

Estimated cost-based generic prices for molnupiravir v. 2

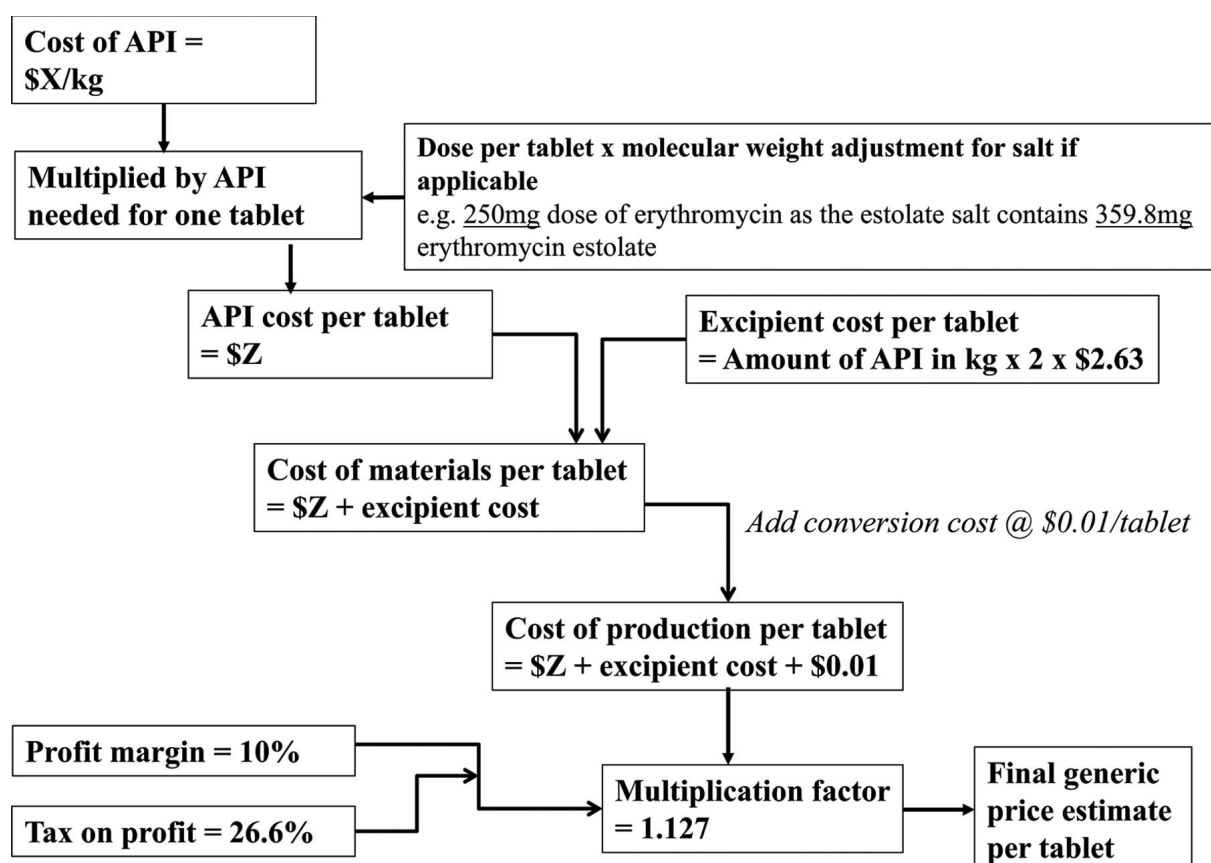
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Methodology

Methods followed are those reported in Hill, Barber, and Gotham 2018.^A

A figure outlining the estimation formula for an solid oral dosage form medicine is copied below.



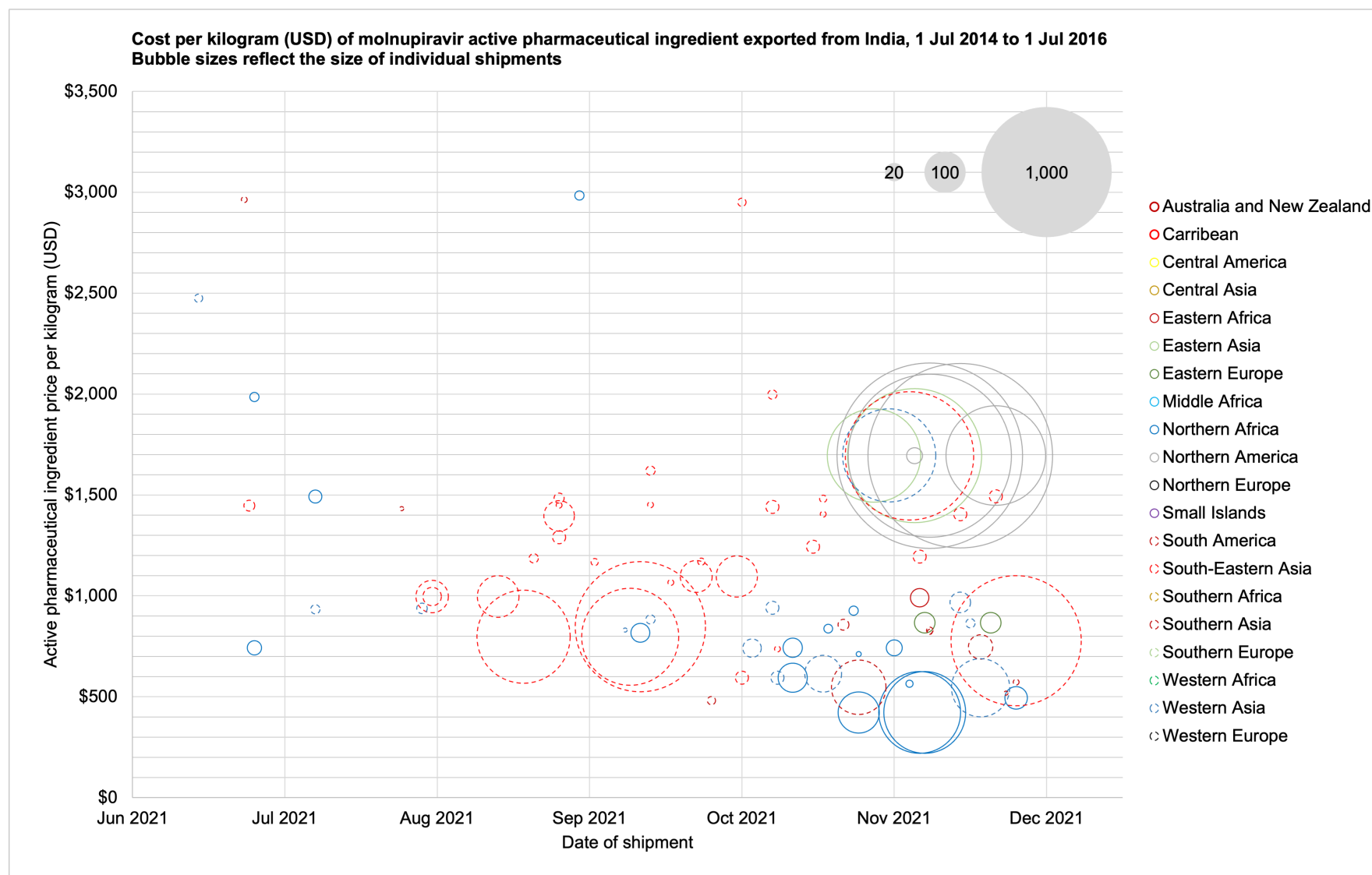
In order to identify shipments of API, a proprietary export/import database (Panjiva) was searched for the word 'molnupiravir' in the shipment description, for dates between 2016 and Nov 30, 2021. For this analysis, shipments exported from India were included and analyzed

Results

After data cleaning,^B 94 viable lines of data from India (i.e. individual shipments) were identified, amounting to 28,393 kg of API.

^A Hill AM, Barber MJ, Gotham D. Estimated costs of production and potential prices for the WHO Essential Medicines List. *BMJ Global Health* 2018; **3**: e000571. ;
Gotham D, Barber MJ, Hill AM. Estimation of cost-based prices for injectable medicines in the WHO Essential Medicines List. *BMJ Open* 2019; **9**: e027780.

^B See Appendix of Hill et al. 2018 for details on approach to data cleaning, available here:
<https://gh.bmj.com/content/bmjgh/3/1/e000571/DC1/embed/inline-supplementary-material-1.pdf?download=true>



These data suggest an average API market price of US\$1,515/kg, down by about 30% since the earlier version of this analysis was published in 1 October when the average price was US\$2,162/kg.

We assumed a treatment regimen of 800 mg molnupiravir twice daily 5 days (10 doses total), as in the Phase 3 MOVE-OUT trial.^C

Assuming current API market prices:

Cost of production – 200mg molnupiravir capsule	\$0.31
Cost of production – treatment regimen	\$12.56
Estimated generic price per capsule – (cost of production + 10% profit margin, and 26.6% tax on profit)	\$0.34
Estimated generic price per regimen– (cost of production + 10% profit margin, and 26.6% tax on profit)	\$14.16

Analysis

The total amount of API represented by the shipments identified in this analysis is substantial (overall 28,393 kg, sufficient for almost 18 million patient treatments^D).

API can be produced according to different quality specifications, for example USP or Ph. Eur. The average price of API shipped to the US ranged between US\$1499/kg and US\$1696/kg, implying that API can be produced in line with US pharmacopeial standards for costs similar to the estimated global average market price (US\$1,515).

The United States Food & Drug Administration narrowly approved an emergency use authorization (EUA) for molnupiravir, authorizing use for “the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.”^E

Merck announced on 27 April 2021 that they had entered into non-exclusive voluntary licensing agreements for molnupiravir with five Indian generics manufacturers (Cipla Limited, Dr. Reddy’s Laboratories Limited, Emcure Pharmaceuticals Limited, Hetero Labs Limited and Sun Pharmaceutical Industries Limited).

The US government has ordered 1.7 million treatment courses, at about \$700 per patient.^F The UK has ordered 480,00 courses, at an unknown cost.^G France ordered 50,000 but has since cancelled the order, citing concerns about efficacy.^H

The US price per course (\$700) is 49x the estimated cost per regimen (\$14.16).

^C <https://clinicaltrials.gov/ct2/show/NCT04575597>

^D Assuming 5950 mg fomepizole over 72 hours of treatment for a 70kg patient, based on regimen described in Brent et al. N Engl J Med 2001; 344:424-429 DOI: 10.1056/NEJM200102083440605

^E <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

^F <https://www.nytimes.com/live/2021/09/30/world/covid-delta-variant-vaccines#merck-antiviral-pill-covid>

^G <https://www.bbc.co.uk/news/health-59163899>

^H https://www.has-sante.fr/jcms/p_3304161/fr/covid-19-deux-nouveaux-traitements-evalues-par-la-has