Availability and Coverage of New Drugs in 6 High-Income Countries with Health Technology Assessment Bodies

Olivier J. Wouters, PhD[1]; Huseyin Naci, PhD[1]; Irene Papanicolas, PhD[1,2*]

[1] Department of Health Policy, London School of Economics and Political Science, London, United Kingdom
[2] Department of Health Services, Policy and Practice, Brown School of Public Health, Providence, Rhode Island

Olivier J Wouters, PhD
Assistant Professor of Health Policy
O.J.Wouters@lse.ac.uk

Huseyin Naci, PhD
Associate Professor of Health Policy
H.Naci@lse.ac.uk

Irene Papanicolas, PhD
Professor of Health Services, Policy and Practice
Brown School of Public Health
121 South Main Street
Providence, Rhode Island 02903, USA
Irene_Papanicolas@brown.edu
*Corresponding author

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Most rich countries, with the US a notable exception, rely on health technology assessment (HTA) to ensure the prices paid for new medicines reflect the value they provide.[1,2] HTA bodies assess the relative clinical or economic impact of new drugs to guide pricing and coverage decisions. These assessments usually occur after marketing authorization by a medicines regulatory body (e.g., European Medicines Agency), and patients may have little or no access to therapies that are not assessed favorably by HTA bodies.

As Medicare considers using comparative effectiveness data to negotiate drug prices, examining HTA decisions abroad can inform US policymakers about how HTA affects the availability and coverage of new medicines.[3] We analyzed HTA outcomes and review times in 6 countries (Australia, Canada, England, France, Germany, and Switzerland) for all novel therapeutic agents approved by the US Food and Drug Administration (FDA) from 2014 to 2018.

METHODS

We identified all new drugs approved by the FDA from 2014 to 2018 using the Drugs@FDA database. We classified drugs according to orphan status, therapeutic area (oncology vs non-oncology), therapeutic value (high vs. low), and inclusion in the FDA accelerated approval pathway. High-value drugs were those judged to provide moderate or greater added therapeutic benefit by authorities in Canada, France, or Germany; all other drugs were categorized as low-value (**eTable 1**).[4,5]

We determined whether and when the FDA-approved products were authorized by each medicines regulatory body. For drugs reviewed by HTA bodies, we recorded the HTA recommendation, date of first submission, and date of decision through August 2022 (**eTable 2**). Recommendations to cover a product in full (i.e., within its licensed indication) or for a subgroup of patients (i.e., restricted coverage) were classified as positive.

For each country, we reported the percentage of drugs that received positive HTA decisions and median duration of HTA reviews. Kruskal-Wallis tests were used to examine whether differences in durations across countries were statistically significant.

RESULTS

The US FDA authorized 213 new drugs from 2014 to 2018 (**Table 1**). Foreign regulators authorized between 63% (134/213; Australia) and 82% (174/213; England, France, and Germany) of these products. Of the drugs authorized in each country, between 63% (109/174; Germany) and 96% (129/134; Australia) were reviewed by HTA bodies. Most drugs reviewed by HTA bodies were assessed favorably, ranging from 84% (98/116; England) to 95% (104/109; Switzerland) (**Figure 1**). Over 90% of high-value drugs were assessed favorably in all countries.

HTA review times ranged from a median of 5.6 months in Germany to 10.8 months in England (**Figure 1**; no times were available for Australia or Switzerland). For most drug categories, there were statistically significant differences between countries in HTA review

times, with Canada and Germany always having the shortest median times and England and France the longest (**Figure 1**).

DISCUSSION

Foreign regulators authorized fewer drugs than the FDA, but most authorized drugs were assessed favorably by national HTA bodies. This suggests that HTA does not have a meaningful negative impact on drug availability, especially for those products that are judged to offer added therapeutic benefits over existing alternatives. We found variability in the duration of HTA, ranging from a median of 6 to 11 months, likely reflecting different HTA designs and procedures across countries.

Our study was limited in that we did not distinguish between HTA recommendations to cover a product in full or with restrictions, and some of the FDA-approved drugs may not have been reviewed by foreign authorities by August 2022. Our results support further use of HTA as a mechanism for determining the value of new drugs, without considerably delaying or limiting access to new drugs.

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TABLES AND FIGURES

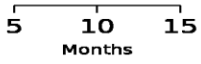
Table 1. Characteristics of the 213 novel therapeutics approved by the US Food and Drug Administration from 2014 to 2018.

Characteristics	No. (%)
Therapeutic area	
Cancer	51 (24)
Non-cancer	162 (76)
Orphan status	
Orphan	98 (46)
Non-orphan	115 (54)
Added therapeutic value	
High	54 (25)
Low	159 (75)
Approval pathway	
Accelerated	30 (14)
Non-accelerated	183 (86)
Year of approval	
2014	41 (19)
2015	45 (21)
2016	22 (10)
2017	46 (22)
2018	59 (28)
Approved by national regulator	
Australia	134 (63)
Canada	152 (71)
England	174 (82)
France	174 (82)
Germany	174 (82)
Switzerland	144 (68)

Figure 1. Outcome and duration of health technology assessments, by country.

	% drugs recommended for coverage [a]	HTA review time [b] Median (months)	P Value
All drugs			<0.001
Australia	91% (117 / 129)		
Canada	85% (105 / 124)	6.5	
France	90% (123 / 136)	7.5	
Germany	94% (127 / 135)	5.6	
Switzerland	95% (104 / 109)		
England	84% (98 / 116)	10.8	
Therapeutic area			
Cancer			<0.001
Australia	86% (36 / 42)		
Canada	84% (36 / 43)	6.7	
France	90% (37 / 41)	7.3	
Germany	98% (45 / 46)	5.6	
Switzerland	100% (36 / 36)		
England	84% (37 / 44)	10.8	
Non-cancer			<0.001
Australia	93% (81 / 87)		
Canada	84% (68 / 81)	6.5	
France	91% (86 / 95)	8.0	
Germany	92% (82 / 89)	5.6	
Switzerland	93% (68 / 73)		
England	85% (61 / 72)	10.9	
Orphan status			
Orphan			<0.001
Australia	84% (49 / 58)		
Canada	84% (51 / 61)	6.9	
France	91% (59 / 65)	7.5	
Germany	96% (65 / 68)	5.6	
Switzerland	98% (44 / 45)		
England	80% (47 / 59)	11.8	
Non-orphan			<0.001
Australia	96% (68 / 71)		
Canada	84% (53 / 63)	6.3	
France	90% (64 / 71)	7.5	
Germany	93% (62 / 67)	5.6	
Switzerland	94% (60 / 64)		
England	89% (51 / 57)	9.6	

Therapeutic value			
High			<0.001
Australia	91% (41 / 45)		
Canada	93% (43 / 46)	6.6	
France	96% (44 / 46)	6.7	
Germany	94% (46 / 49)	5.6	
Switzerland	95% (38 / 40)		
England	91% (41 / 45)	11.2	
Low			<0.001
Australia	90% (76 / 84)		
Canada	78% (61 / 78)	6.5	
France	88% (79 / 90)	8.0	
Germany	94% (81 / 86)	5.6	
Switzerland	96% (66 / 69)		
England	80% (57 / 71)	10.8	
Approval pathway			
Accelerated			<0.001
Australia	91% (20 / 22)		
Canada	90% (19 / 21)	7.0	
France	83% (20 / 24)	7.5	
Germany	96% (23 / 24)	5.6	
Switzerland	100% (20 / 20)		
England	92% (22 / 24)	10.8	
Non-accelerated			<0.001
Australia	91% (97 / 107)		
Canada	83% (85 / 103)	6.5	
France	92% (103 / 112)	7.5	
Germany	94% (104 / 111)	5.6	
Switzerland	94% (84 / 89)		
England	83% (76 / 92)	10.8	



HTA indicates health technology assessment.

[a] Denominators do not correspond to the total number of drugs authorized in each country, since not all drugs were reviewed by health technology assessment bodies.

[b] Median review times were based on data for drugs assessed favorably by health technology assessment bodies; review times were virtually unchanged when calculated based on data for drugs assessed both favorably and unfavorably (using time until positive decision for drugs assessed favorably, and time until last negative decision for drugs assessed unfavorably). No data on HTA review times were available for Australia or Switzerland.