Assessing the definition of innovation and the outcomes of innovative drugs in England, France, and Italy in Q1 2023

HTA37

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SUMMARY

OBJECTIVES

- To investigate how health technology assessment (HTA) bodies in England, France, and Italy define and measure innovation for different drugs and technologies
- To compare approaches and outcomes related to innovation assessment and reimbursement across the three countries
- To explore the potential impact of reimbursing innovative drugs on patient access

METHODS

- Data was collected from the websites of three HTA bodies during the first quarter of 2023 (January to March): NICE (England), HAS (France), and AIFA (Italy). An extensive review of HTA and innovation reports was carried out to determine which medicines were classified 'innovative' and identify any prevailing trends regarding the types of innovative medicines gaining reimbursement.

FINDINGS

- The granting of innovative status was often based on whether drugs represented a significant advancement in treatment or addressed conditions with substantial unmet needs. Most innovative products were for oncology treatments.
- This study highlights the need for consistent international standards in defining and evaluating innovation for fair recognition of innovative medicines.

BACKGROUND & AIMS

- An ‘innovative’ designation is significant for both pharmaceutical companies and HTA bodies [1]. Recognising a medicine as innovative brings potential rewards, such as compensation for the manufacturer and accelerated approval processes [2]. However, the definition and interpretation of innovation varies across jurisdictions, which can lead to discrepancies in the recognition and reward of innovative medicines [3].
- The objective of this research is to examine how HTA bodies in three countries, England (National Institute for Health and Care Excellence; NICE), France (Haute Autorité de Santé; HAS), and Italy (Agenzia Italiana del Farmaco; AIFA), define, measure, and subsequently assess innovation.
- It also seeks to compare the definitions of innovation, ask whether innovative status leads to reimbursement in these countries, and determine what impact this may have for patients and the healthcare system.

METHODS

- Data was collected from the websites of three HTA bodies during the first quarter of 2023 (January to March): NICE (England), HAS (France), and AIFA (Italy) [4-6].
- An extensive review of HTA and innovation reports was carried out to determine which drugs were classified as 'innovative' and identify any prevailing trends regarding the types of innovative medicines gaining reimbursement.

Table 1. Recognition of innovative drugs by NICE, HAS, and AIFA

HTA body	Number of appraisals	Number of innovative drugs	% of drugs deemed ‘innovative’
NICE	27	9	33.3%
HAS	36	16	44.4%
AIFA	14	2	14.3%

RESULTS

- Of a total of 77 publicly available appraisals, 27 (35.1%) technologies were recognised as 'innovative' by either NICE (9/27 [33.3%]), HAS (16/36 [44.4%]), or AIFA (2/14 [14.3%]) (**Table 1**).
- Only 1 innovative drug was denied, while 26 received confirmed, renewed, or accepted reimbursement status.
- A significant proportion of assessments classified as innovative by HAS were orphan drugs (9/16 [56.3%]), but NICE and AIFA both only classified one orphan drug as innovative.
- A majority of innovative products were related to oncology treatment (18/27 [66.7%]) (**Figure 1**).
- The most common criteria for recognising innovation was that a drug addressed unmet medical needs (16/27 [59%]), introduced a new treatment modality (14/27 [52%]), or had a well-defined development plan (13/27 [48%]) (**Figure 2**).
- A significant majority of technologies submitted to HAS (14/16 [87.5%]) underwent evaluation through the early access authorisation (AAP) programme.
- These findings should be interpreted with care, particularly considering the higher prevalence of innovative drugs in France.

Figure 1. Frequency of innovative technologies according to disease area

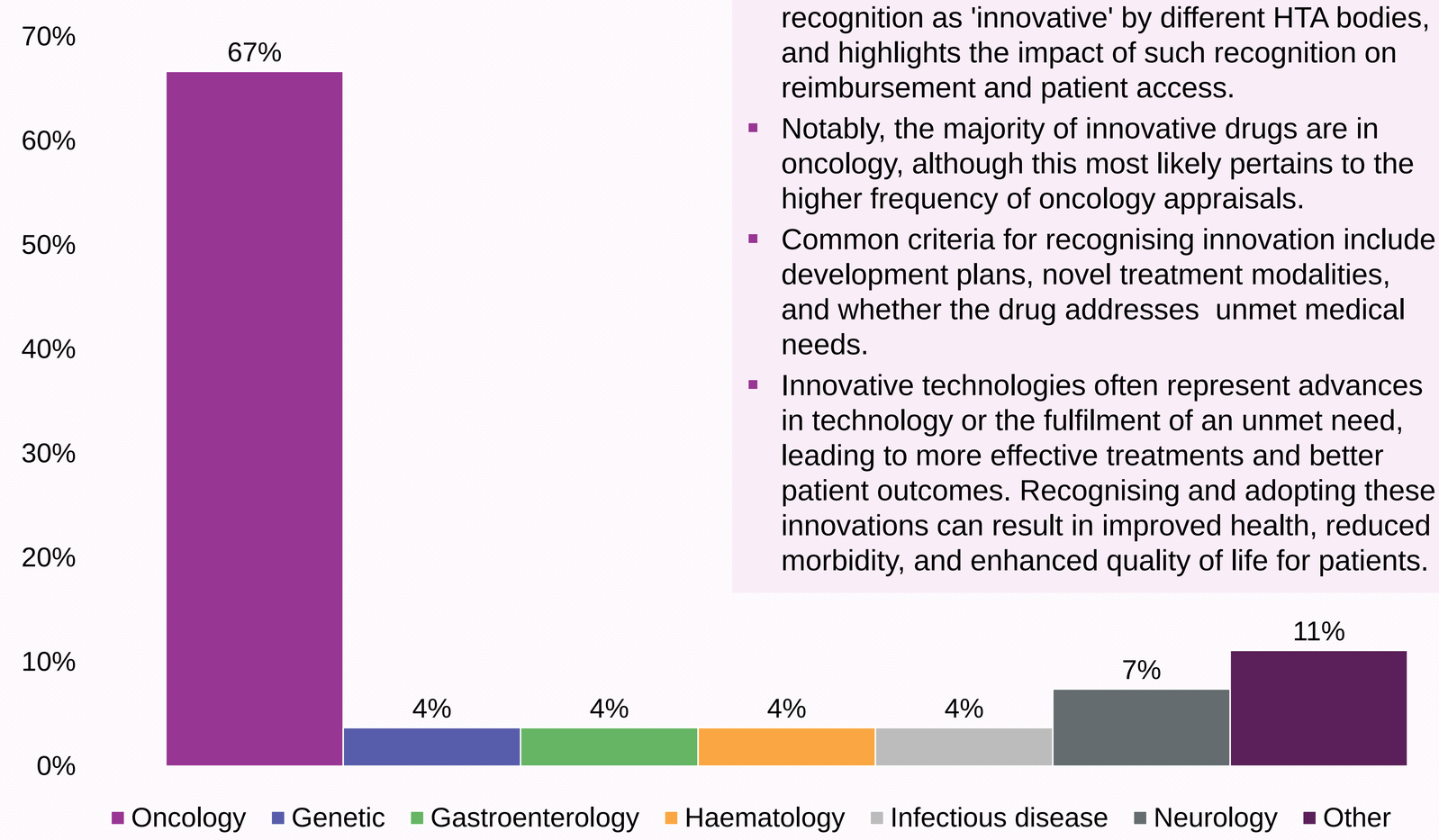

Figure 2. Most common criteria for measuring drug innovation across NICE, HAS and AIFA

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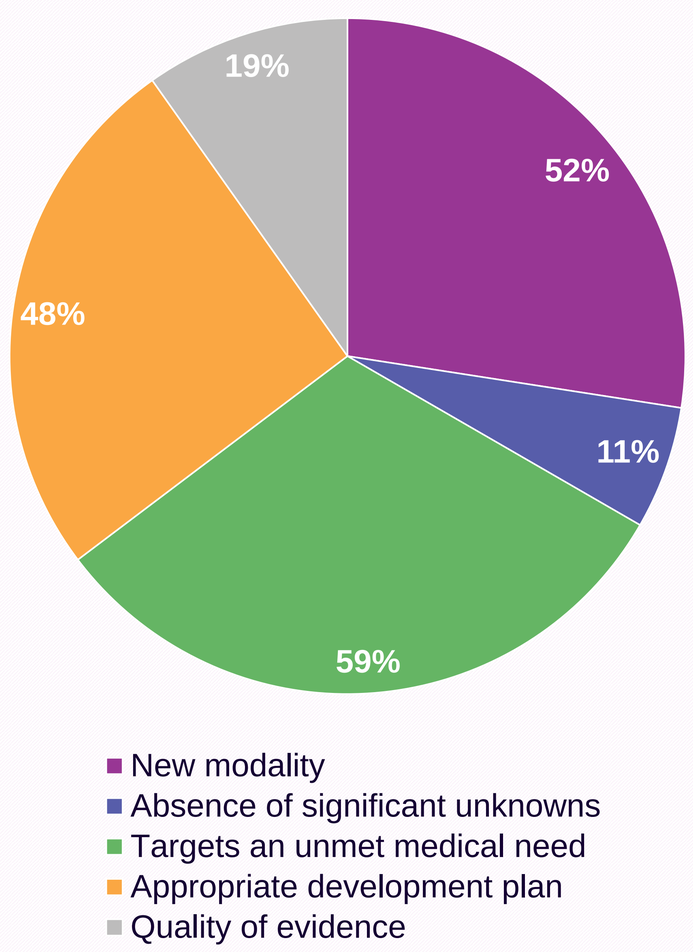

CONCLUSIONS

- This study reveals varying rates of technology recognition as 'innovative' by different HTA bodies, and highlights the impact of such recognition on reimbursement and patient access.
- Notably, the majority of innovative drugs are in oncology, although this most likely pertains to the higher frequency of oncology appraisals.
- Common criteria for recognising innovation include development plans, novel treatment modalities, and whether the drug addresses unmet medical needs.
- Innovative technologies often represent advances in technology or the fulfilment of an unmet need, leading to more effective treatments and better patient outcomes. Recognising and adopting these innovations can result in improved health, reduced morbidity, and enhanced quality of life for patients.

References

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