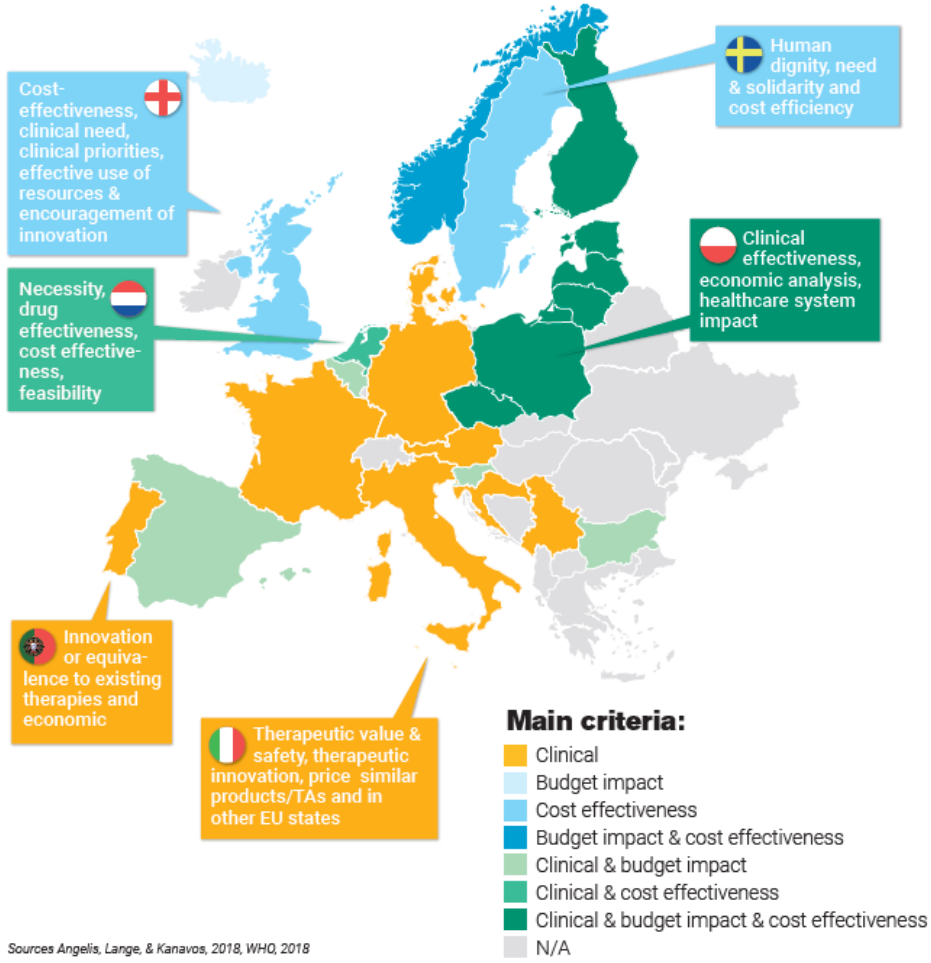
Fig. 6

Despite different contexts, in general European countries follow an access pathway comprising
Five phases to make evidence-based decisions on public healthcare expenditures



Main reimbursement criteria

The context in which reimbursement decisions are made differs significantly between European countries: main reimbursement criteria applied



Sources Angelis, Lange, & Kanavos, 2018, WHO, 2018

Source: White Paper: Every Day Counts by Vintura, July 2020

Looking forward..what does this mean for the pharmaceutical industry?

- HTA and the process of successful market access is critical for acceptance of a products' use within a healthcare system.
- Restrictions to drug budgets and increased co-operation across countries are key trends to keep a watch of…

- Of note, market access is also a term increasingly used to describe schemes that provide access to medicines (more recently **managed entry agreements (MEA's)**)…
  - Schemes can be classified according to whether they are essentially finance-based, in which discounts and rebates are linked to usage at a patient or population level; or whether they are outcomes-based, in which reimbursement is linked to performance guarantees or the generation of further clinical evidence.
  - Many countries, notably the UK and Italy are seeing the development of market access schemes. Italy pioneered one of the earliest risk-sharing schemes when the government launched the Cronos project to assess the possible reimbursement of Alzheimer drugs, and are actively being encouraged to review this in 2023.
  - Price-volume agreements are the norm in France, comparable to the situation in Australia where some 80+ price-volume agreements have been developed with the Pharmaceutical Benefits Advisory Committee (PBAC), and in Canada, where price-volume agreements are almost mandatory in the major provinces.

Emerging market access trends post Covid & post Brexit?

COVID-19 Pandemic delays for Health Technology Assessments (HTA)

- The short-term impact of COVID-19 on HTA processes was significant, with several agencies (NICE, SMC etc) temporarily halting assessments.
- As 2020 progressed, the consequences were mixed, dependent on how severely affected the working processes of the HTA agency were.
- Some countries continued unaffected (the G-BA in Germany increased their output by 7% in 2020) while others (e.g. UK and France) have focused only on critical medicines.
- France and the UK have reduced the number of HTA publications in March-June 2020 (down 30% and 31% respectively compared to the 2015-19 average in the same months).

So for 2023?

- In countries affected by a slowdown in HTA activities, a backlog of applications is likely to slow the market access of drugs deprioritised as being non-critical.
- In the less affected markets, payer price pressure and budgetary concerns are likely to be of more importance, as pressure mounts to begin recouping the costs of the COVID-19 pandemic.

Is the UK still an early launch country given Brexit?

- In the short term, there are limited changes to the UK's position as an early launch country.
- The split from the European Medicines Agency (EMA) will result in pharmaceutical countries submitting separate regulatory dossiers to the EMA and the Medicines and Healthcare products Regulatory Agency (MHRA).

So for 2023 and beyond?

- Given the significant cost and time resource involved in a regulatory submission, small pharmaceutical and biotech companies may prioritise an EMA submission over the MHRA
- EU collaboration of HTA with new legislation from 2025 is one to watch to see if it brings material change
- An altered launch sequence will impact on international reference pricing (IRP), given that the UK is referenced by many countries within Europe
- The UK may lose status as an early launch country, with NHS patients facing delayed access to innovative medicines. While this is unlikely to happen in the very near term, companies will still have to carefully consider the impact of Brexit on European-wide pricing and launch strategies.

Summary

- HTA procedures strongly depend on the economic, financial, cultural and medico-philosophical context of any given country

- Even with the best intentions and scientific methodology, HTA procedures remain highly variable in terms of data selection, data appraisal, data valuation and final outcome in terms of price

- The implications of future EC intervention are as yet unknown, as are the real impacts of the Covid pandemic

Workshop 1: group debate with active online student participation

Please consider the following question and be prepared to share your thoughts with the group

Do you think there should be a standard approach to HTA across the EU, and if so why?

HTA: the UK experience

Market Access in a UK context...

- The UK pharmaceutical market has an international importance greater than its current size would suggest, in part due to its' advanced market.

- The UK is quoted as the world's seventh largest market for prescription drugs (2021). Historically, relatively high prices, minimal launch delays, a relatively liberal regulatory environment, and a strong R&D base made the UK an attractive market in Europe for the research-based pharmaceutical industry…

- …however, in recent years, the pharmaceutical and biotech sector has faced many challenges with the patent-expiry of blockbuster drugs, shrinking pipelines and fewer drugs entering the market.

- This is coupled with the role of the **'payer'** in determining market access success becoming significantly more pronounced, with the need to demonstrate '**value**' to the healthcare system.

The path to achieving Market Access in the UK can include hurdles related to...

- Securing funding for a product that has a negative NICE (National Institute for Health and Care Excellence)
- Securing funding for a product that is awaiting review by NICE
- Ensuring effective implementation of NICE guidance at a local level
- Ensuring the NHS has sufficient service and / or financial plans in place to support entry of new products
- Lack of clinical demand impacting on the level of funding secured/amount of product commissioned

Market Access in 2023…the post Brexit horizon and the promise of faster market access?

- Whilst regulatory approval is only a starting step on market access, the UK has made steps to put the UK on the priority list for companies seeking marketing authorisation. The UK joined two initiatives in October 2020 that should bear fruit in the future: **Project Orbis** and the **Access Consortium**.

- **Project Orbis** is coordinated by the US Food and Drug Administration and includes Canada, Australia, Switzerland, Singapore and Brazil and focuses upon review and approval of cancer treatments that offer promise.

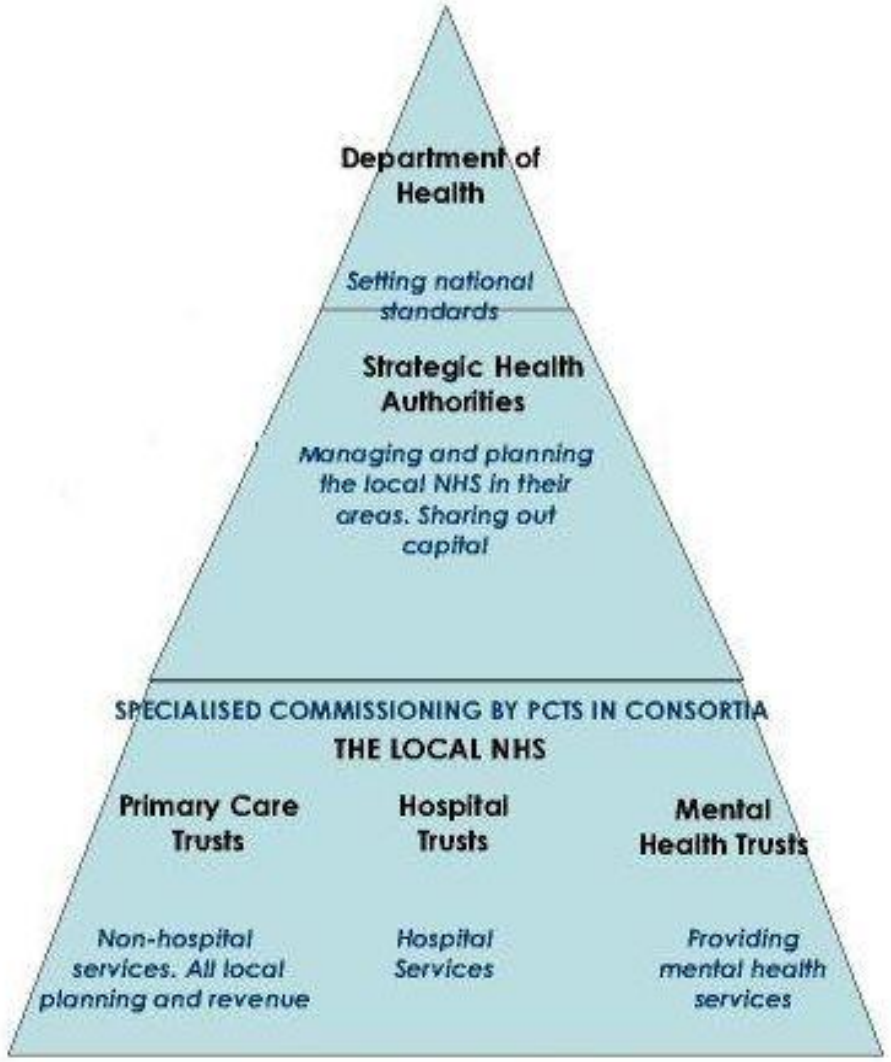
- **The Access Consortium** includes some of the same players – Australia, Canada, Switzerland and Singapore – and looks more broadly at securing patient access to high-quality, safe and effective medicines. The ABPI has seen these as another way to help the UK deliver faster access.

- From 1 January 2021, the new 'innovation licensing and access pathway' **(ILAP)** at the Medicines and Healthcare Regulatory products Agency (MHRA) offers the chance (for a fee) for faster access for medicines that meet the criteria for the scheme.

- ILAP has notably for the first time facilitated collaboration between NICE, the AWTTC, and the SMC under a unified umbrella to support activities, provide scientific advice, and engage a variety of stakeholders in the health technology assessment (HTA) evaluation of new technologies.

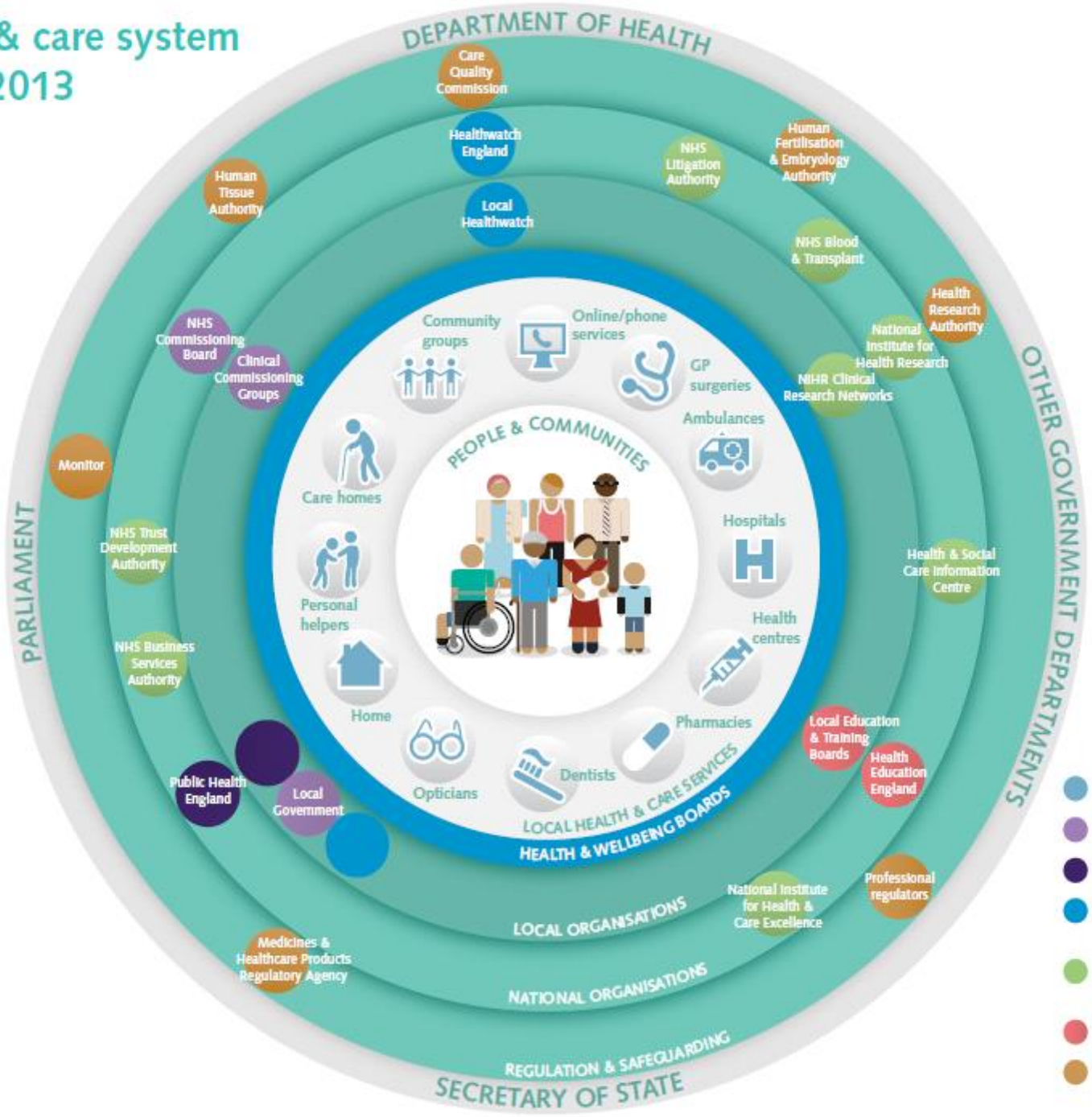
- Within the first year of ILAP, 58% of applicant medicines were approved, 10% not accepted and 32% still ongoing
  - First was for Belzutifan from MSD (a treatment for adults with a rare genetic disorder that causes cancer)

England NHS in brief…historically...



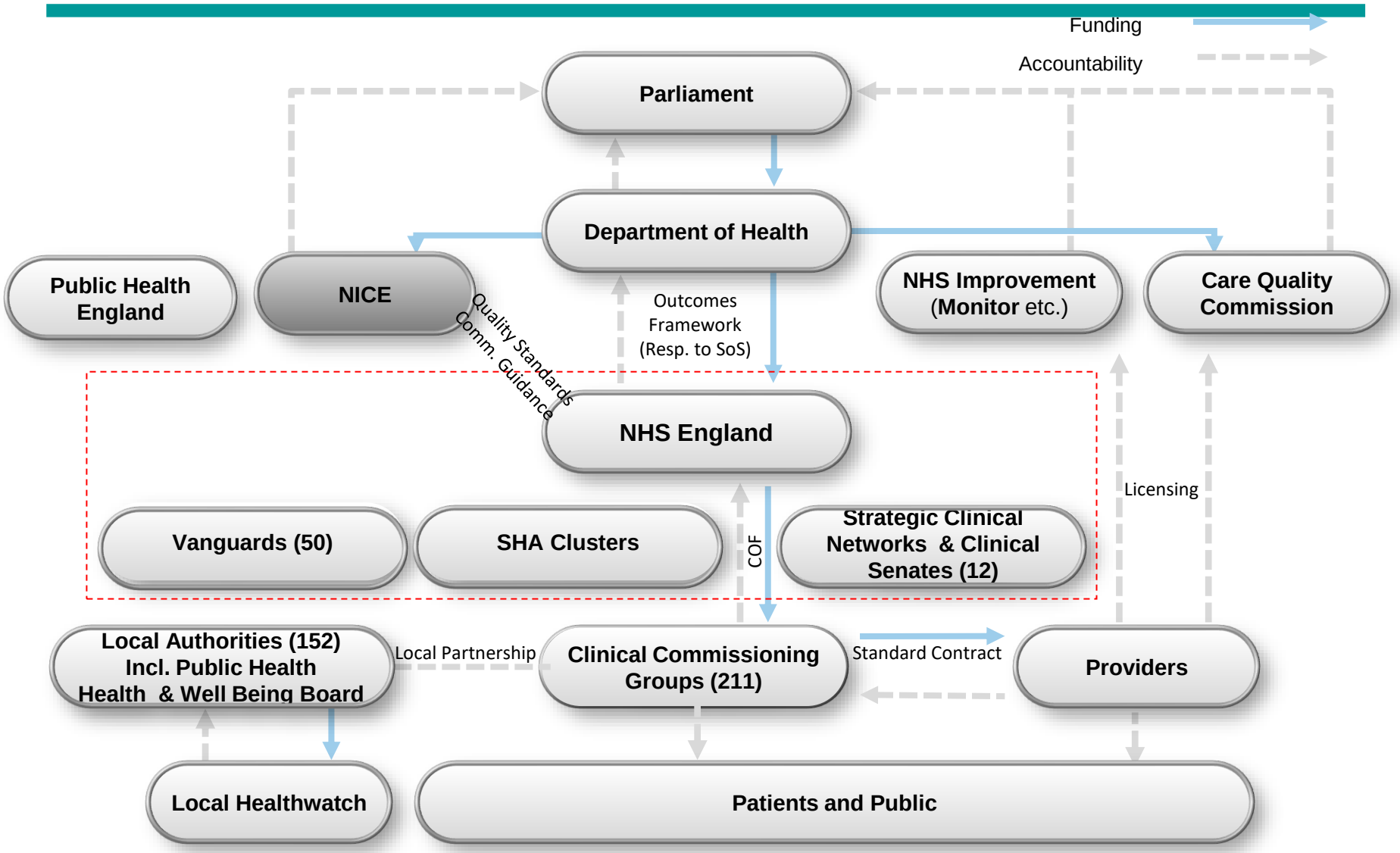
Source: HealthLink

The health & care system from April 2013



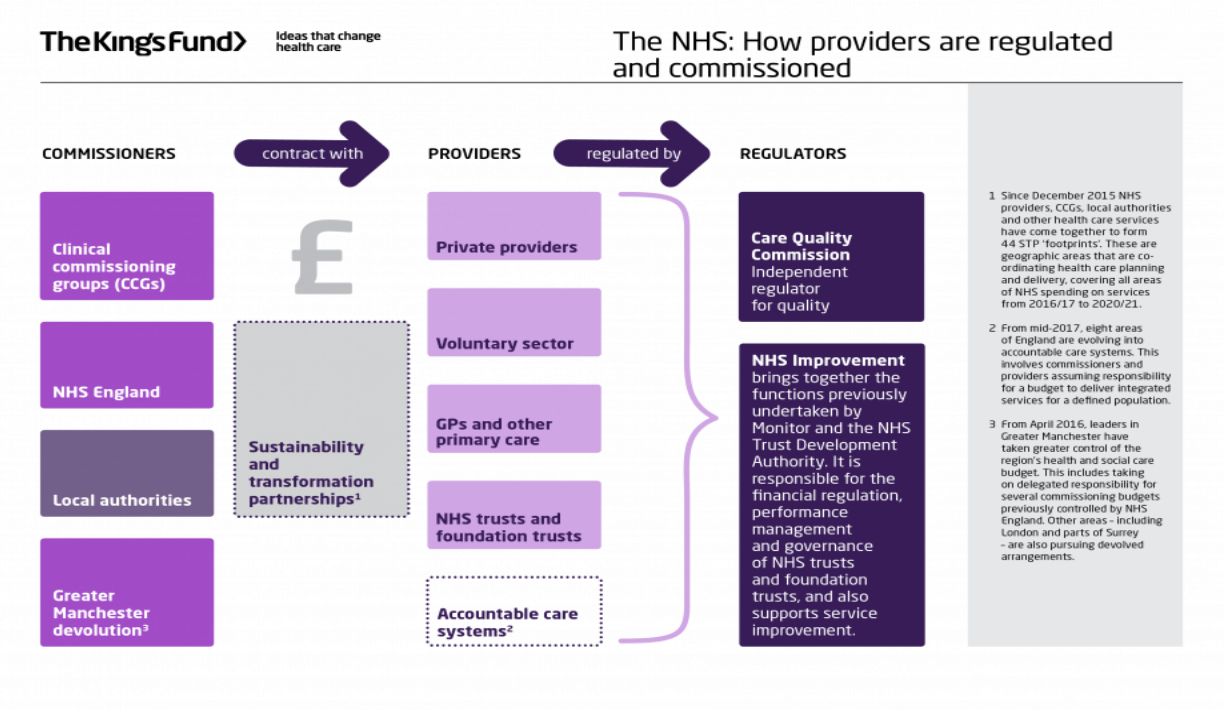
Source: http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhsstructure.aspx

The new NHS in England: complex and changing



Source: Adapted and reviewed from the NHS Plan and www.bma.org.uk, 2023

...simply put ... with changes from April 2021 … and more change ahead!



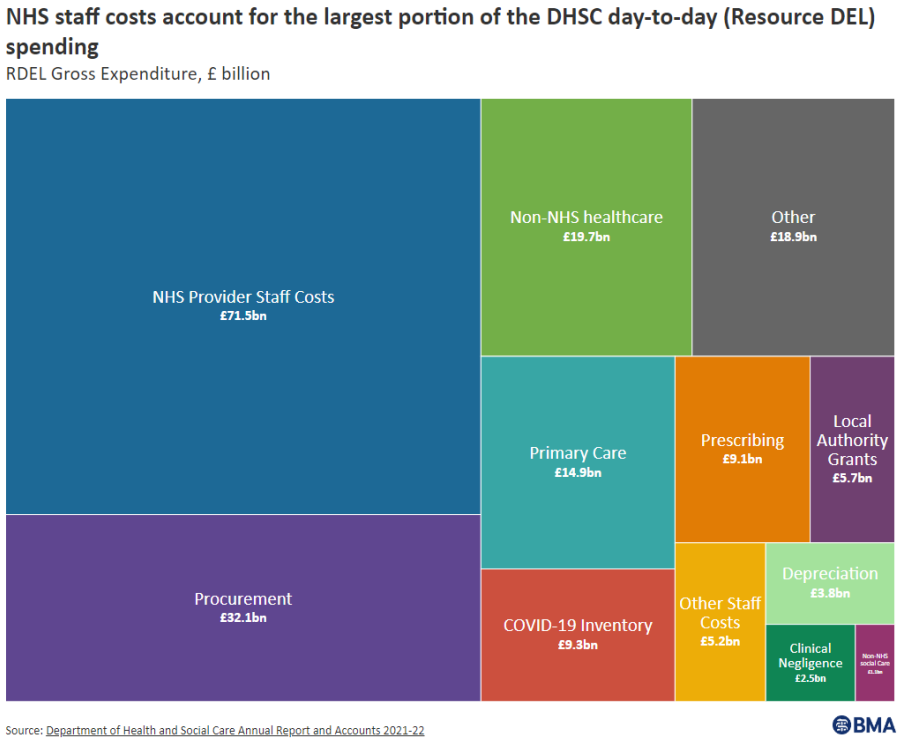
2016 saw the launch of local plans to improve health and care known as Sustainability and Transformation Plans (STPs) now evolving into Integrated Care Systems (ICS's).

*"**Integrated care systems (ICSs)** are new partnerships between the organisations that meet health and care needs across an area, to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups.*
Since 2018, they have been deepening the relationship in many areas between the NHS, local councils and other important strategic partners such as the voluntary, community and social enterprise sector. They have developed better and more convenient services, invested in keeping people healthy and out of hospital and set shared priorities for the future."

July 2022 saw Integrated Care Boards legally established, replacing the 135 CCG's reduced to 106, with 42 ICB's and 15 Academic Health Science Networks

Source: www.kingsfund.org.uk and NHS BSA 2023

It is recognised that spend on medicines are not the single solution to the ‘big issue’ of managing healthcare costs



- Total health care spending rises sharply with age and with an aging population the pressure on the NHS is set to continue with the ‘catch up’ post Covid
- The total expenditure on medicines in England by the NHS in 2020/21 was estimated to be £16.7 billion (increase of 4.6% over previous year)
- 2023/24 NHS budget £188.2 billion

Source: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/funding/health-funding-data-analysis

National Institute for Health and Care Excellence (NICE) was established in 1999 to …

- encourage **faster uptake** of clinically & cost effective new treatments,
- promote **more equitable access** to treatments (new or existing) of proven clinical and cost effectiveness
- promote the **better use of resources** in the NHS, by focussing resources on treatments which achieve most health gain in relation to the NHS/PSS resources expended
- promote the longer-term interest of the NHS in the development of **innovative treatments** for the future.

National Institute for Health and Care Excellence (NICE) today…

- Recognised across the world for its health technology appraisals, it now has a key partnership with NHS England

- Responsibility for appraising all new oncology drugs, to determine which will have access to the £340m Cancer Drugs Fund (CDF) established in 2016
  - Publishing a ‘yes’, ‘no’ or ‘maybe’ decision even before approval from the European Medicines Agency’s CHMP scientific advisory committee

- Key driver and main stakeholder for market access to deliver acceptance and endorsement of product use and uptake in the UK

A short history of NICE

1999 - established as Special Health Authority

- Technology appraisals / Interventional Procedures

2000/1 - creation of the National Collaborating Centres

- Clinical Guidelines

2003 - funding 'directions' to PCTs and NHS trusts

- WHO review positions NICE as world leader

2004 - focus on implementation

2005 - take over Health Development Agency functions

2006 - speeding up appraisals & administration of topic selection

- Single Technology Appraisals

2007 - pilot patient safety guidance

2008 - external 'consultancy' launched

- International Policy & Scientific Advice

2009 - fourth process review, three judicial reviews

2013/6 - established in primary legislation and positioned itself at the heart of ongoing NHS changes...

- Increasing focus on standards and indicators

2017-8 - improving social care through evidence-based guidance and providing information services

2019 - 500th technology appraisal published

2021- Launch of new 5 year strategy ("Dynamic, Collaborative, Excellent")

Source: adapted from M Boysen at HTA World December 2009 and updated 2021

NICE is now in place to … “Improve health and wellbeing by putting science and evidence at the heart of health and care decision making.”

- **Provide guidance to ensure quality and value for money**
  - NICE guidance supports healthcare professionals and others to make sure that the care they provide is of the best possible quality and offers the best value for money.

- **Provide independent, authoritative and evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation**
  - Guidance is for the NHS, local authorities, charities, and anyone with a responsibility for commissioning or providing healthcare, public health or social care services.
  - NICE also supports these groups in putting their guidance into practice…the focus being on implementation and monitoring.

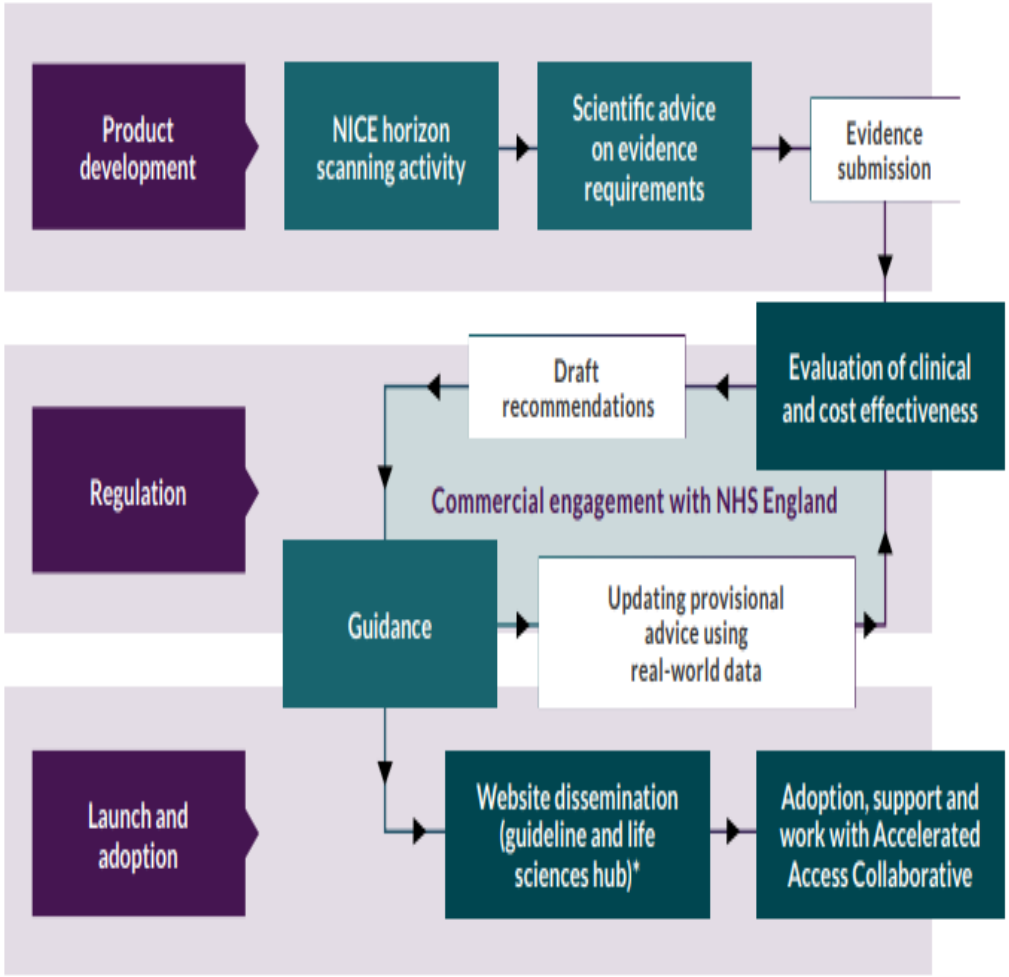
Source: www.nice.org.uk

The new strategic ambition of NICE (2021-2026) is reflected in four key pillars that underpin where they will focus transformation efforts

1. Rapid, robust, and responsive technology evaluation	• providing independent, world-leading assessments of new treatments at pace, quickening access for patients, and increasing uptake.
2. Dynamic, living guideline recommendations	• creating and maintaining up-to-date guidance that integrates the latest evidence, practice and technologies in a useful and useable format.
3. Effective guidance uptake to maximise our impact	• working with our strategic partners to increase the use of our guidance, monitor adoption and measure impact on health outcomes and health inequalities.
4. Leadership in data, research and science	• becoming scientific leaders by driving the research agenda, using real-world data to resolve gaps in knowledge and drive forward access to innovations for patients.

Source: www.nice.org.uk accessed May 2023

Life sciences process according to NICE

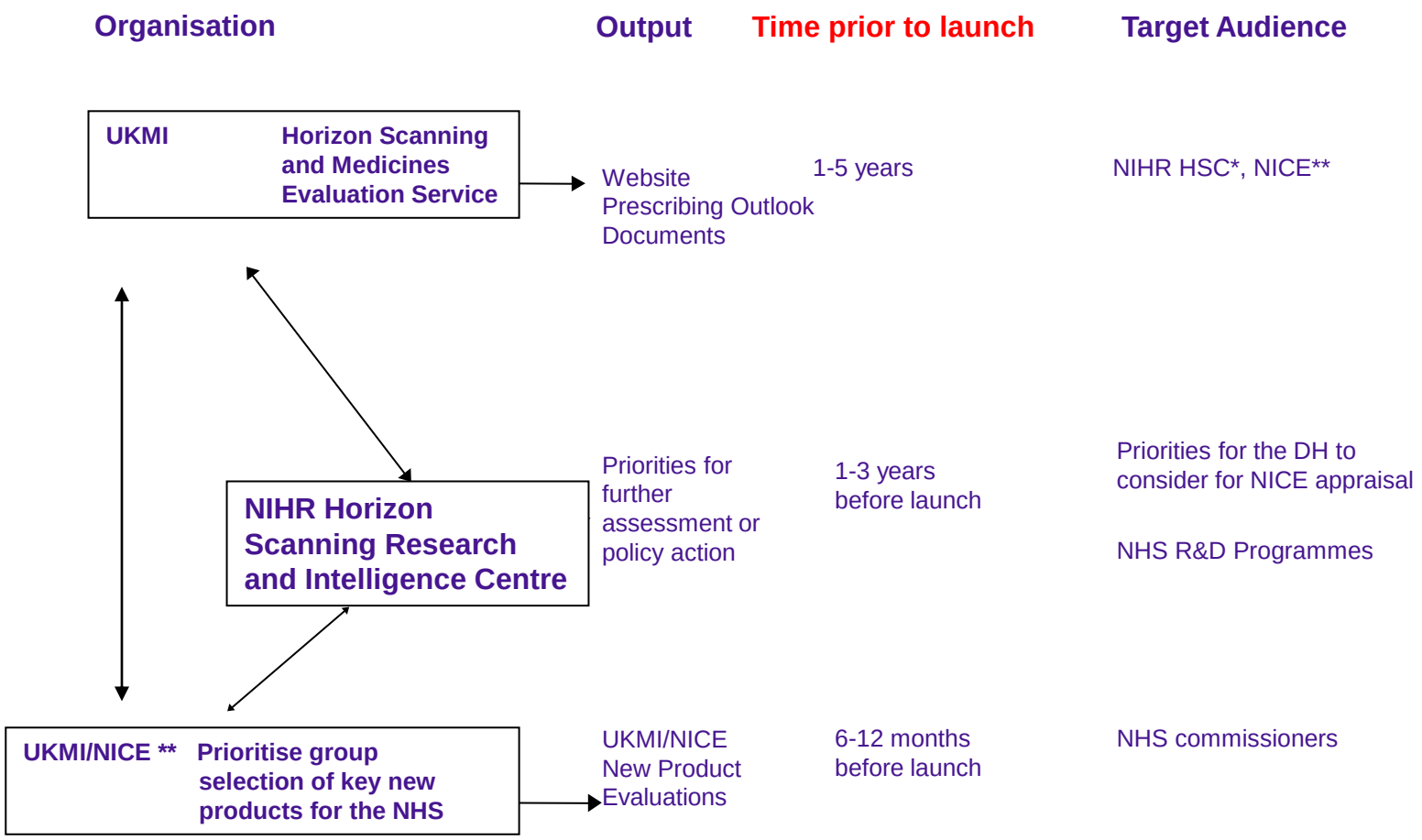


"Evaluating the clinical and cost effectiveness of technologies to determine funding decisions and assessing new interventional procedures for safety and effectiveness.

The health economic lever is a critical one in the innovation pathway that impacts on the commissioning, funding and adoption of new technologies"

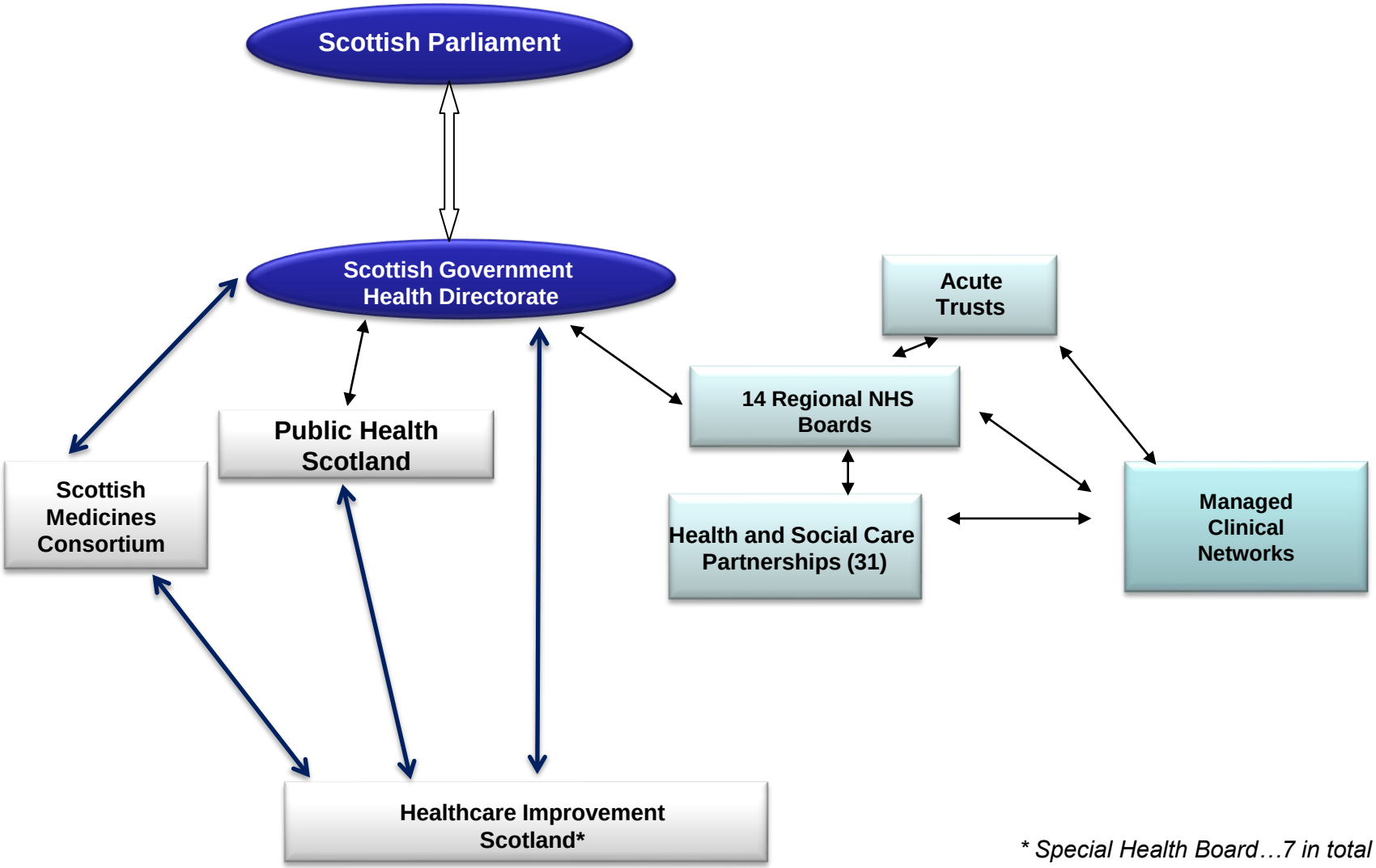
Source: www.nice.org.uk

From horizon scanning to guidance: the relationship between NIHR HSC*, NICE** & UKMI



**National Institute for Health Research: Horizon Scanning Research and Intelligence Centre, Birmingham*
***NICE Medicines and Prescribing Centre (formerly the NPC)*

NHS Scotland: Overview



** Special Health Board…7 in total*

Source: Adapted from 'Healthcare across the UK: A comparison of the NHS in England, Scotland, Wales and Northern Ireland' National Audit Office, 2015

NHS Wales: Overview

All Wales Medicines Strategy Group

The National Assembly for Wales Minister for Health & Social Services

Wales Medicines Partnership

New Medicines Group

3 x NHS Trusts: Public Health Wales, Velindre and Welsh Ambulance Services

Department of Health and Social Services

National Delivery Group and National Advisory Board

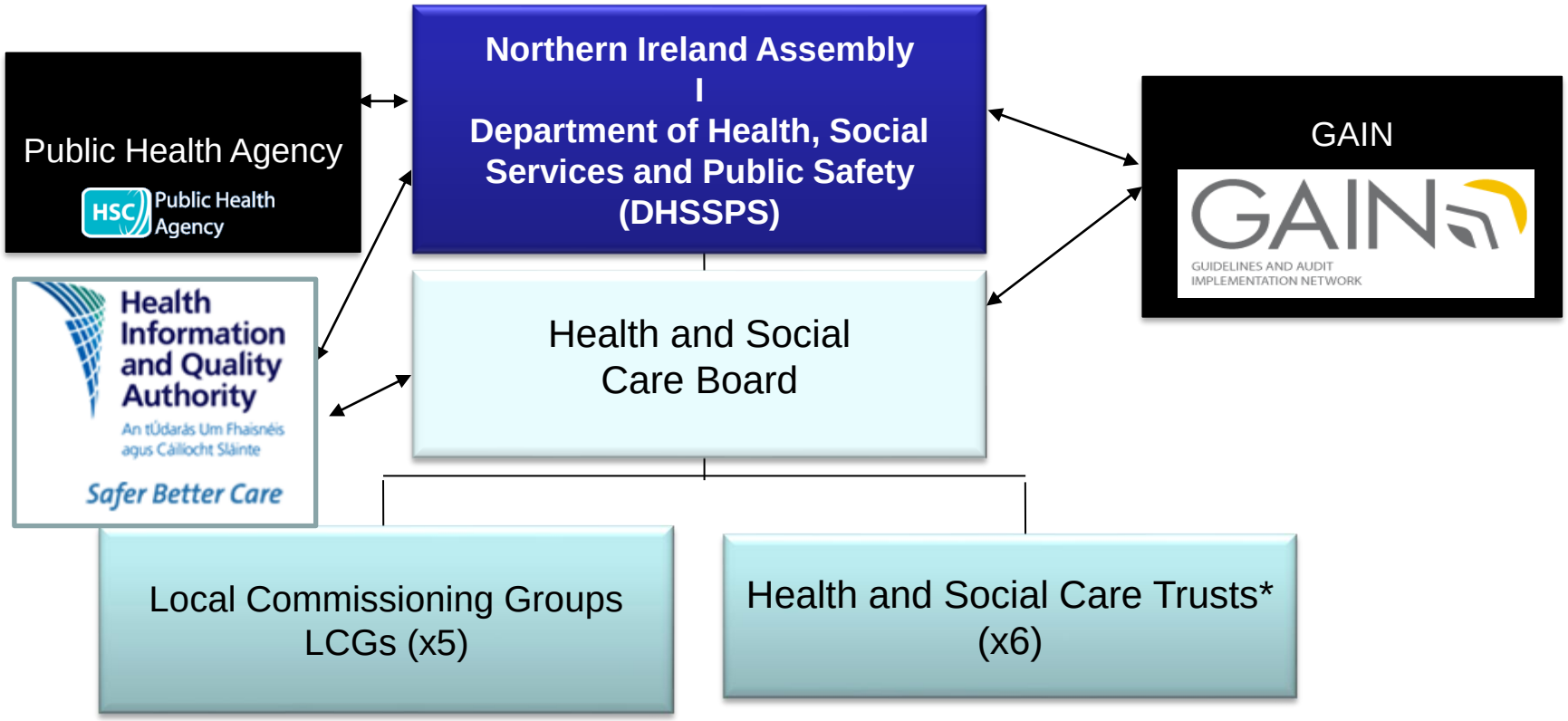
Local Health Boards (x7)

Note that Health Boards are responsible for GP and Hospital services.

- ✓ NICE guidance covers Wales
- ✓ AWMSG generally aim to review products six months prior to launch if cost threshold exceeds £2000 per patient per annum
- ✓ Appraises new high cost, cardiac and cancer medicines for which no NICE guidance is expected for at least 12 months from the date of submission (i.e. at least 6 months from AWMSG appraisal and the anticipated date of NICE final advice).

Source: Adapted from 'Healthcare across the UK: A comparison of the NHS in England, Scotland, Wales & Northern Ireland' NAO

NHS Northern Ireland: Overview



* Belfast, Northern, Southern, South Eastern and Western and NI Ambulance Service

✓ Northern Ireland generally looks to endorse national UK and international guidance (e.g. BHS, SIGN), and since July 2006 has a formal link to NICE
✓ GAIN has a new role as the single clinical and social care regional audit and guidelines body for Northern Ireland
✓ Economics Branch within DHSSPS may review products as it assesses most new guidance to ensure advice to the HSSB is up to date.

Source: Adapted from 'Healthcare across the UK: A comparison of the NHS in England, Scotland, Wales and Northern Ireland' National Audit Office, 2022 web access to all N Ireland Health and Social Care sites.

Workshop 2: your thoughts matter!

Given the changing UK healthcare environment over the past decade, what do you think these changes mean to the pharmaceutical industry, and to the pharmaceutical marketer?

Please take time to consider your response and then share your thoughts with the rest of the group

Lunch

HTA submissions and the review process in the UK

HTA Submissions in the UK: who reviews?

National Institute for Health and Care Excellence (NICE) review new technologies as mapped out within their work programmes, producing guidance. They use evidence to develop recommendations that guide decisions in health, public health and social care. As well as considering the scientific value of evidence, they now follow a set of principles for making social value judgements

- **Guidelines** to promote integrated care
  - A wide range of topics from preventing and managing specific conditions to planning broader services
- Technology appraisals **guidance**
  - Assess clinical and cost effectiveness of pharmaceutical and biopharmaceutical products
- Interventional procedures guidance
  - Recommend whether interventional procedures – such as laser treatment for eye problems – are effective and safe for use in the NHS
- Medical technologies guidance, diagnostics guidance and highly specialised technologies guidance

With the exception of technology appraisals and highly specialist technology evaluations, which carry a funding directive for commissioners, NICE guidance is not mandatory. Healthcare professionals should take NICE guidance fully into account when exercising their clinical judgment, but it does not override their responsibility to make decisions appropriate to the circumstances and wishes of the individual patient. The reasons for any differences should be documented.

Source: www.nice.org.uk

HTA Submissions in the UK: who reviews?

- **Scottish Medicines Consortium (SMC)** review all newly licensed medicines, all new formulations of existing medicines and any major new indications for existing medicines

- **All Wales Medicines Strategy Group (AWMSG)** aim to review products six months prior to launch, if cost threshold exceeds £2000 per patient per annum (in addition to all new treatments for which no NICE guidance is expected for at least 12 months).
  Companies should submit a form A to the AWMSG one month prior to receiving a licence and the AWMSG will decide whether to appraise

- **Health Information and Quality Authority (HIQA) and the Guidelines and Audit Implementation Audit (GAIN)** often endorse existing national and international guidance
  - Since 2006 GAIN formally comes under the remit of NICE through a formal relationship and collaboration between NICE and the N Ireland Executive. This enables local review of the applicability of NICE guidance to Northern Ireland, and the development of guidance for local health boards as required.

HTA Submissions: what is required?

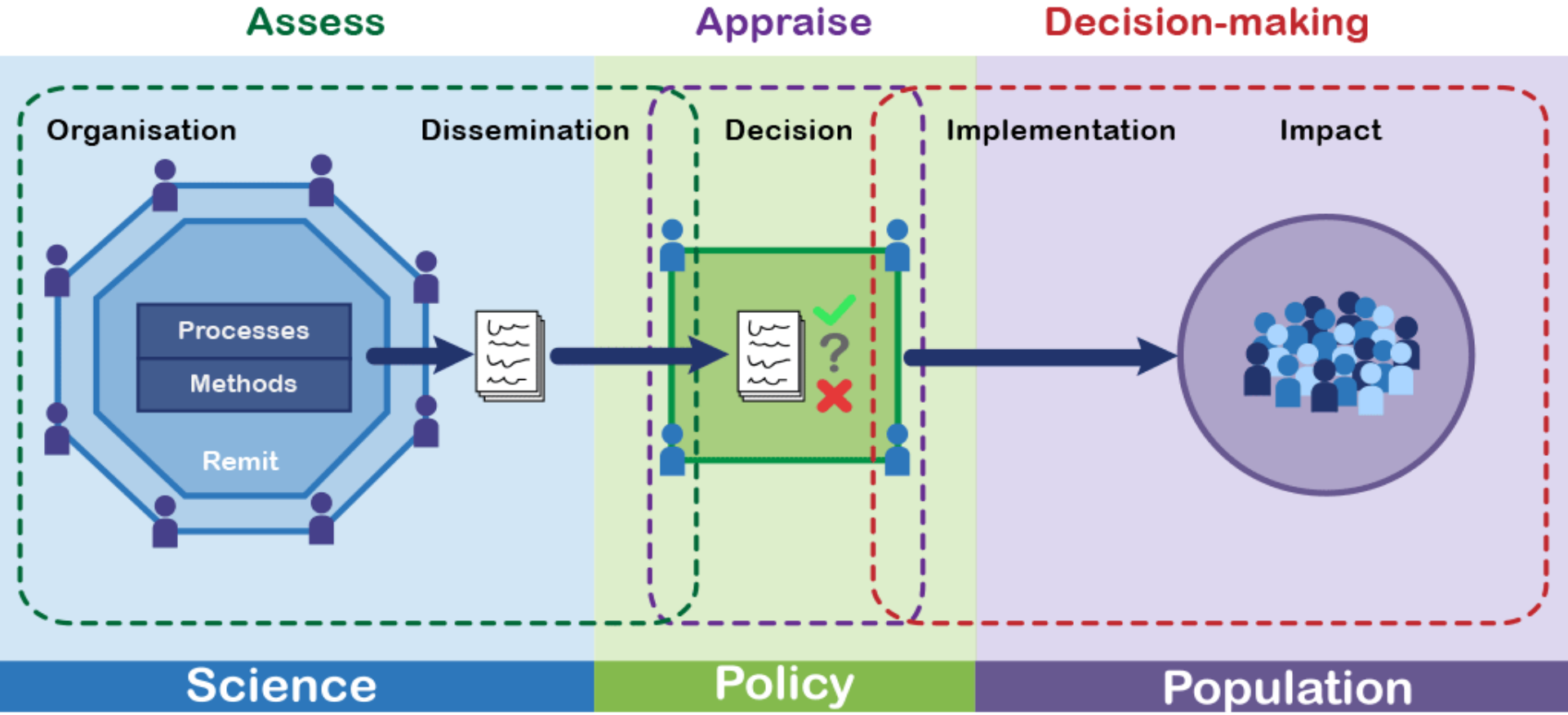
Ideally, to achieve positive endorsement:

- Submit with strong clinical evidence and a compelling economic argument

However the following can support where the above is weak:

- The product is a genuine innovation
- There is a strong unmet clinical need
- There is a subset of patients in whom the economic argument and data can be clearly justified
- High quality submission

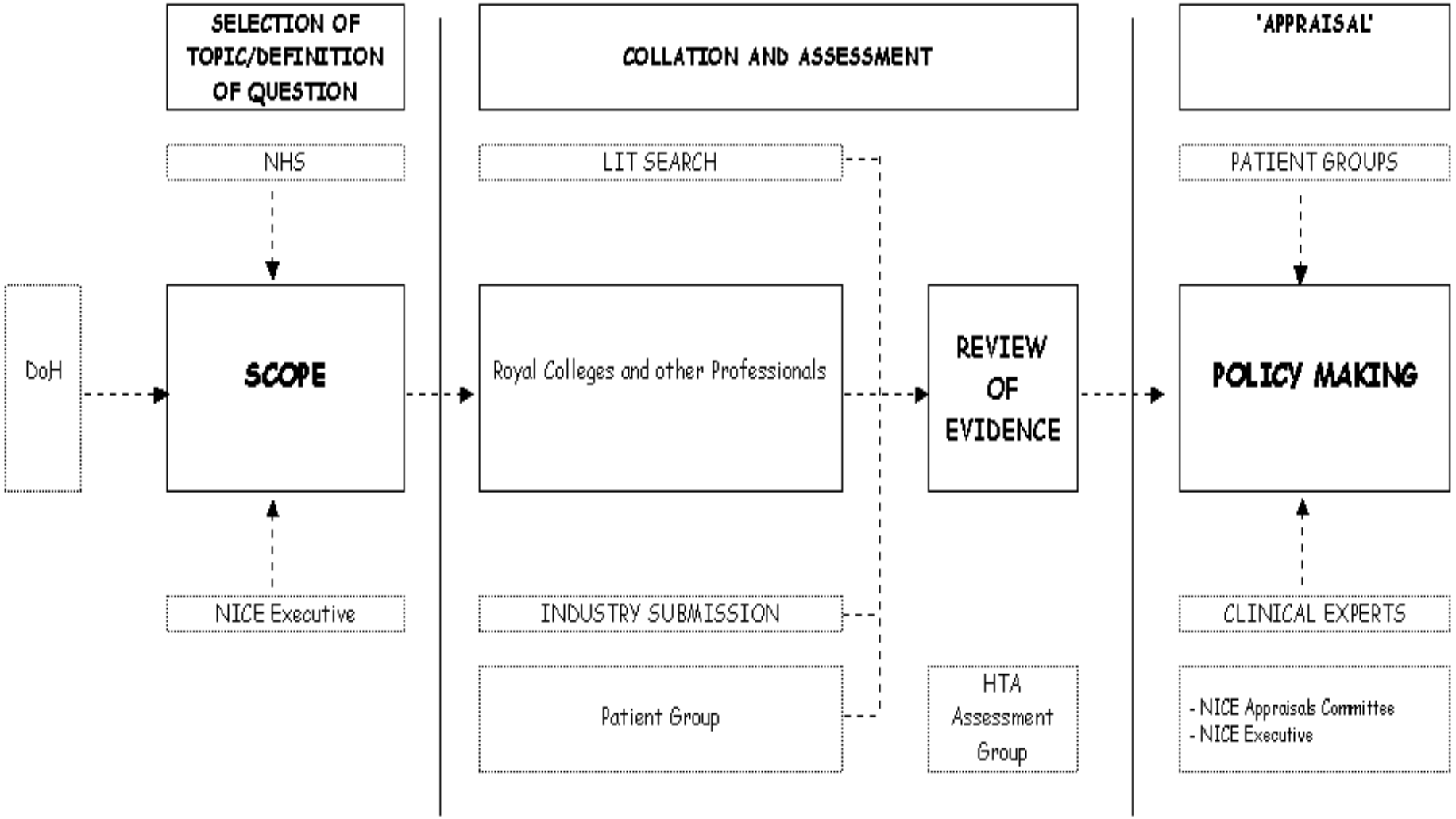
Health Technology Assessment process: Three-phase model



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

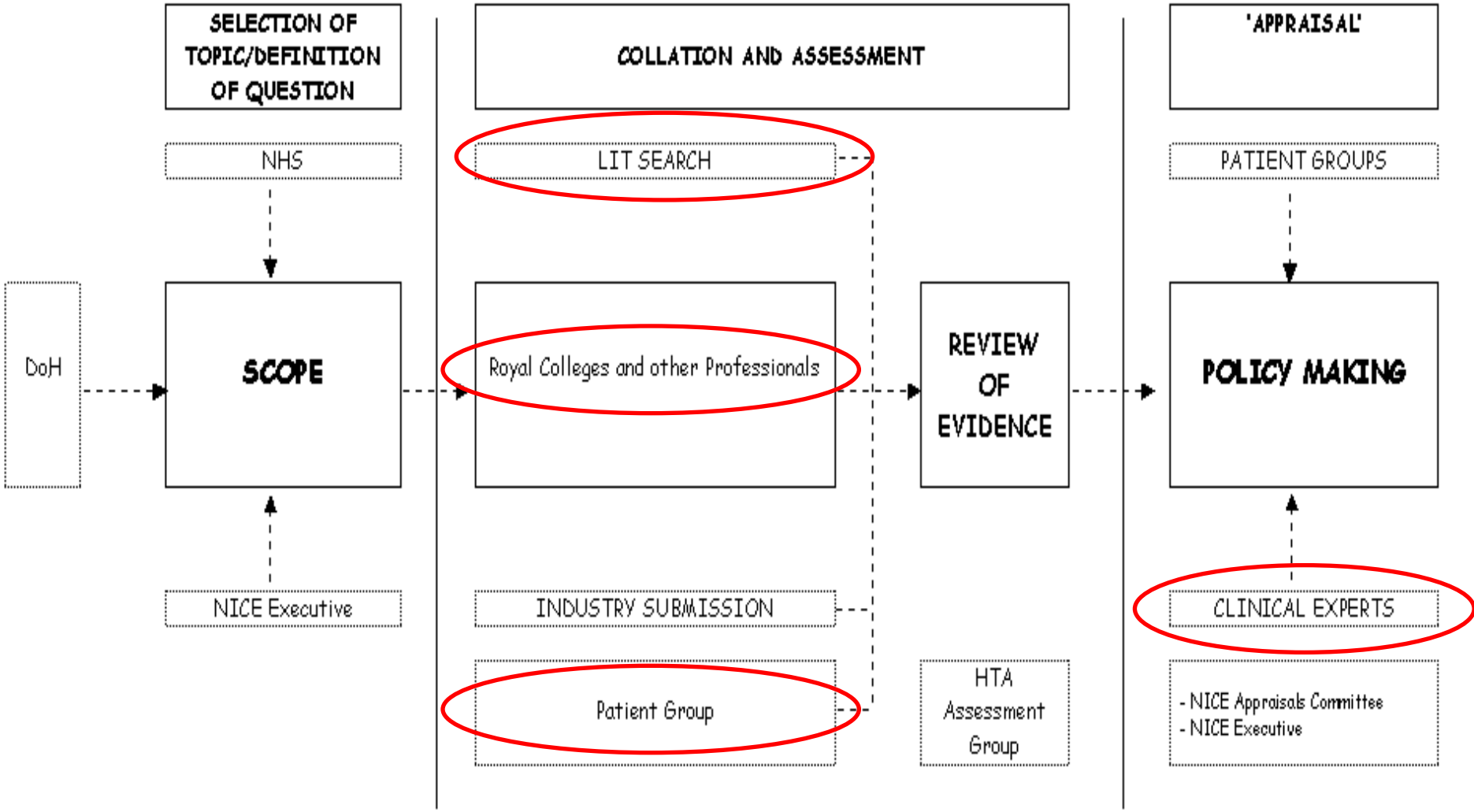
Source: https://www.eupati.eu/health-technology-assessment/fundamentals-of-health-technology-assessment-process/

Model of UK Health Technology Assessment



Source: The University of Sheffield School of Health and Related Research (ScHARR)

Model of UK Health Technology Assessment



Source: The University of Sheffield School of Health and Related Research (ScHARR)

Appraisal & appeals processes

What does NICE do?

NICE guidance is:

- designed to promote good health and prevent ill health
- produced by the people affected by their work, including health and social care professionals, patients and the public
- based on the best evidence and on a rigorous development process
- identifying good value for money in healthcare, weighing up the cost and benefits of treatments
- internationally recognised for its excellence

Description of guidance	Number since March 2000
Technology Appraisals	878*
Total number of guidance and guidelines, including quality standards etc	*1947*
Clinical guidelines	221
Public Health Guidelines	61
Medical technologies guidance	64
Diagnostics guidance	42

** Number published by NICE to April 2023*

Source: adapted from www.nice.org.uk 2023

Topic selection and scoping: how does NICE decide what to appraise?

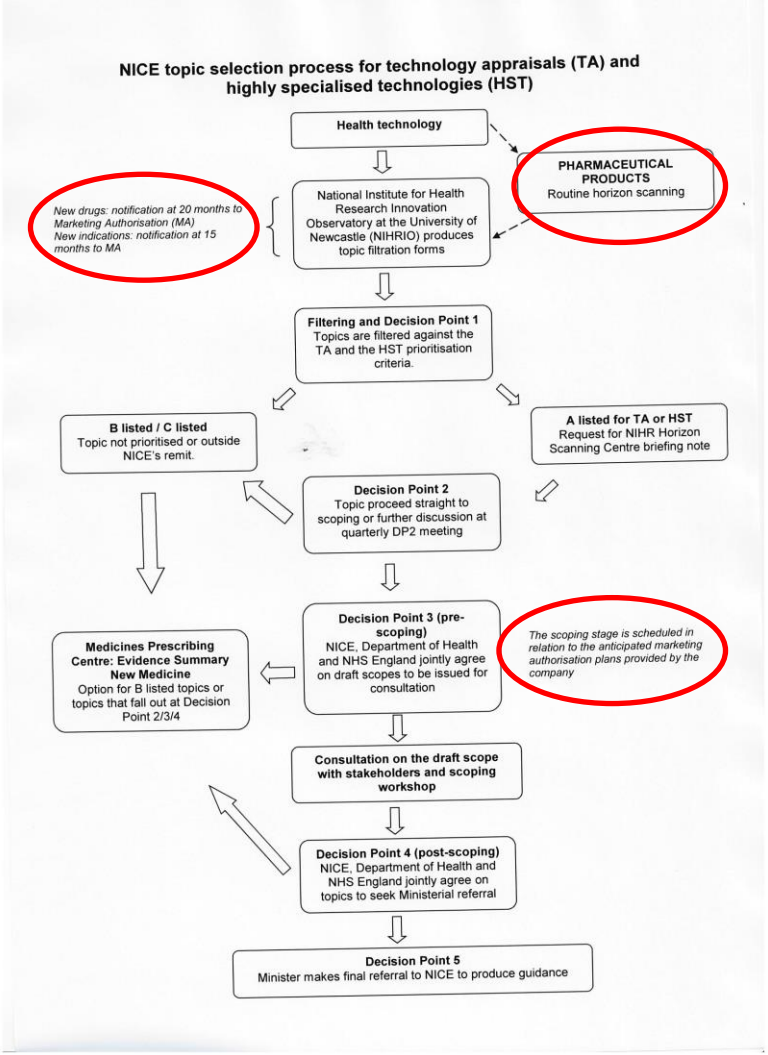
The importance of each topic is considered against a prioritisation criteria that help the DH decide which topics should be referred to NICE. The criteria, assisted by the Topic Advisory Workshop (TAW) are:

•Population (the larger the population the more important a technology is for evaluation)

•Disease Severity (the greater the severity, the more important, however not just based on mortality)

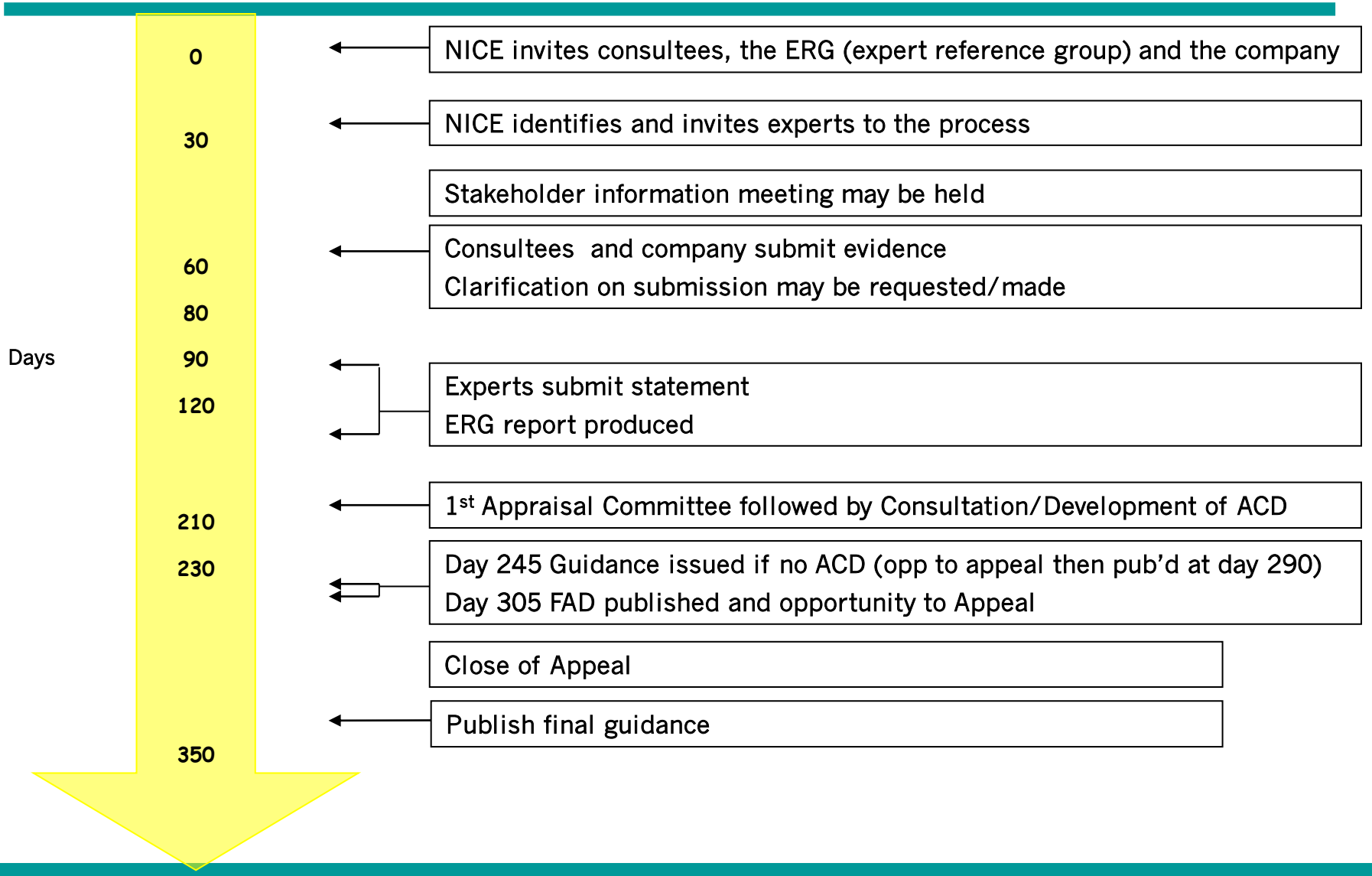
•Resource Impact (cost or savings of implementing guidance)

•Claimed Therapeutic Benefit (over what is currently available)



Source: www.NICE.org.uk

NICE Appraisal Process



Source: Adapted from MTA Timeline, www.nice.org.uk

NICE STA Process

- The Institute's multiple technology appraisals or MTAs, are focused on groups of drugs, devices or health technologies used to treat a disease

- The STA process is the same, however as it focuses on just one technology it aims to be considerably faster (43 versus 60 weeks)

- The Single Technology Appraisal (STA) process produces guidance more quickly on life-saving drugs that have already been licensed and on new, potentially high cost medicines close to when they first become available.

- 1 April 2017 saw the launch of the FTA, the Fast Track Appraisal for technologies that offer exceptional value for money. A product will be appraised through the FTA process if:
  - "The company's base-case incremental cost-effectiveness ratio (ICER) is less than £10,000 per quality-adjusted life year (QALY) gained.
  - It is likely that the most plausible ICER is less than £20,000 per QALY gained, and it is highly unlikely that it is greater than £30,000 per QALY gained.
    or
  - A cost comparison case can be made that shows it is likely to provide similar or greater health benefits at similar or lower cost than technologies already recommended in technology appraisal guidance for the same indication.
  - If a positive recommendation is made through the FTA process, NHS England/commissioners have committed to providing funding for the technologies within 30 days of guidance publication"

Source: www.nice.org.uk 2023

NICE Appeals Process

- Companies have 15 working days from receipt of the FAD in which to lodge an appeal (oral or written).

- Appeals are heard by the Institute's Appeal Panel which comprises 5 members drawn from the Appeals Committee with no previous involvement in the appraisal.

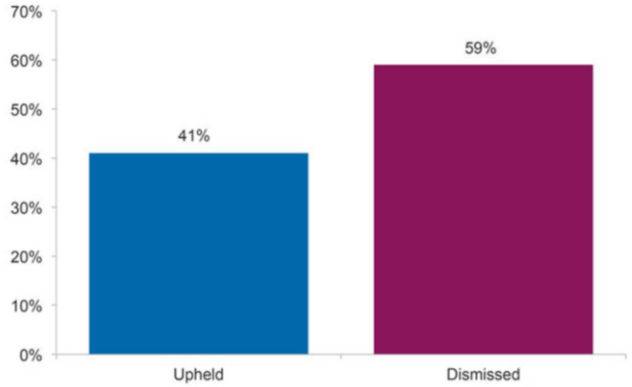
- It is not possible to appeal simply if the company does not agree with the outcome; may be on the following grounds;
  - Ground one: The Institute has failed to act fairly or exceeded its' powers
  - Ground two: The Institute has formulated guidance which is unreasonable in the light of the evidence submitted to NICE.

- Timing of appeals varies, though NICE aim to hear an appeal within 10 weeks of the appeal being lodged (10 weeks for a written appeal).

Summary of appeal panel decisions

A retrospective review of technology appraisal appeals and their associated outcomes from 2000 to 2011;

- 1/4 of appraisals resulted in an appeal, and 41% of these appeals were upheld
- the most common ground for appeal was perversity of the decision with 59%, based on misinterpretation of the clinical or cost-effectiveness evidence (now classified under Ground 2, “cannot be reasonably justified”).
- While stakeholders from industry were the most common appellant type, professional organisations and patient groups had the highest percentage of appeals upheld



A total of 106 appeals have been held from 2000 to the present day (May 2023) (also 8 rejected and 5 cancelled).

Source: https://www.xcenda.com/insights/htaq-spring-2017-outcome-of-appraisal-is-not-nice accessed 2023

NICE in 2020 & beyond: more change

January 2020: updated publication of their principles; essentially a framework for how the agency goes about its work – from working on national priority areas through to publishing their work and updating as necessary.

March 2020: their final statement of intent on increasing the use of health and social data in their guidance. The statement covers one of the buzz phrases in market access – 'real world data' – and signals a greater willingness for NICE to consider its use in their work.

June 2020: NICE let industry know about their changes to the process used in Single Technology Appraisals (STAs), moving from technical reports from Evidence Review Groups (ERGs) – independent academics – to present issues. That allows for easier engagement but also offers companies a right to reply to ERGs.

October 2020: proposals to change the selection of treatments for evaluation. The aim is for simplification as well as confirming promises made in VPAS (the voluntary scheme for branded medicines pricing and access*) that NICE will appraise all new active substances and significant new indications.

October 2020: - NICE, building on their international links, was one of seven agencies who took part in the first ever World Evidence-based Healthcare Day

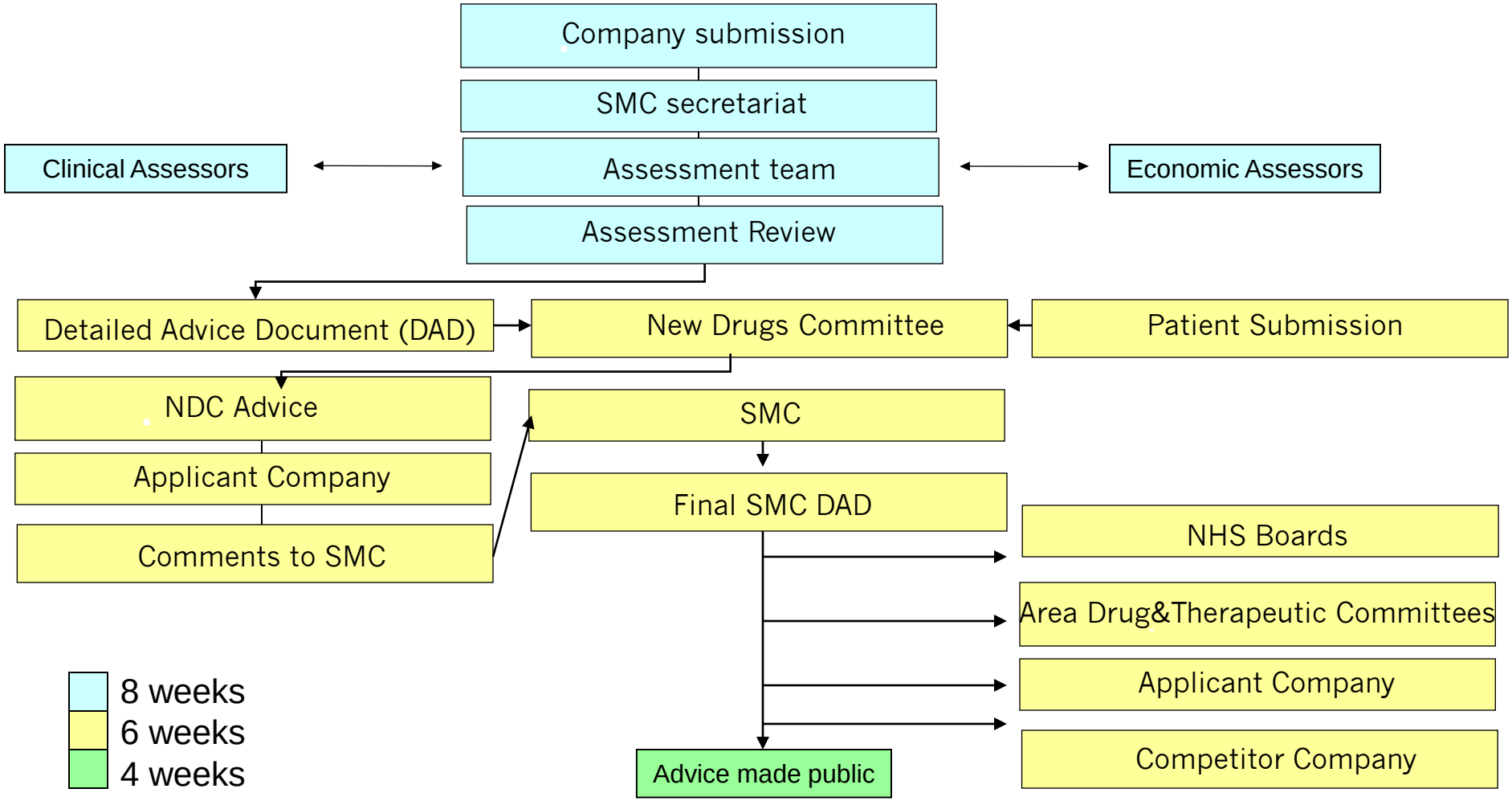
2023 has seen reforms taking shape from the new strategy for 2021-2026 launched. This will also be when changes to selection processes will be implemented too. Companies are going to need to keep refining their inputs to NICE as new guidance emerges

- The future could see big changes that provide opportunities for pharma for faster NICE appraisals but as ever, the devil is in the detail and the full impact won't be possible to see until a number of treatments have gone through the new methods and processes
  - Faster guidance published, links with ILAP/registration/implementation at a local level?

**VPAS sets a cap on the total allowed sales value of branded medicines to the NHS each year. The cap grows at an agreed rate of 2% per annum and any medicine sales above the cap are paid back to DHSC via a levy.*

Source: www.nice.org.uk

SMC Review Process: 18 weeks maximum*



** Although 22-26 weeks for end of life, orphan drugs*

Source: Adapted from SMC website 2023

SMC Appeals Process: The IRP (independent review panel)

- An IRP may be requested up to 12 months after completion of a full SMC assessment.
- The review group (Independent Review Panel - IRP) is appointed by the SMC on advice from the Chairman and Secretariat, and comprises 7 members:
  - 3 appointed from the SMC/NDC who, by reason of absence, have not been involved in the particular case.
  - 4 appointed from Scottish NHS Board Area Drug and Therapeutics Committees (or their successors/equivalents) and/or other respected experts in the relevant scientific field who need not necessarily be working in Scotland.
- The IRP will be able to review the original material considered by Pharmatrak, the NDC and the SMC. New evidence or analysis will mean a resubmission as opposed to Independent Review.
- The IRP will report back to the SMC who shall remain the final arbiter in all cases.
- Timelines for the review in Scotland are not clearly defined and dependant on a case by base basis (at least 6 months)

AWMSG
(The All Wales Medicines Strategy Group)

All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

- Six months prior to launch, review of all newly licensed products, new indications and significant formulation changes.
- AWMSG consider NICE guidance and generally will not appraise a product if NICE is due to issue guidance within 12 months
- Relatively few submissions to date, though increasing with a capacity to deliver a maximum of 38 appraisals per year
- Health Boards are expected to implement guidance and provide funding accordingly within 3 months of guidance being issued

AWMSG Independent Review (IR) Process

- Companies have 10 working days within which to request an IR
- The grounds of a review may be due to;
  - complaints relating to process
  - concerns of the applicant relating to differences in scientific opinion and/or interpretation of data
- IR panel will consist of 7 members
- Timing: “as soon as is practicably possible”

Summary

- There are a significant number of different stakeholders across the NHS to manage in order to support product endorsement.

- Successful HTA submissions are required at a national level to ensure commissioning, endorsement and regional uptake.
  - Many pharma companies now have dedicated ‘market access’ teams who work with marketing, health outcome and communications to manage the environment and prepare positively for a given brand(s)

- ‘Market Access’ and the role of HTA has become increasingly important due to the impact on sales and product uptake in the UK. Positive guidance is key to success and a way of doing business for the pharma industry.

Workshop 3:

Individually consider the following and be prepared to share one key point with the group when asked

What do you believe is the role of the marketer within the process of guidance development?

HTA requirements for the healthcare industry in the UK

SMC: the quality of the submission….getting through successfully

- **A submission with a good chance:**
  - Presentation clear and concise
  - Has made a lot of effort to adjust to Scotland
  - Uses generic outcome, often QALYs
  - Clear and transparent model

- **A submission with less chance:**
  - Presentation complex, messy, inconsistent
  - Comparator is not Scottish practice
  - Uses disease specific outcomes
  - Model assumptions not justified or in reference cited
  - Relies extensively on long-term savings

Evidence examined by the SMC

1. Registration details and competitor treatments
    - Indication of product, launch date
    - Competitor treatments
2. Summary
    - Main messages and points of the submission, the relation to Scotland and the case for prescribing the product in Scotland (300 words max.)
3. Efficacy
    - Evidence relevant to section 1:
        - Historical overview of study programme and ongoing studies giving evidence in next 6-12 months
        - Description of studies
        - Results
4. Comparative Safety
    - Information on safety from clinical studies/regulatory summaries, particularly those comparing with alternative treatments

Evidence examined by the SMC

5. Clinical Effectiveness
    - Health benefits patients will gain through treatment (ensure relevant to Scotland)
    - Balanced account of advantages and disadvantages
6. Pharmaco-economic Evaluation
    - Design, methods and results of economic evaluation
7. Resource Implications
    - Total number of pts in Scotland who have condition
    - Estimate of newly diagnosed each year (over first five years of product introduction) with source
    - Number of people in Scotland currently treated & number likely to be prescribed
    - Identify any savings
    - Net resource implication for Scotland for first five years

References

Evidence examined by NICE

Section 1 & 2:
An Introduction to Disease & Product / Clinical Effectiveness

SECTION ONE

- Decision problem (epidemiological data, prevalence, incidence)
- Current service provision
- Cost and burden of disease
- Description of product being appraised and position in treatment pathway
- Problem definition (will be referenced to the scope)

SECTION TWO

- All efficacy data, all effectiveness data (comparisons with other treatments)
- Outcome measurement; justification of endpoints and methodologies and statistical analyses
- Other benefits, e.g.QoL

Evidence examined by NICE

Section 3:
Cost Effectiveness / Impact on the NHS

SECTION THREE

- Published cost-effectiveness studies
- Economic analysis (presentation of model and forms of analysis)
- Net cost of product, valuation of outcome
- QoL gains, cost effectiveness of product
- Interpretation and conclusions of economic evidence
  - Cost of product
  - Budget and service impact on NHS infrastructure and workload
  - Cost-savings and other benefits brought by the product

Summary

- Submissions process varies in time depending on HTA body; financial and time pressures are increasingly leading to shorter timelines
- Quality of dossier (evidence, economic modelling, budget impact) is critical and requires investment from the pharma company
- The media and patient groups have the potential to influence through shaping the market environment and supporting a submission.

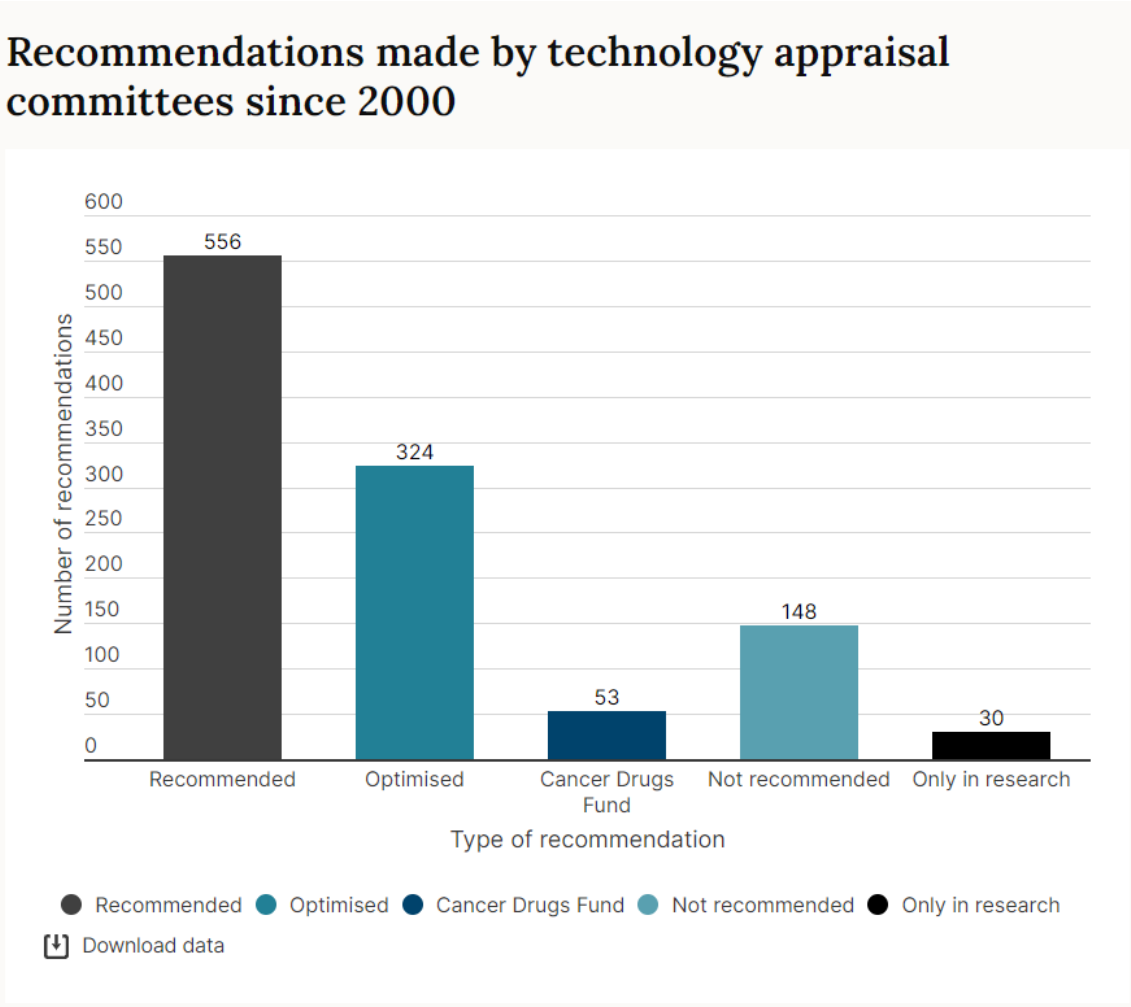
Workshop 4: individual task

What impact do you think HTA and the need for positive guidance for a product has had / will have on clinical trial design?

Please take time to prepare your thoughts, and be ready to share your comments with the group

Impact of guidance on prescribing and funding in the UK

What decisions have been made by NICE?



NICE guidance has five types of decision that may be made (of which 84% of decisions are recommended, optimised or recommended for use in the CDF)

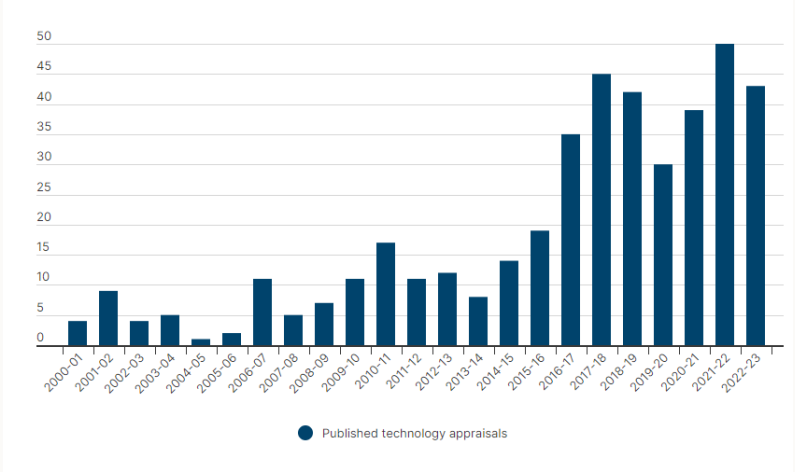
Source: www.nice.org.uk 2023

NICE and cancer drugs

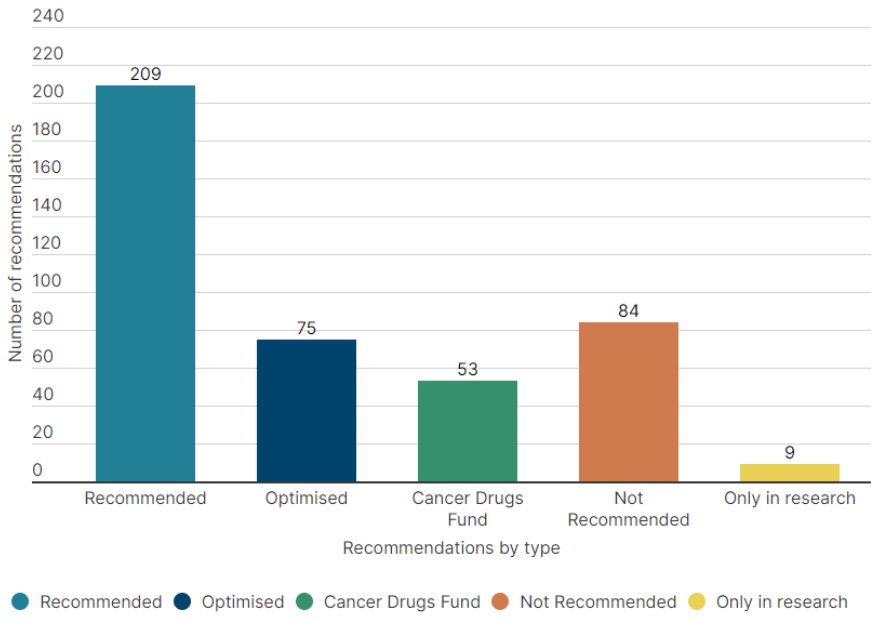
- Since 2000, when NICE started to produce cancer guidance, NICE has published **494** individual recommendations on cancer drugs in **424** technology appraisals.
- 78% of recommendations on cancer drugs are positive

Cancer appraisals published each year

Technology appraisal cancer guidance published since 2000



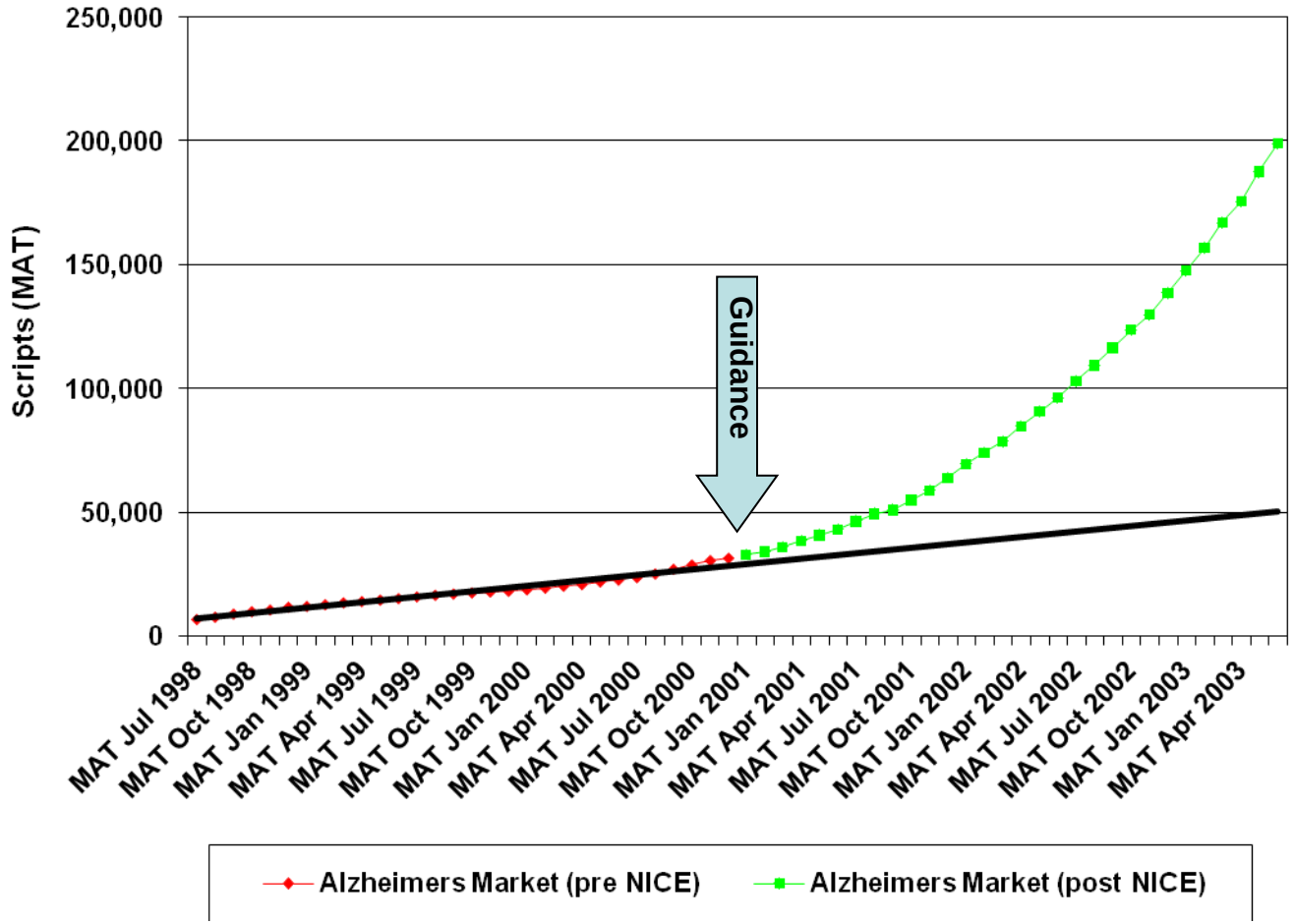
Recommendations on cancer drugs made by technology appraisal committees since 2000



Source: www.nice.org.uk Data to 11 April 2023, accessed May 2023

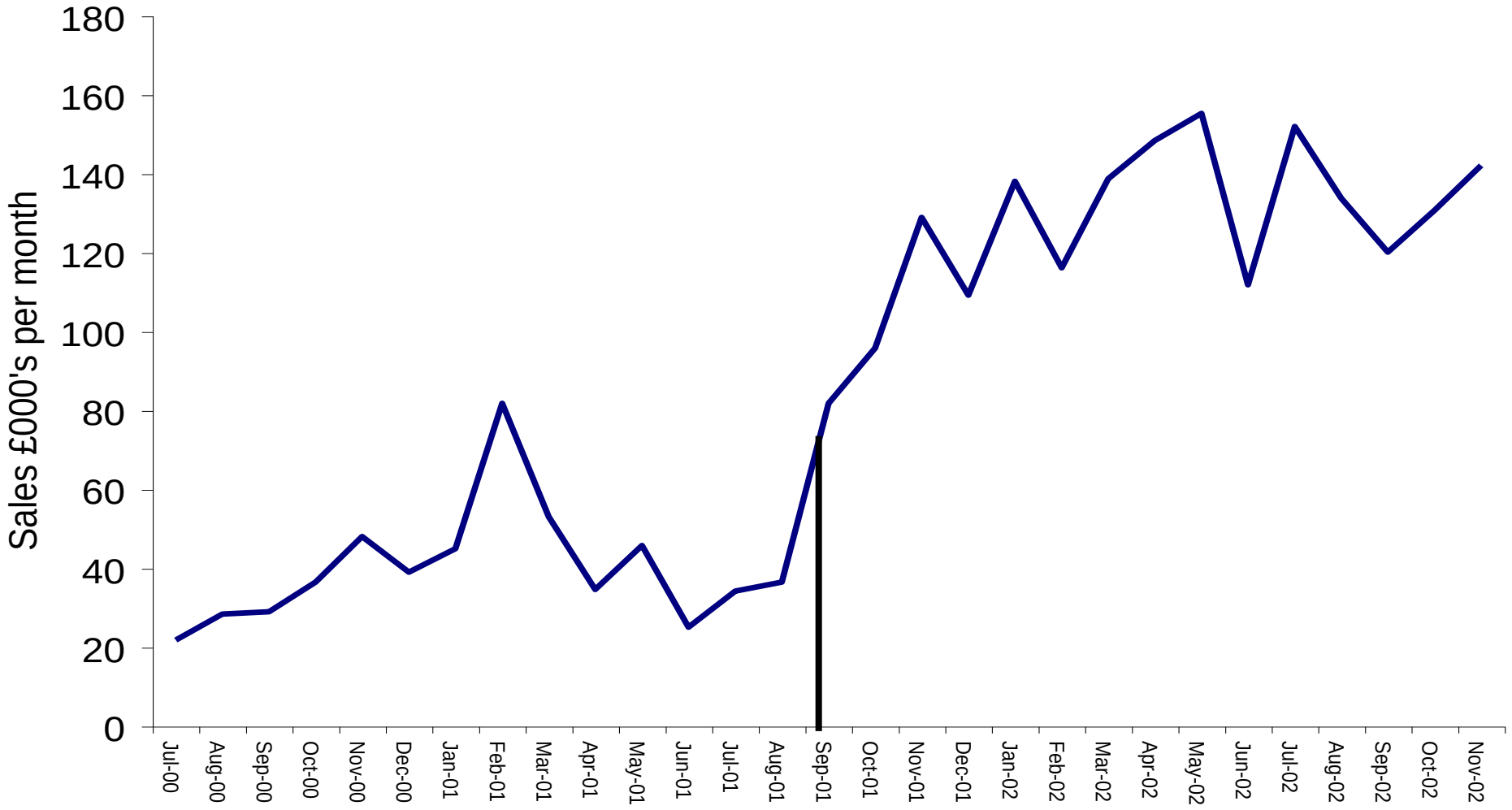
…some early examples

Alzheimers Market (blight or accelerated uptake?)



Trend not diminished to date despite ongoing controversy concerning recent reviews.

Secondary Care Medicine: Topotecan (ovarian cancer)



Source: ABPI, 2003

Early challenges for Roche and BMS/AZ

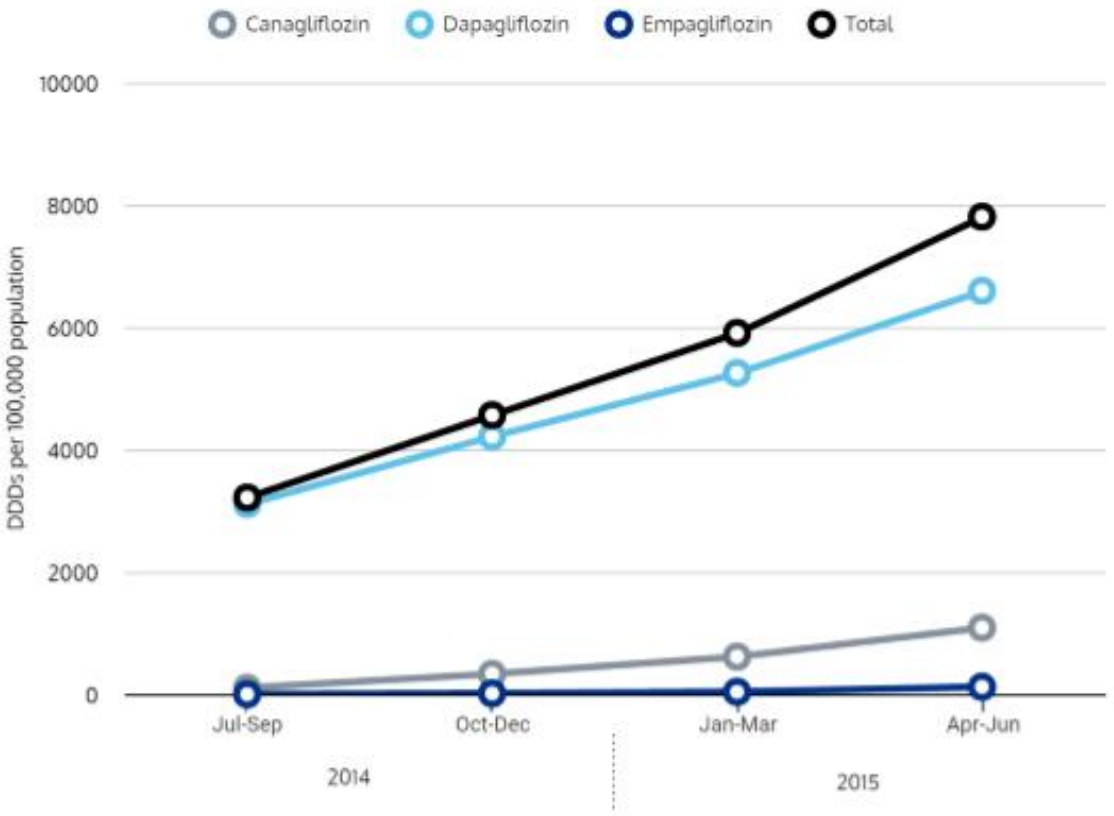
"Unfortunately the appraisal committee is currently unable to recommend dapagliflozin, one of the options, for the treatment of this condition,"

We understand there are limited treatment options available to women with recurrent advanced ovarian cancer and it is always disappointing when we are not able to recommend a treatment."

Source: www.nice.org.uk

…UK uptake and impact reporting

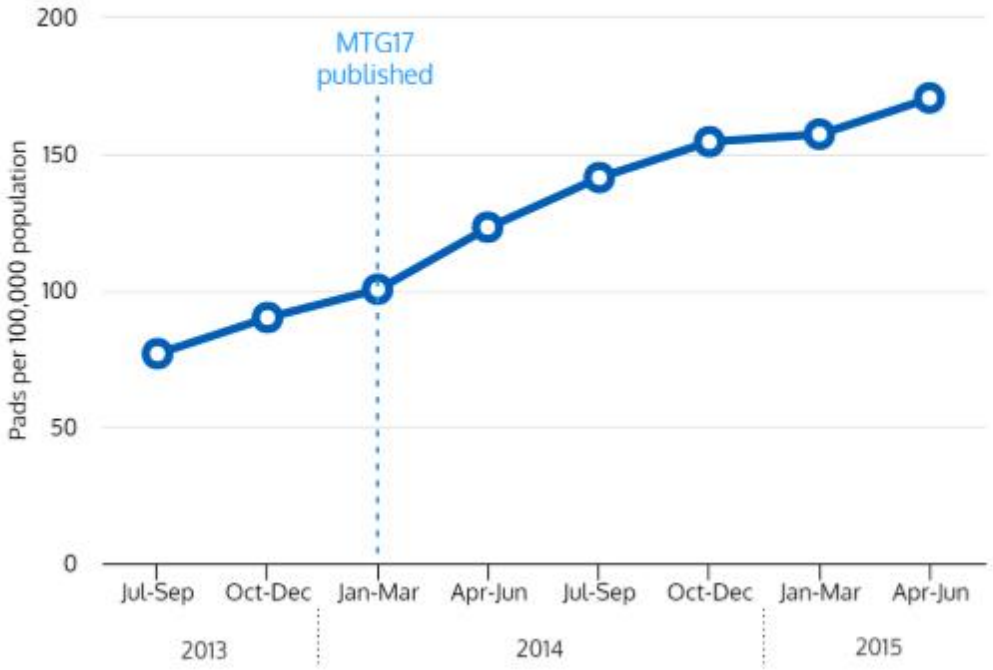
Prescribing of empagliflozin, canagliflozin and dapagliflozin between July 2014 and June 2015



"Although it is encouraging to see that uptake of these medicines has increased, QOF data from England show that only 60% of people with diabetes had a glycated haemoglobin (HbA1c) level of 59 mmol/mol or less, uncontrolled despite the increase in prescribing of these treatments"

Source: NICE uptake and impact report, September 2016

Use of Debrisoft in England between July 2013 and June 2015



Debrisoft is a single-use debridement pad used to remove dead tissue, debris and hyperkeratotic skin caused by chronic and acute wounds. NICE recommended the use of Debrisoft in March 2014 and reported that the case for adoption was supported by limited information, but showed likely benefits including cost savings. The chart shows the use of Debrisoft in England before and after the NICE guidance was published, and shows a continuing increase in its use.

Source: NICE uptake and impact report, September 2016

Summary

- Historically, from examples of products that have been through the NICE process, and today, there is a clear impact on uptake in the majority of products

- It is of note that the majority of guidance issued to date is either positive, or positive with certain restrictions

- With ongoing NHS changes, continuing cost pressures and a drive to prove the value for money in healthcare the role of HTA is set to stay

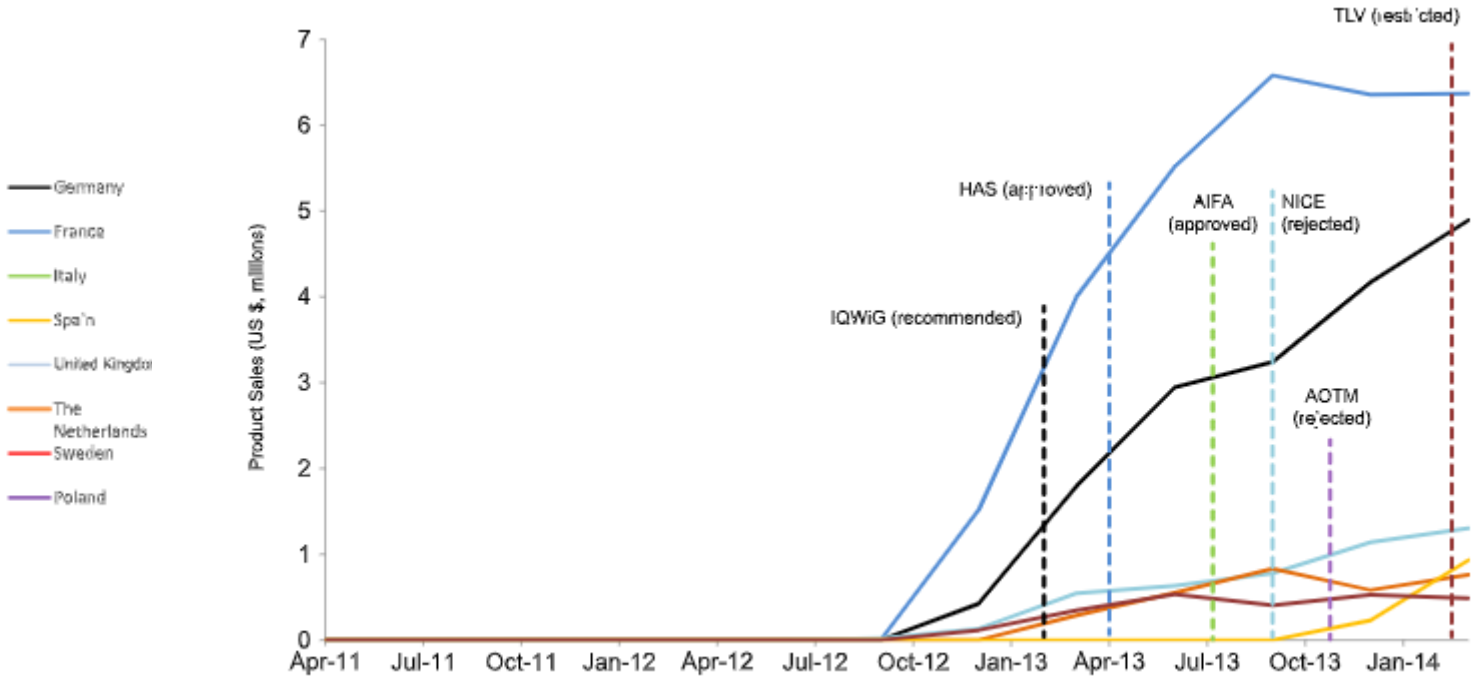
…EU uptake and impact reporting

Observations…

- In most countries access for oncology products can occur outside the HTA process
- Product sales generally follow HTA approval in France (exception of Xalkori)
- Little alignment in other countries between HTA and sales because products are made available immediately after EMA authorisation
- Stronger alignment between HTA and sales in non oncology products (exception being Germany)

Source: Variation in Health Technology Assessment and Reimbursement Processes in Europe, Akehurst et al, Elsevier, 2017

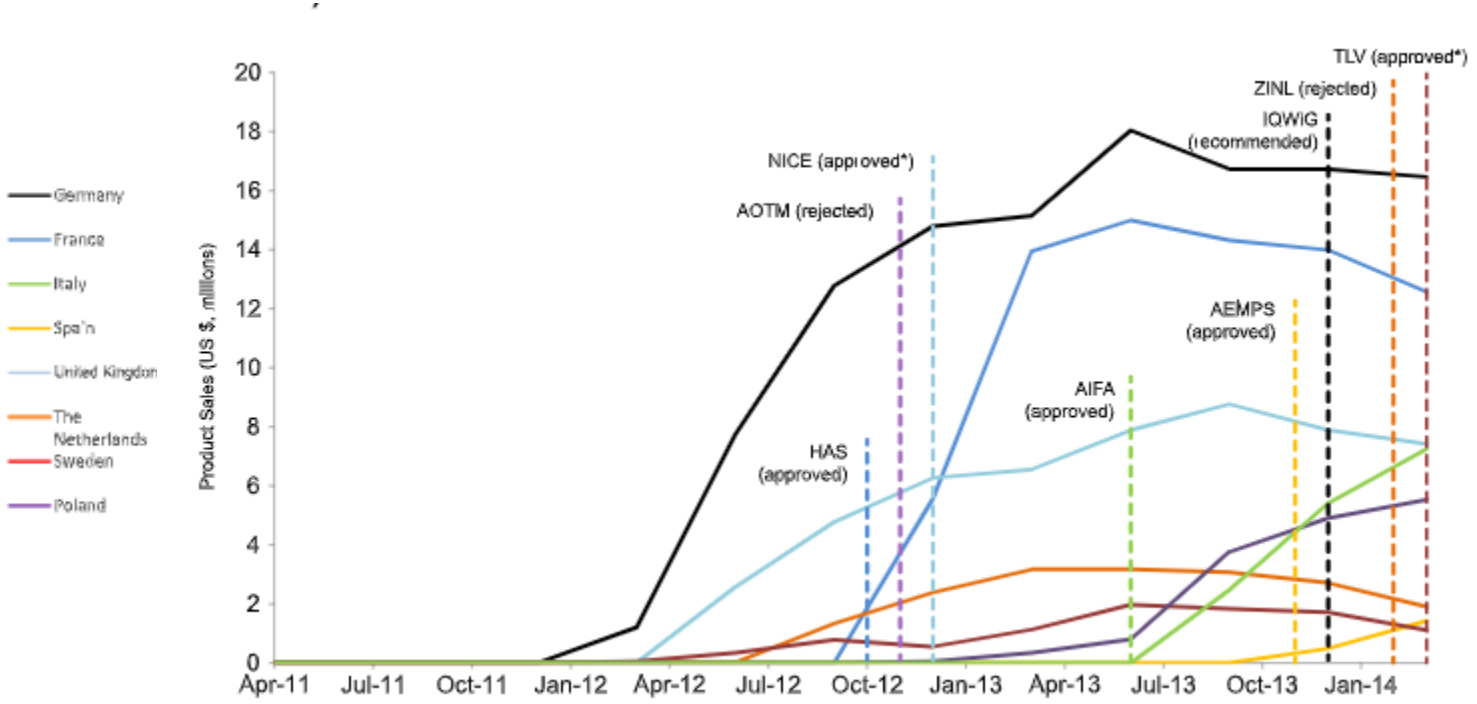
Xalkori: NICE rejection but a continuation in sales



Xalkori (crizotinib) from Pfizer for the treatment of patients with metastatic non-small cell lung cancer, whose tumours are anaplastic lymphoma kinase (ALK)

Source: Variation in Health Technology Assessment and Reimbursement Processes in Europe, Akehurst et al, Elsevier, 2017

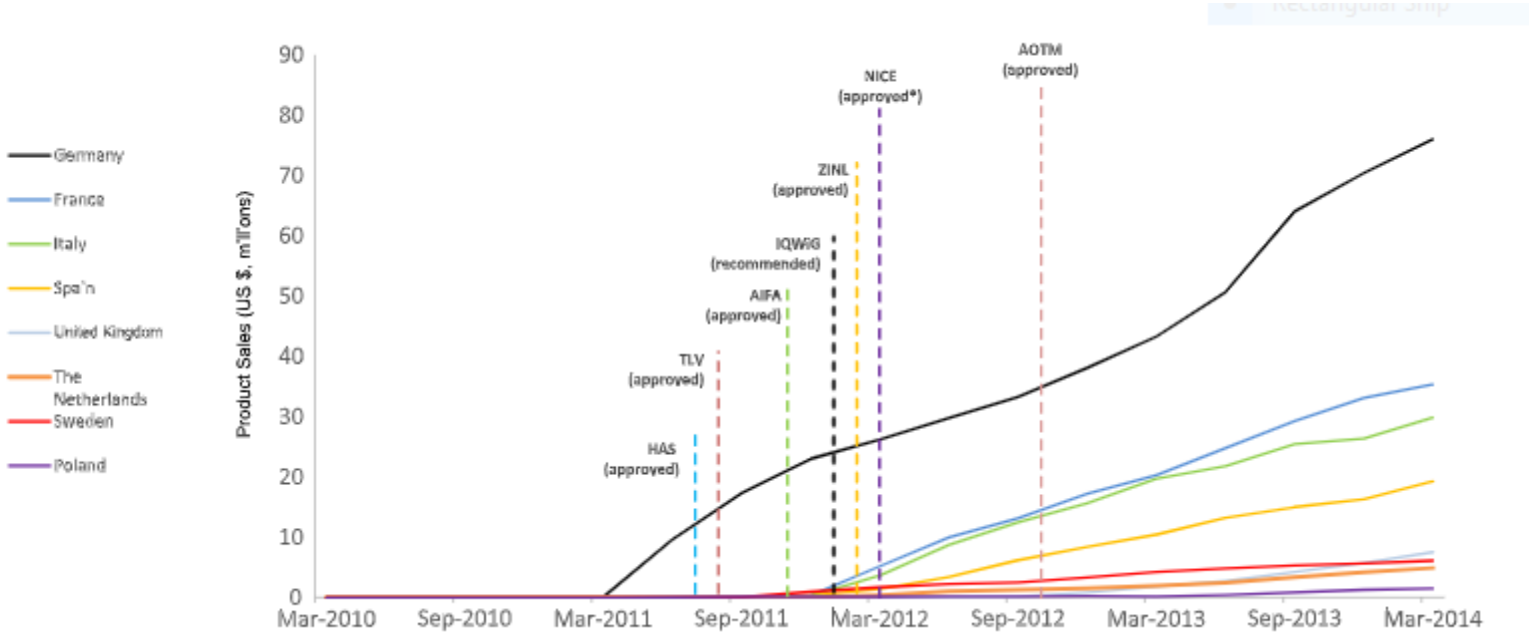
Halaven: NICE approval and a continuation in sales



Halaven (eribulin; a chemotherapy drug) from Eisai for the treatment of locally advanced or metastatic breast cancer

Source: Variation in Health Technology Assessment and Reimbursement Processes in Europe, Akehurst et al, Elsevier, 2017

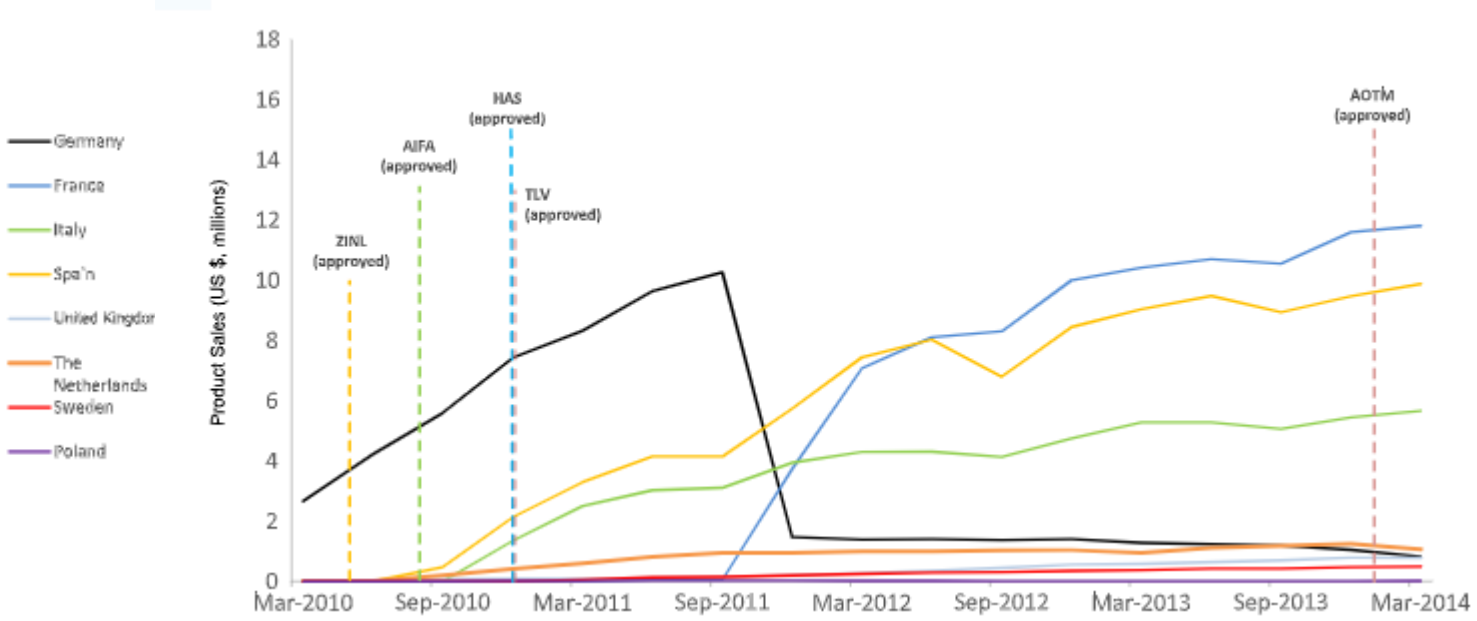
Gilenya: approval and sales growth



Gilenya (fingolimod) from Novartis is a disease modifying drug for relapse remitting multiple sclerosis (which reduces the number and severity of relapses)

Source: Variation in Health Technology Assessment and Reimbursement Processes in Europe, Akehurst et al, Elsevier, 2017

Onbrez Breezhaler: approved by G-BA in 2011 but with price restrictions



Onbrez Breezhaler (indacterol) from Novartis for COPD (used in adults for the treatment of acute episodes of bronchospasm)

Source: Variation in Health Technology Assessment and Reimbursement Processes in Europe, Akehurst et al, Elsevier, 2017

Workshop 5: group discussion

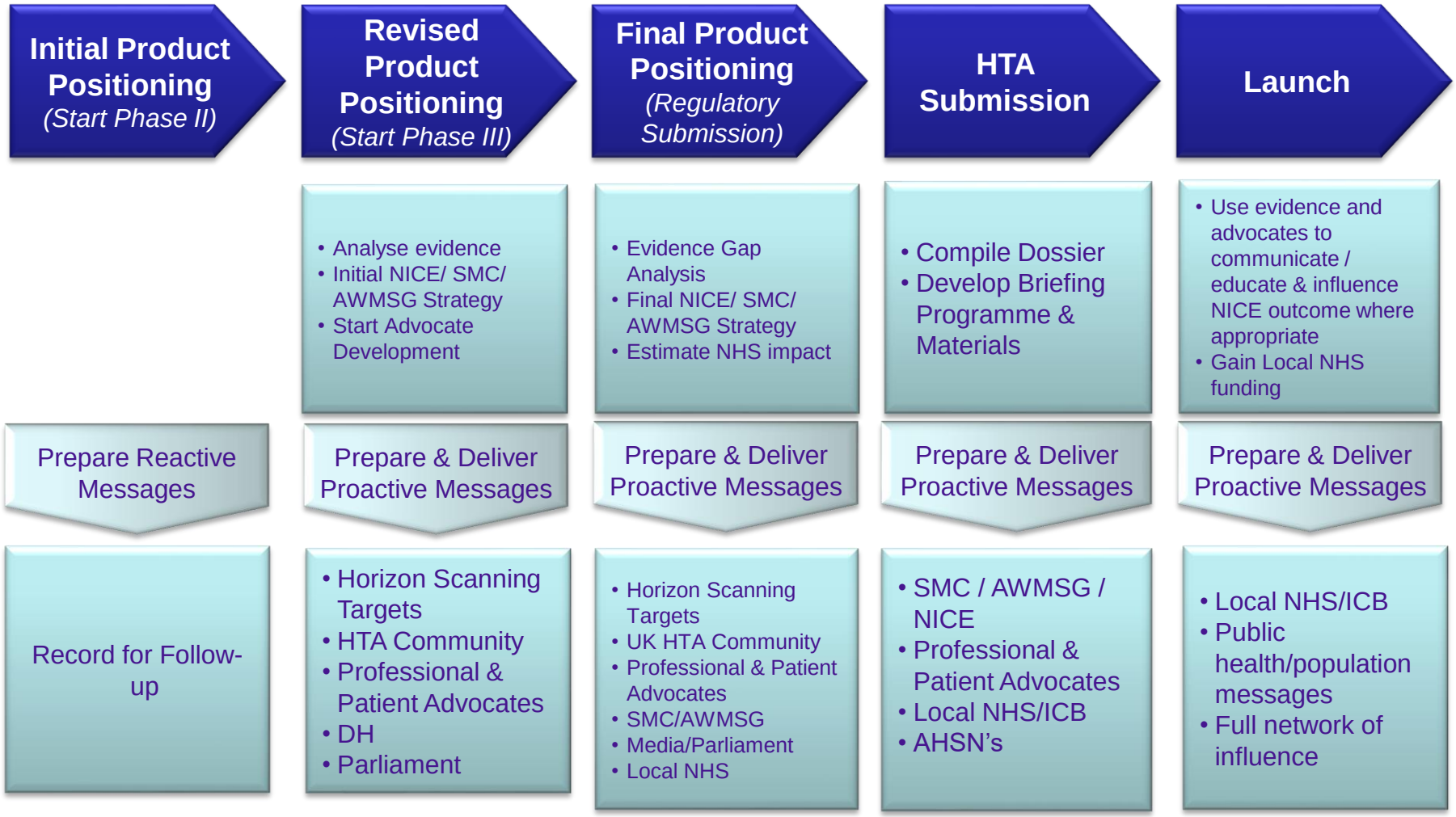
As a pharmaceutical marketer, what can you do to ensure sales uptake at launch?

Individually decide on what your top priority would be, and be prepared to share with the group

Managing communication pre- and post product launch

Market Access Process Overview

"right message, right people, right time"



Communication as part of the marketing mix: the media environment for NICE

- NICE has been a key influencer upon media content
  - journalists look for negative stories about patients‘ lack of access to medicines‘ (e.g. Cancer drugs)
- NICE has also led to the media exposing the perceived high cost of medicines, which can further damage the reputation of the pharma industry (Covid in part has reversed this trend)
- Confusion exists within the healthcare journalists as to the differences between NICE and the regulatory bodies
- Apathy amongst journalists about NICE issues becoming old news, especially when faced with lengthy appraisals

Media environment – some considerations

- The Government‘s commitment to improve the state of the NHS continues to ensure that health matters remain high on the agenda, coupled with radical cost savings and post Covid claw back, this makes news!

- Government targets of CHD, cancer and mental health, also drive content of the media which can work both for and against pharma

- Media generally tend to want to cover stories of suffering and mis-treatment rather than good news („my trust will not precribe me product X“)

- SMC guidance has an influence in the media beyond the border

Communication – the media environment

NHS 'allow retired nurse to lose sight'

Lung cancer hope as health chiefs make drug u-turn

'Alzheimer's drug ban is here to stay, court rules

YOURCEPTIN

Cancer drug victory for all women

Lung patients 'condemned to death' by NHS drug rationing

Give Herceptin on NHS to early cancer patients, says watchdog

Daily Mail

24 HOURS A DAY

03/03/05 - Health section

£2.50 Alzheimer's drugs 'too expensive'

Nasty truth about NICE: It's the body that rations NHS drugs. But this leading cancer specialist says its decisions are deeply flawed

Herceptin approved for NHS use – but can trusts afford it?

By Julia Whalden

Science Correspondent

Mail Online

Home U.K. Home News Sport U.S. Showbiz Femail Health Science Money Rig

Health Home | Health Directory | Health Boards | Diets | MyDish Recipe Finder

Don't give out cancer drugs if it's just to extend life: Treatment costs can't be justified, say experts

- NHS spends £5bn annually on cancer treatments up from £3bn in 2002
- Around 310,000 Britons a year are diagnosed with cancer

By SOPHIE BORLAND

Last updated at 2:50 PM on 27th September 2011

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Patients with terminal cancer should not be given life-extending drugs, doctors said yesterday.

The treatments give false hope and are too costly for the public purse, they warned.

The group of 37 cancer experts, including British specialist Karol Sikora, claimed a 'culture of excess' had led doctors to 'overtreat, overdiagnose and overpromise'.

The life-prolonging drug called Sutent which is given to kidney cancer patients. Right, Karol Sikora who is one of the 37 experts who warn that the cost of cancer treatments cannot be justified

New antiviral pills to keep patients out of hospital

Stockpile of two drugs awaits regulator approval

Data requirements and opportunities to communicate

- In the absence of published landmark studies, the following areas of the marketing mix play a role in communicating key messages and clinical data to target audiences;
  - Advisory Consensus reports/statements (medical education)
  - Letters to the Editor
  - Integrated Care Pathways
  - Professional Organisations opinion
  - Patient case studies
  - Patient Group submissions
  - Clinical champions

Common Organisational Pitfalls

The strategic objective of R&D is to gain marketing authorisation not reimbursement, funding or access

Market Access is considered **too late** in the launch planning process or not at all in the case of launched brands

Market Access capabilities sit within a specific function which leads to **lack of integration** into other internal processes

Lack of true insight into the needs and value drivers of non clinical customers

Industry approach to Market Access: a wide variety but should be at the centre

Traditional role of the Marketer

- Management of the 4 P’s
- Branding
- Competitive and differential positioning
- Strategy, campaign and message development
- KOL development
- Sales force support

The role of the Marketer today ...

- Maximise return (ROI) by seizing opportunities and **minimising barriers to NHS** market access

- NHS Market Access processes start up to five years before launch....**start early**: an integrated market access strategy across the marketing mix is required

- **Manage relationships** with key bodies and individuals proactively (increased focus on demonstrating outcome through evidence, medical education, patient group support etc.)

- **Manage the messages** systematically to inform key decision makers and influencers.

...integration across functions and across the marketing mix

... questions to be considered in the development of any marketing plan

- Is the brand/disease area high on the health agenda and targeted for a NICE technology appraisal, STA or FTA?
- Is the brand or disease area on any government targets?
- Is the brand considered to be costly? Can I demonstrate value?
- Have I developed a value proposition for the NHS?
- Are there any issues within the brand/disease area that would make good news stories?
- Can patient case studies be developed? Is there a defined patient pathway?
- What relationships exist with patient organisations?
- Will patient groups support media coverage?
- How complex is the brand/disease area?
- How has it been covered in the past by the media?
- Are there issues of NICE guidance not being implemented?
- Do strong opinion leader relationships exist and who will be willing to publicly endorse drug positioning and clinical messages?

... 10 steps to Market Access planning

10. The right conditions surrounding the prescriber
9. The right funding
8. The right reimbursement/coverage
7. The right price
6. The right label
5. The right Regulatory Strategy
4. The right Phase III development programme
3. The right Phase II development programme
2. The right asset selection
1. The right disease strategy

Source : Adapted from C Wight 2014

In summary....why is Market Access so important? Challenges for the marketing mix...

- Increasing costs, advances in treatments, aging populations and reduced budgets.....
- Centralised guidance with localised decisions covering an increasingly complex array of stakeholders and influencers
- Increasing demand for health economic data to prove value for money
- Increasing potential for MEA's (managed entry agreements) to support drug funding

In summary … Market Access trends to watch for

1. The United States government's regulations will continue to impact manufacturers' gross-to-net and profitability in both expected and unexpected ways
2. Increased cost pressures will amplify tensions between distributors and manufacturers
3. Payers are human and, therefore, consumers, too. Using an omnichannel approach to communication is more critical than ever
4. Ensuring global access in an uncertain economy will require telling a compelling clinical and economic story
5. Post-pandemic healthcare consumer expectations will drive manufacturer innovation in the site of care and method of administration determinations
6. Evolutions across the healthcare industry will accelerate the acceptance of digital therapeutics as a viable treatment option
7. Customer relationship management will be the key to igniting a data revolution in market access
8. Creativity will be a force for access
9. The right patient support solution will be about putting the right support in the right place at the right time
10. Ensuring equity in access will drive improved health outcomes for patients and business outcomes for manufacturers

Questions?

Assignment

"Understanding and planning for changes in the external environment"

VUCA (volatility, uncertainty, complexity and ambiguity) is the normal environment in which pharmaceutical businesses operate in any part of the world, and pharmaceutical marketers must be ready to adapt their marketing strategies to work within the changed environment whilst achieving competitive advantage.

The assignment requires you to identify and analyse the macro-level external factors that are impacting the pharmaceutical market in a geography of your choice (e.g. UK or Europe or EMEA) and to discuss the impact the resultant opportunities and threats will have on marketers in that geography.

The report must include and be structured thus:

1. A brief outline of the pharmaceutical market in your chosen geography.
2. A detailed and robust PESTEL analysis of the impact that macro-level external factors are having/ will have on pharmaceutical marketing in your chosen geography.
    - The output from this should be the **implications** of these changes and whether these changes represent an **opportunity** or a **threat**.
3. A discussion of how these opportunities and threats will impact pharmaceutical marketers and pharmaceutical marketing in your chosen geography.

Marking scheme for the Assignment

	Topic	Marks (%)
1	A brief outline of the pharmaceutical market in your chosen geography	10
2	A detailed and robust analysis of the impact that macro-level external factors are having / will have on pharmaceutical marketing in your chosen geography	40
3	A discussion of how these opportunities and threats will impact pharmaceutical marketers and pharmaceutical marketing in your chosen geography	30
6	Relevant use and understanding of academic concepts / models	10
7	Referencing and presentation	10
	Total	100

Thank you

Close

Resources and References (1)

Articles of interest;

‘Market access, please no more talk of hurdles and obstacles’ Dr Beverly Barr February 2013 (old but useful principles)
http://www.pharmafile.com/news/178236/market-access-please-no-more-talk-hurdles-and-obstacles
Early dialogue between regulators and health technology assessment bodies key to medicines development
www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001979.jsp&mid=WC0b01ac058004d5c1
HTA Network reflection paper on “Synergies between regulatory and HTA Issues on Pharmaceuticals” November 2016
https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co06_en.pdf
Getting UK market access right; Quintiles article by Haigh and Williams
https://www.iqvia.com/-/media/library/white-papers/getting-uk-market-access-right.pdf?vs=1
Variation in HTA and Reimbursement Processes in Europe, R Akehurst et al, 2017; https://reader.elsevier.com
10 Market Access Trends to Watch for in 2023, C Meese, 2023
https://www.pharmexec.com/view/10-market-access-trends-to-watch-for-in-2023

Resources and weblinks;

NHS England: www.england.nhs.uk
NICE: www.nice.org.uk
Scottish Medicines Consortium: www.scottishmedicines.org.uk
All Wales Medicines Strategy Group: https://awttc.nhs.wales/use-of-site/about-us1/our-committees/#AWMSG
HTA in Ireland: www.hiqa.ie
Health Service Journal: www.hsj.co.uk
Horizon Scanning: www.hsc.nihr.ac.uk
LinkedIn has a Market Access: Pharma Experts Group
http://social.eyeforpharma.com/market-access
Centre for Innovation in Regulatory Science www.cirsci.org

Other;

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EU/ROW;

An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report
https://www.eunethta.eu/wp-content/uploads/2018/02/WP7-Activity-1-Report.pdf

Every Day Counts: Improving time to patient access to innovative oncology therapies in Europe; July 2020 by Vintura (commissioned by EFPIA)

Health Technology Assessment (HTA) Case Studies: Factors Influencing Divergent HTA Reimbursement Recommendations in Australia, Canada, England, and Scotland, 2017
https://www.valueinhealthjournal.com/article/S1098-3015(16)30019-5/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301516300195%3Fshowall%3Dtrue

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https://www.frontiersin.org/articles/10.3389/fphar.2020.594549/full

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Aleksandra Torbica, Rosanna Tarricone & Michael Drummond
The European Journal of Health Economics volume 19 05 Dec 2017

PhRMA, "PhRMA Announces First-Ever, Industry-Wide Principles on Clinical Trial Diversity" (Nov. 17, 2020).
https://www.phrma.org/equity

Useful podcasts;

https://marketaccess-pricingstrategy.de/en/map-podcast/