Comparison of “coverage with evidence development” approaches for digital health technologies and pharmaceuticals

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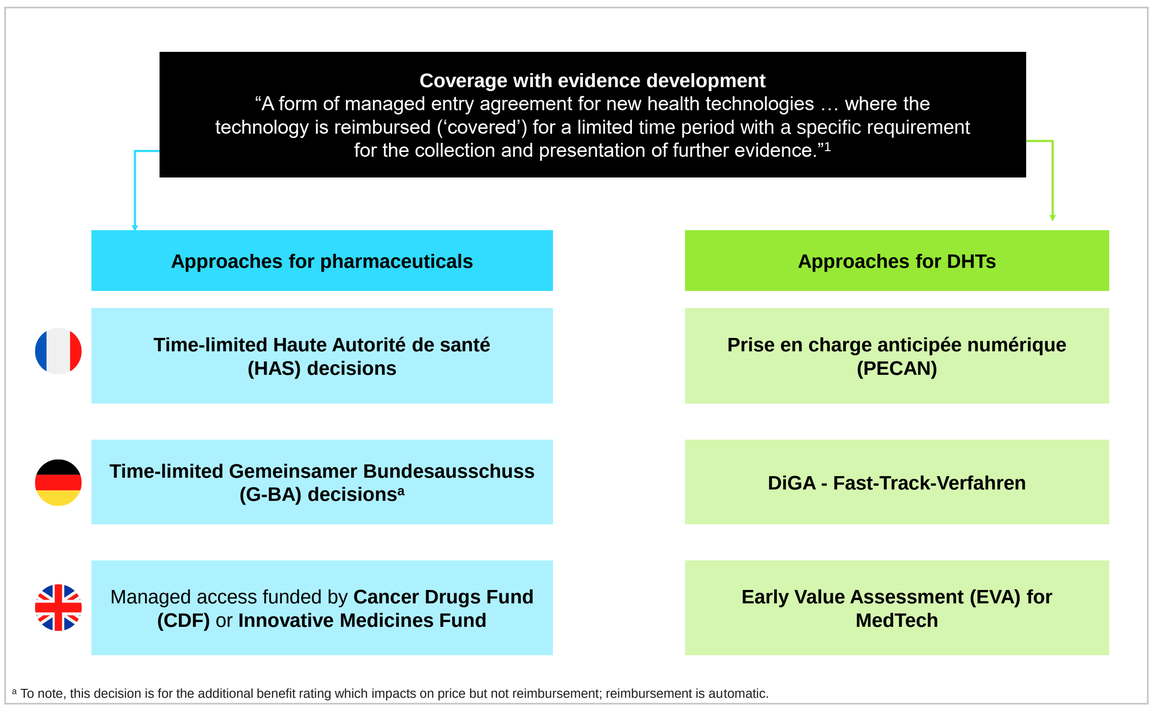
Background

Evaluation approaches for digital health technologies (DHTs) have emerged in markets including France, Germany, and the UK, characterized by “coverage with evidence development” (CED).
Similar approaches are used for pharmaceuticals in these markets, with considerable historical experience of their use and evidence generation expectations.
All schemes allow for public health system reimbursement of interventions (either through routine funding routes or dedicated funds) before subsequent reassessment and final decision.
We aimed to understand the parallels and disparities between these approaches to determine if experience from pharmaceuticals can transfer to DHT evidence generation planning.

Figure 1: Coverage with evidence development approaches for pharmaceuticals versus DHTs



[a] To note, this decision is for the additional benefit rating which impacts on price but not reimbursement; reimbursement is automatic.

Methods

We conducted a targeted literature search for public documents describing the aims, motivation, evidence requirements, and operationalization of these approaches.
Recent assessments were identified and reviewed across markets for both pharmaceuticals and DHTs.
Qualitative comparisons were made within and across markets.

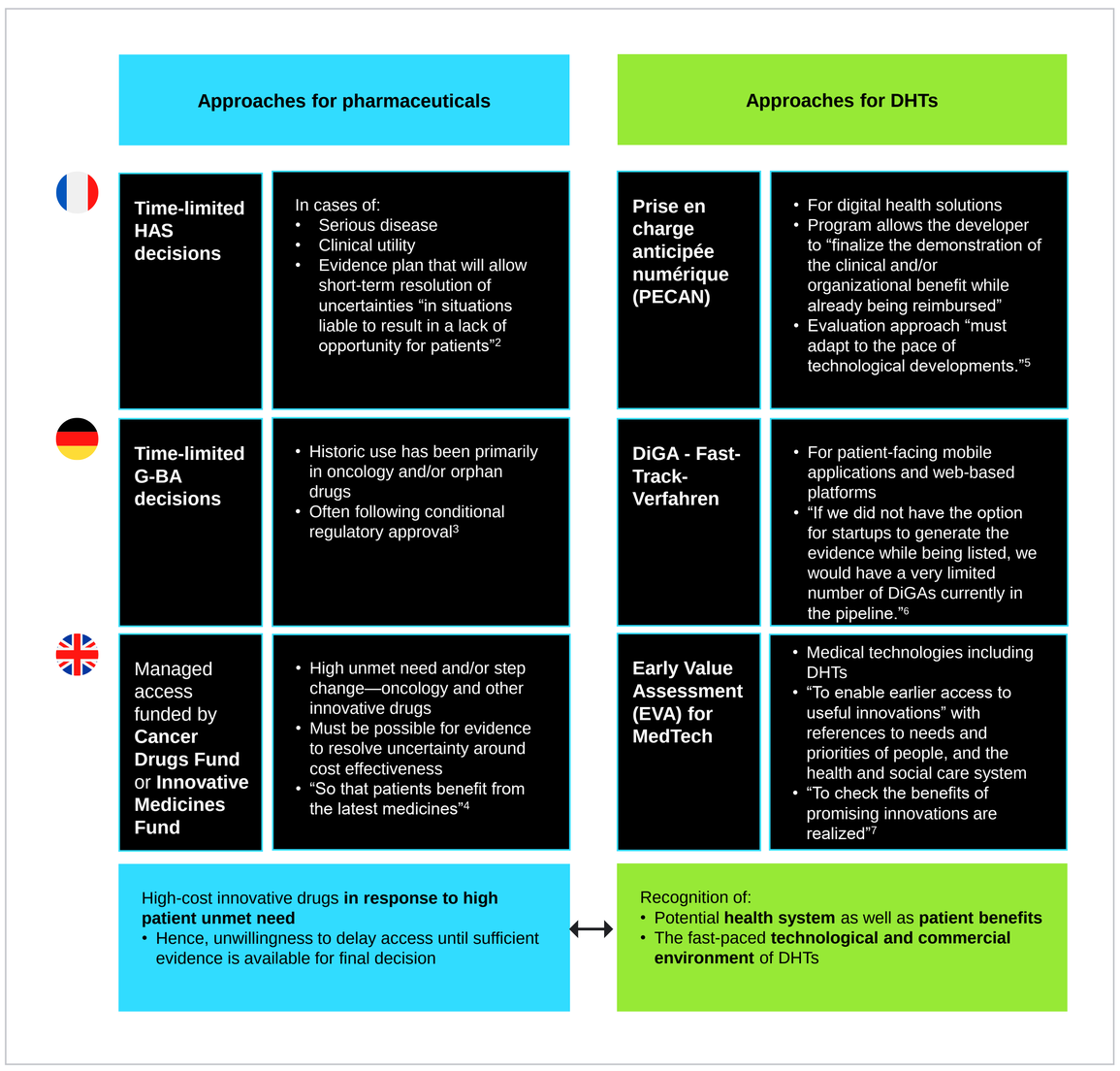
Results

When and why are these approaches used, comparing pharmaceuticals and DHTs?

Published descriptions, commentary, and historic use of these approaches highlight the differing motivation for pharmaceuticals and DHTs in the introduction of these approaches.

- Patient unmet need is fundamentally driving approaches for pharmaceuticals, reflected in their use for innovative therapies in serious and often rare diseases.
- Different drivers are cited for DHT schemes.
  - Allowing data collection for use in the country’s healthcare system.
    - Data may answer evidence gaps with respect to the realities of implementation and allow assessment of real-world benefits that are particularly pertinent.
  - Recognizing the reality of digital health development and the commercial context
    - Smaller developers/start-ups needing speed to market for revenue
    - Speed of innovation so a version can be superseded before longer trials could complete
  - The promise of these therapies in alleviating pressure on health systems to motivate rapid introduction

Figure 2: Scope and rationale for approaches



How do pharmaceuticals and DHTs compare in operationalization and evidence requirements?

This differing motivation is evident in the operationalization and evidence requirements associated with schemes for pharmaceuticals compared with DHTs. However, there is also considerable variation between markets reflecting the differing perspectives and remits of each agency.

Evidence for reassessment

- For pharmaceuticals, clinical trial evidence is usually stipulated as required for later reassessment (typically a later/final trial read-out), with real-world data as supplementary where requested (and usual in the UK).
- Methodological guidelines specific to DHT assessment from France and Germany highlight feasibility challenges for double-blind randomized controlled trial (RCT) study design for these interventions, and state that other study designs may be appropriate. However, in Germany, emphasis on study quality means RCTs are usual.
- In contrast, the UK’s focus on assessing realization of patient/caregiver and health system benefits in a National Health Service (NHS) setting means observational study designs are recommended.

Time for further evidence generation

- The deadline for evidence submission for reassessment of pharmaceuticals is set on an individual basis, usually driven by trial read-out dates (provided within an acceptable time period).
- Schemes for DHTs differ—from six months in France to three years in the UK—which can be interpreted as reflecting the differing stated emphases on data reflecting real-world implementation in their country for the reassessment.

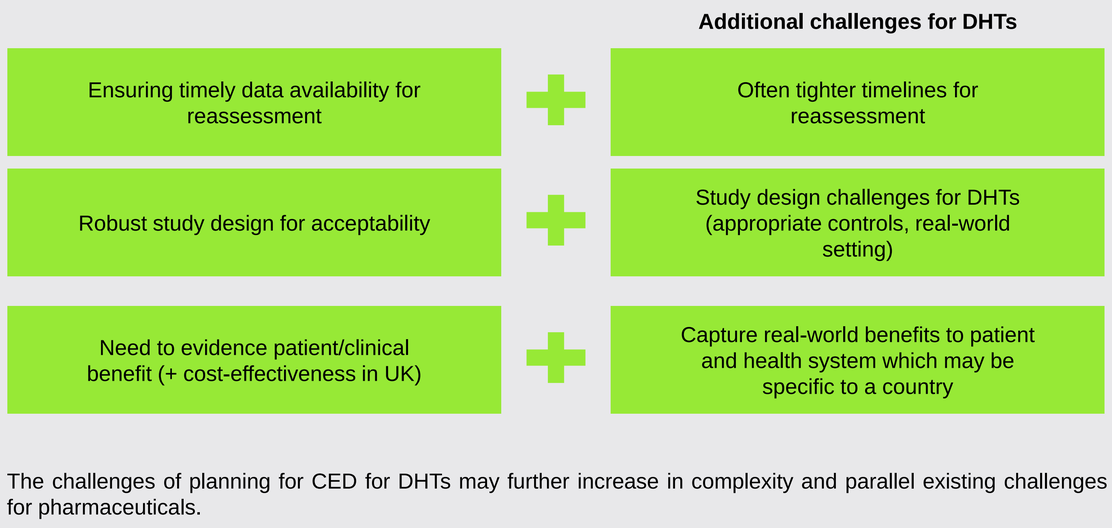
Table 1: How do pharmaceuticals and DHTs compare in operationalization and evidence requirements?

	Pharmaceuticals			DHTs		
	Time-limited HAS decisions[1]	**Time-limited G-BA decisions[2]**	Managed access funded by **Cancer Drugs Fund** or **Innovative Medicines Fund[3,4]**	**Prise en charge anticipée numérique (PECAN)[5]**	**DiGA - Fast-Track-Verfahren[6]**	**Early Value Assessment (EVA) for MedTech[7]**
Evidence needed for reassessment	Evidence of clinical benefit	Evidence of patient-relevant medical benefit	Clinical and other data to demonstrate cost-effectiveness	Evidence of benefit to patient and public health and clinical added value	Evidence of patient relevant medical or system benefit	Evidence of benefit to patients/caregivers and NHS system
Type of evidence to be submitted for reassessment	• Clinical studies (as known at the time of initial assessment) and/or real-world studies • In practice, usually trial evidence in line with regulatory requirements	• Usually clinical trial evidence • Rare instances where registries required	• Usually clinical trial and real-world evidence • Rare instances where only real-world data stipulated	• Double-blind RCT stated as gold standard • Provision for acceptability of other study designs where justified, and with reference to the specific • challenges of medical devices	• Clinical trial or observational study, with consideration of evidence quality and need to reflect German clinical practice • In practice, RCT evidence is usual	• In practice, observational studies of implementation in the NHS • Planning/ collaborations facilitated at the time of EVA
Agreement on data collection	Evidence required stipulated in initial agency decision	Evidence required stipulated in initial agency decision	Managed access includes data collection agreement	No plan required at time of early access assessment	Evaluation concept submitted and stipulated as part of initial decision	Evidence gap analysis and evidence generation plan developed in collaboration with developers and published alongside guidance
Time until reassessment with more evidence	• Dependent on anticipated timing of data read-out • Usually, one to three years	• Dependent on anticipated timing of data read-out • Usually, one to three years • Longer (five years) for registries	Up to five years, usually up to two years for CDF, informed by trial read-out	Dossier submission six months (digital therapeutic) or nine months (remote monitoring device) after initial decision	One year after initial decision, two years granted exceptionally	In practice, usually three years

Conclusions

Experience from pharmaceuticals may provide some guidance in terms of evidence development approaches, but it is clear there are additional challenges in planning evidence generation for DHTs.

Figure 3: Additional challenges for DHTs



The challenges of planning for CED for DHTs may further increase in complexity and parallel existing challenges for pharmaceuticals.

Pan-European assessment of DHTs
It is currently in research, aiming to provide a framework for DHT assessment.
Role of CED has not been determined yet (as is also the case for pan-European health technology assessment).

Increasing data demands for assessment of DHTs
For example, the draft NICE MedTech pathway includes the addition of cost-effectiveness to appraisal criteria to bring in line with pharmaceutical therapies. Relevant data—health resource use, utilities—will need to be considered for evidence generation.

Market shift for DHTs to be brought to a global market by or in collaboration with multinationals
It could bring efficiencies to evidence generation through transferability, or increased speed through multimarket research.
However, challenges to ensure market-specific needs (for specific data and speed of its generation) are still met.

1 York Health Economics Consortium; 2016. https://yhec.co.uk/glossary/coverage-with-evidence-development/
2 Transparency Committee doctrine: Principles of medicinal product assessments and appraisal for reimbursement purposes, HAS, 2020
3 HTA324 Recent Landscape of Drug Re-Assessments by G-BA – What Is the Impact of New Evidence on the Benefit Assessment Outcome? Lach, K. et al. Value in Health, Volume 26, Issue 12, S383
4 Neue Arzneimittel: Studien im Rahmen der anwendungsbegleitenden Datenerhebung, https://www.g-ba.de/studien/abd/
5 Managed Access https://www.nice.org.uk/about/what-we-do/our-programmes/managed-access
6 Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V Ein Leitfaden für Hersteller, Leistungserbringer und Anwender, V3.5
7 Methodology for the clinical development of medical devices, HAS, 2021
8 Early Value Assessment (EVA) for medtech https://www.nice.org.uk/about/what-we-do/eva-for-medtech

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