

Prices versus costs of medicines: the need for transparency

Dr Andrew Hill

**Department of Translational Medicine,
University of Liverpool, UK**

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How cheaply can medicines be produced?

<http://gh.bmj.com/content/3/1/e000571>

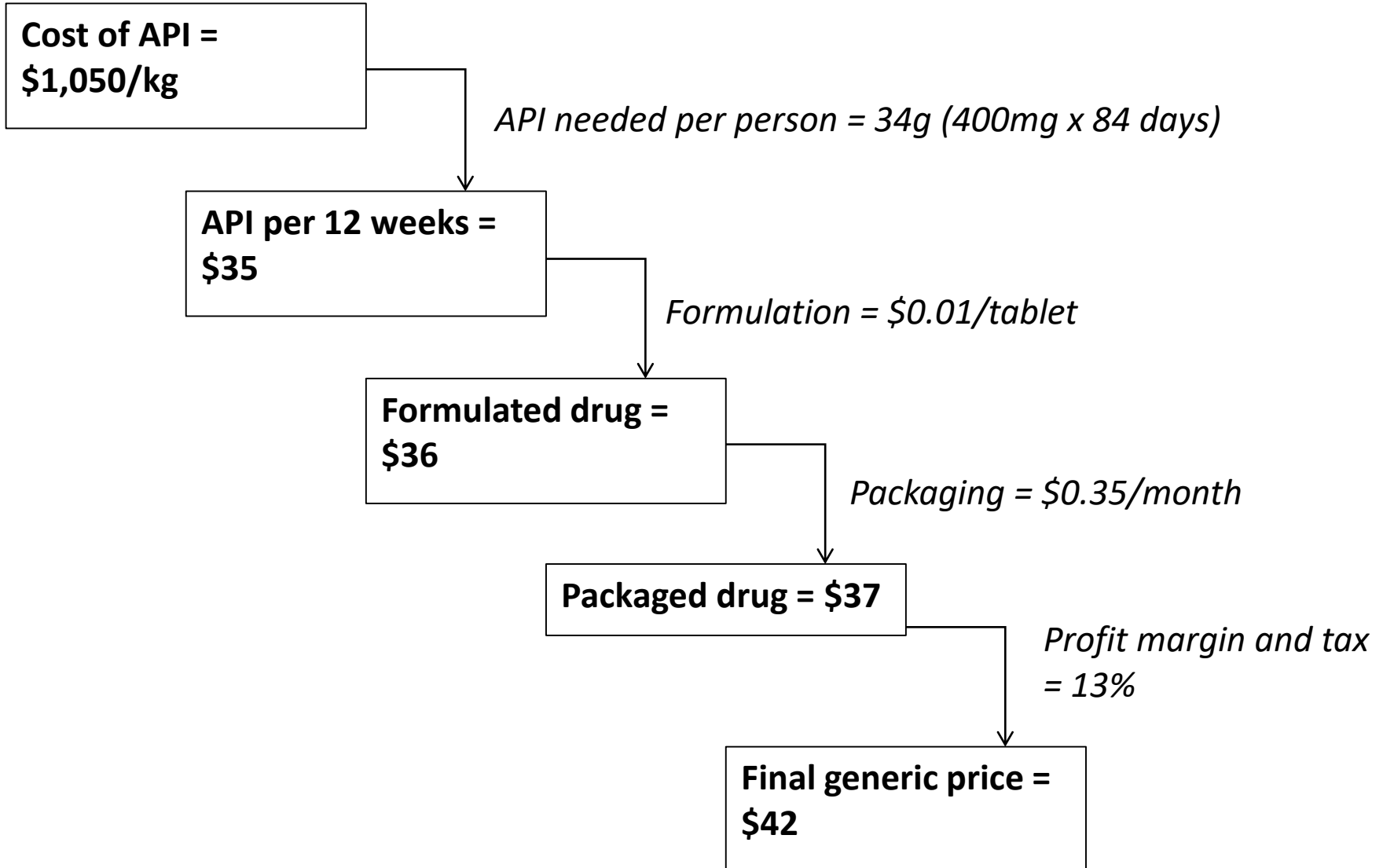
Active Pharmaceutical Ingredient



Raw drug substance

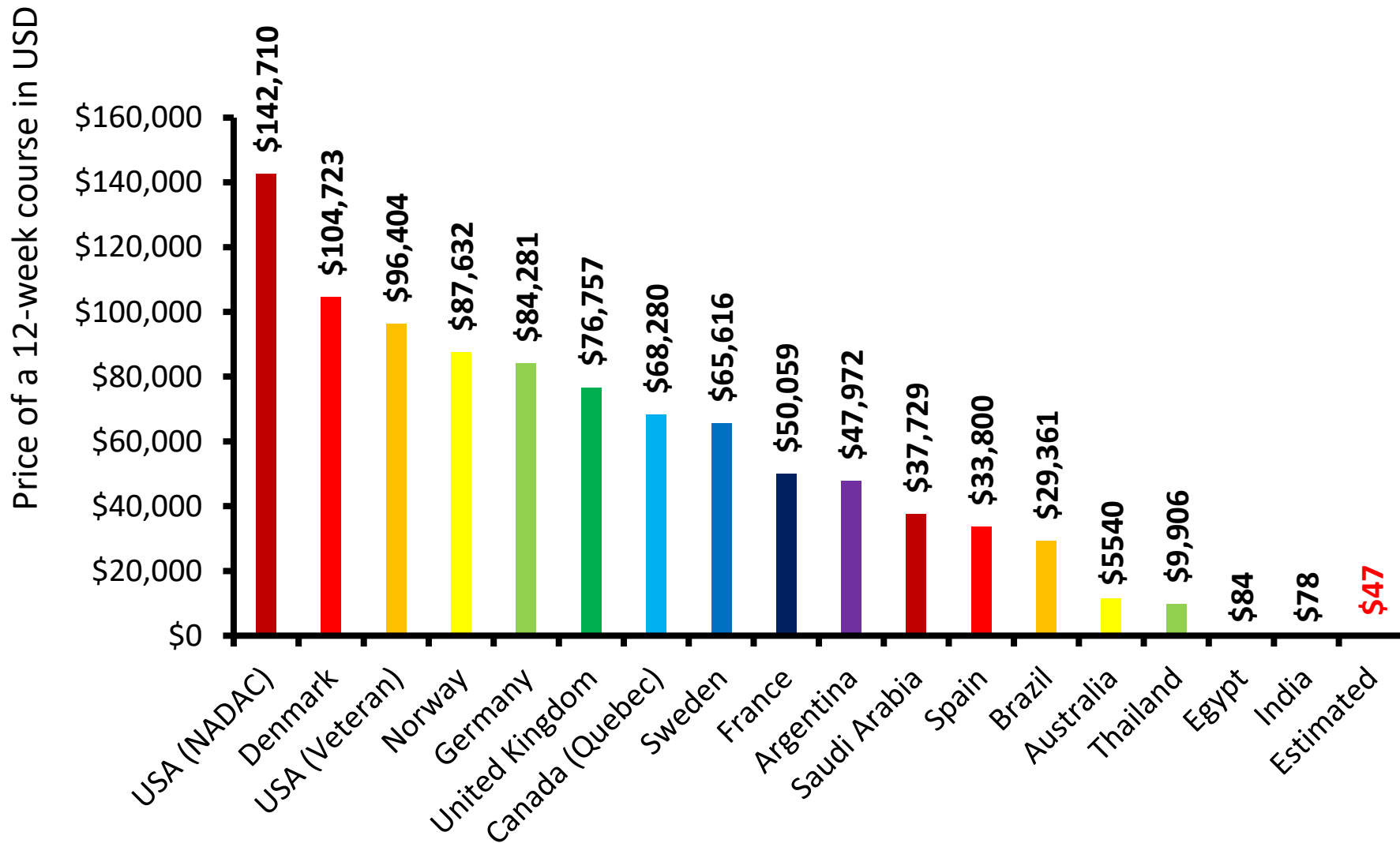
Database www.indiainfodrive.com shows exports of API from India to other countries, with costs per kilogram of API, for many drugs

Cost-based generic price of sofosbuvir (12 weeks)



Prices of drugs to cure Hepatitis C by country

Sofosbuvir plus daclatasvir



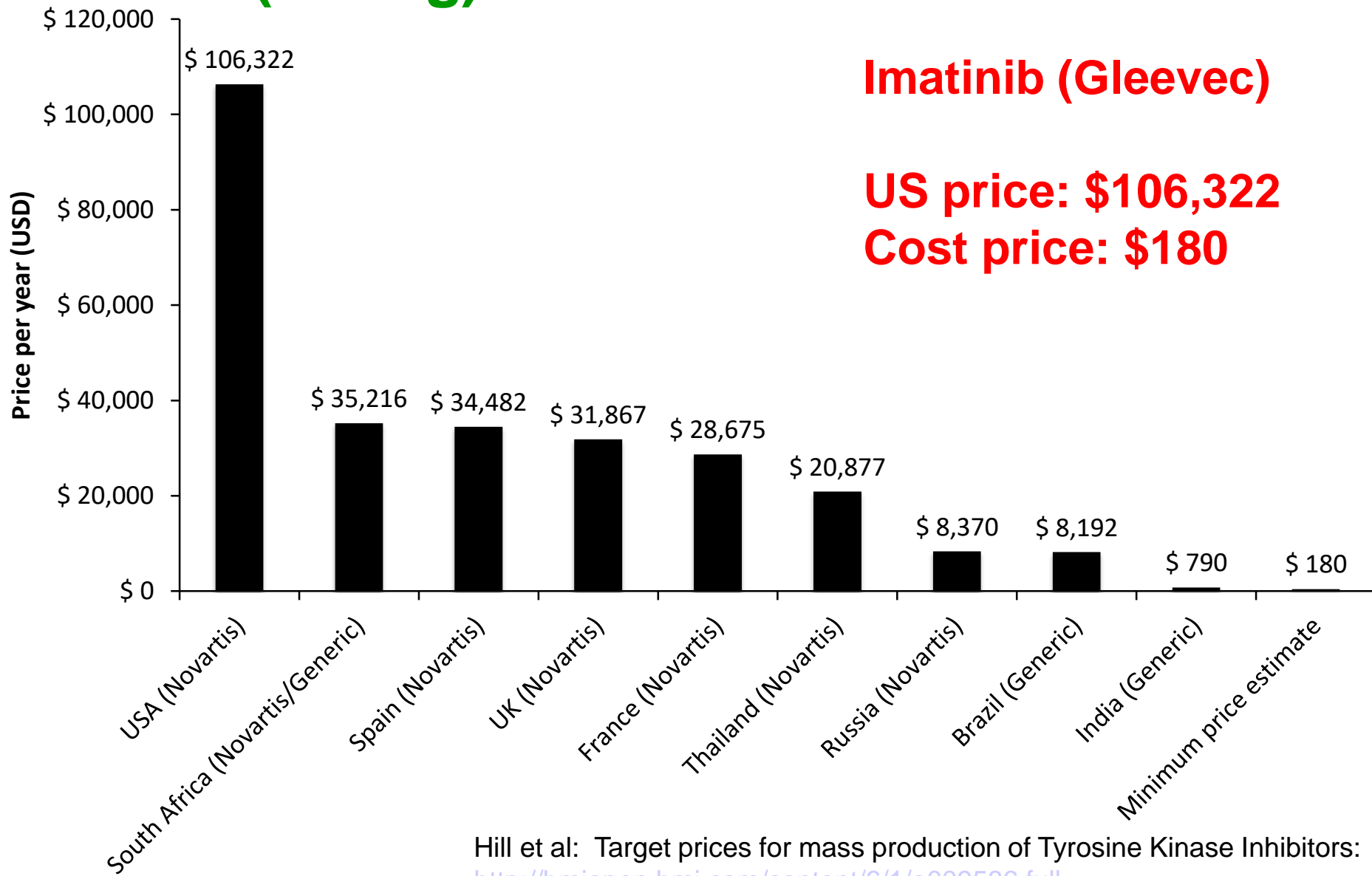
1 year's supply of pomalidomide (Imnovid): 1.0 g
To treat multiple myeloma



Cost in the UK (NHS): £115,809 per year

Cost of production: £100 per year

Lowest available price for Imatinib (400mg) in selected countries



Hill et al: Target prices for mass production of Tyrosine Kinase Inhibitors:

<http://bmjopen.bmj.com/content/6/1/e009586.full>

Costs versus prices of medicines

There are many cases of massive overcharging – drugs sold for 100 to 1000 times more than they cost to make. Some of these drugs are generics.

Almost all medicines are very cheap to manufacture. Prices should be checked by country, to check on overcharging.

Lists of drug costs and prices should be updated every two years, in parallel with updates of the EML. Expand analysis to include new drugs and more countries.

<http://gh.bmj.com/content/3/1/e000571>

Widespread access to generics

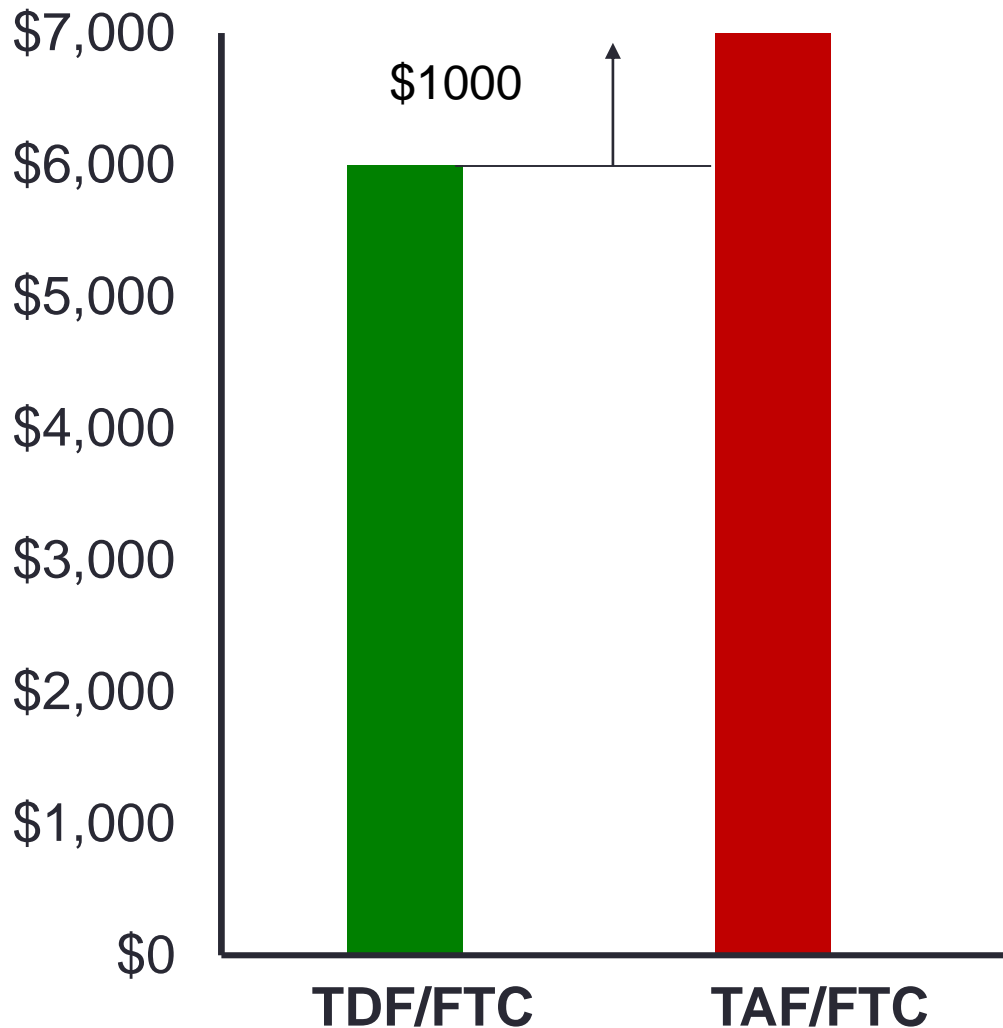
When patents have expired, drugs should be available worldwide, at close to the cost of production

However, few national health services know these costs

Lower costs for generics could drive down patented drug prices in the same therapeutic area

Health and Finance Ministers would be amazed at the savings they could make, or the extra people they could treat, if they could achieve these low prices for drugs.

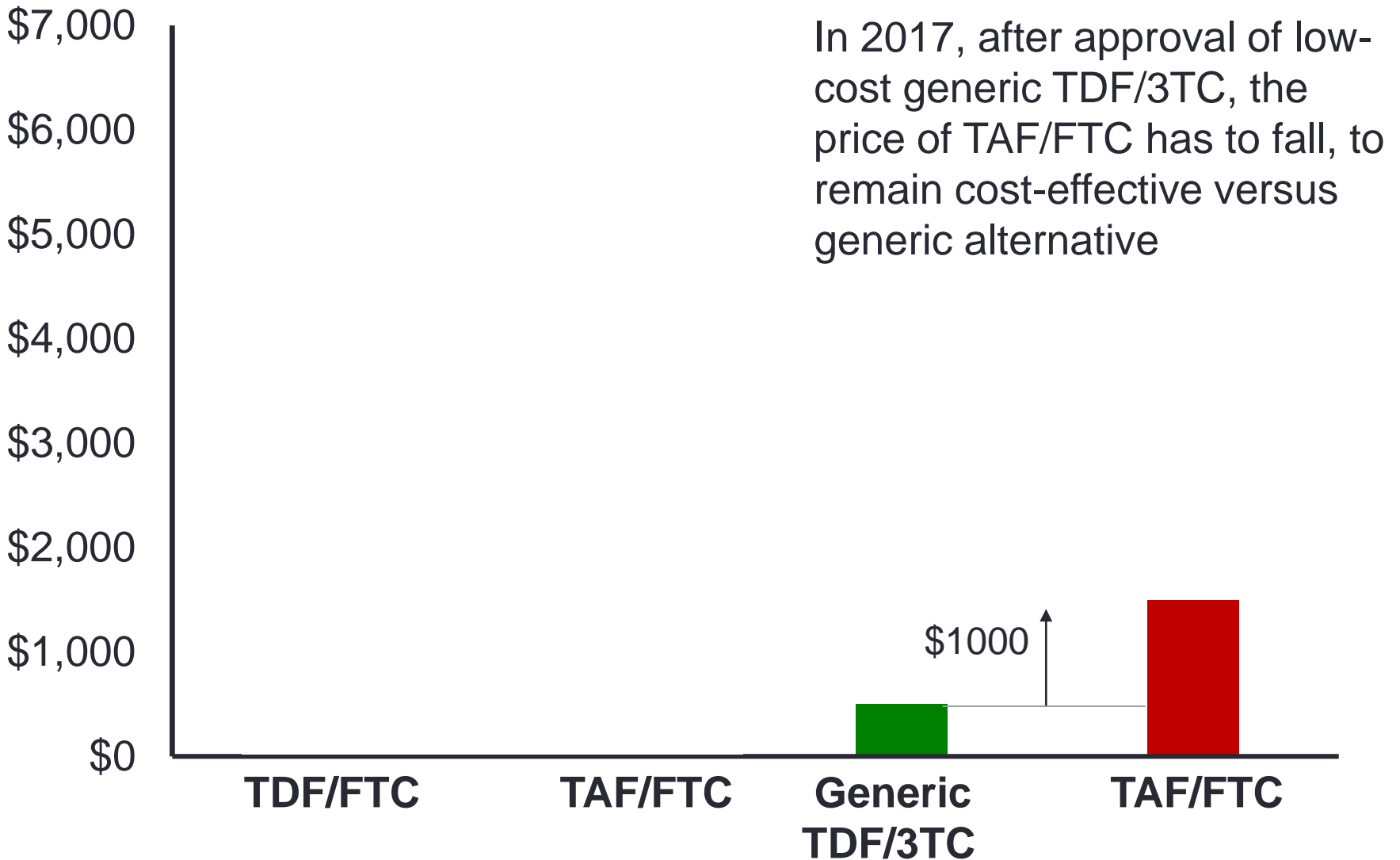
Value of patented drugs before generics have been approved



Pharmaceutical company negotiates additional value of new drug versus price of current branded version

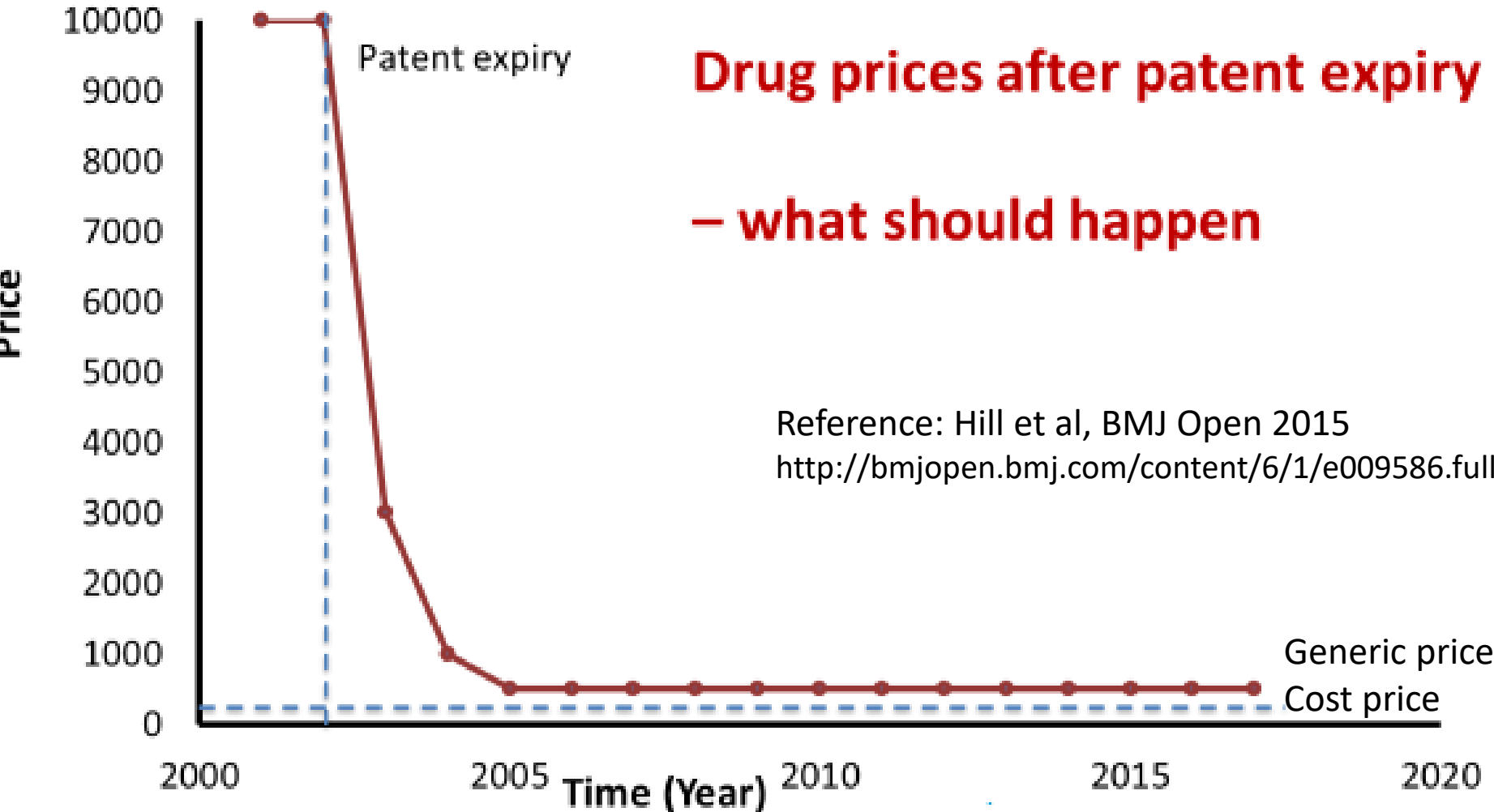
For example:
Tenofovir alafenamide (TAF)
versus
Tenofovir disoproxil fumarate (TDF)

Value of patented drugs after generics have been approved

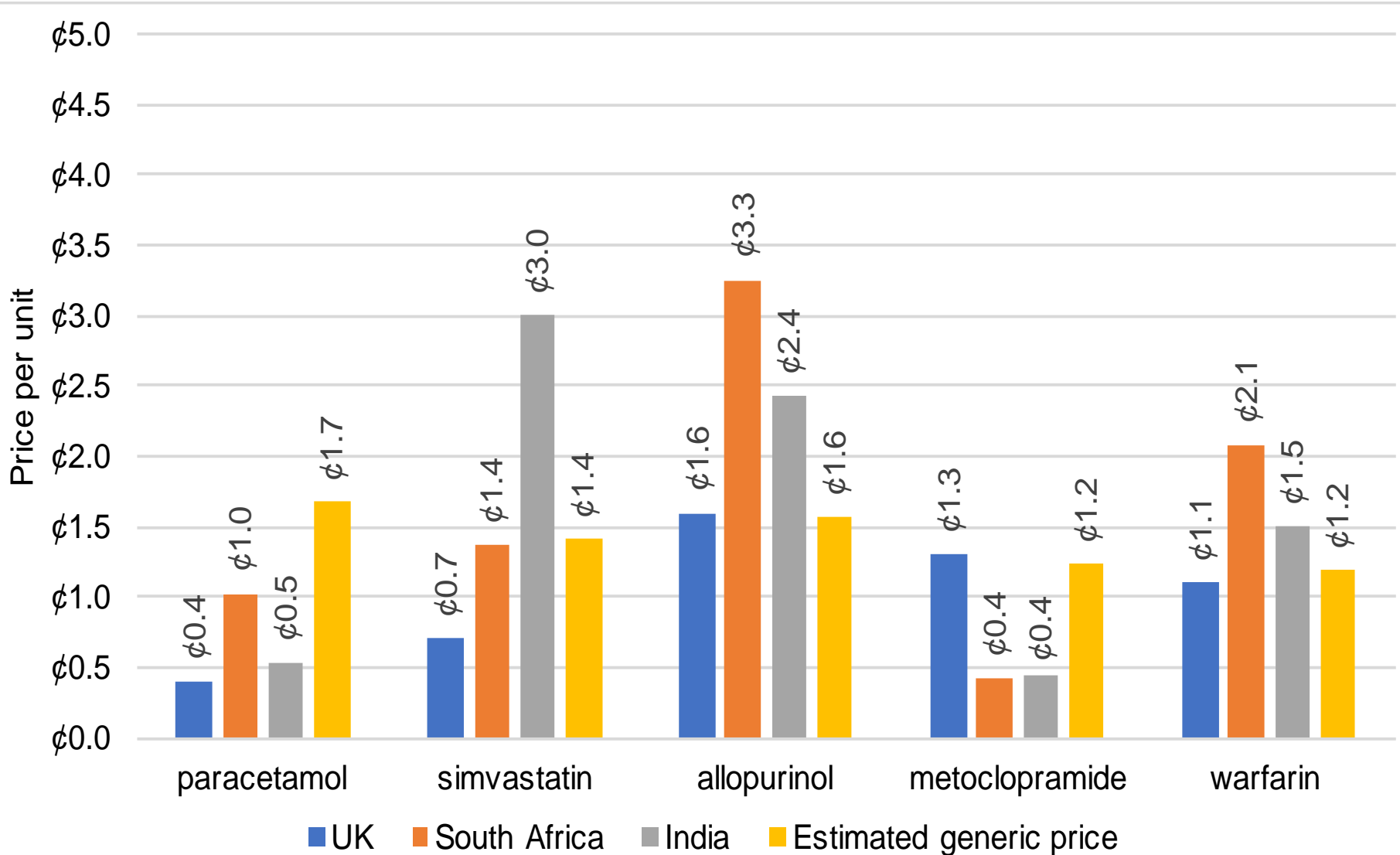


Drug prices after patent expiry

– what should happen



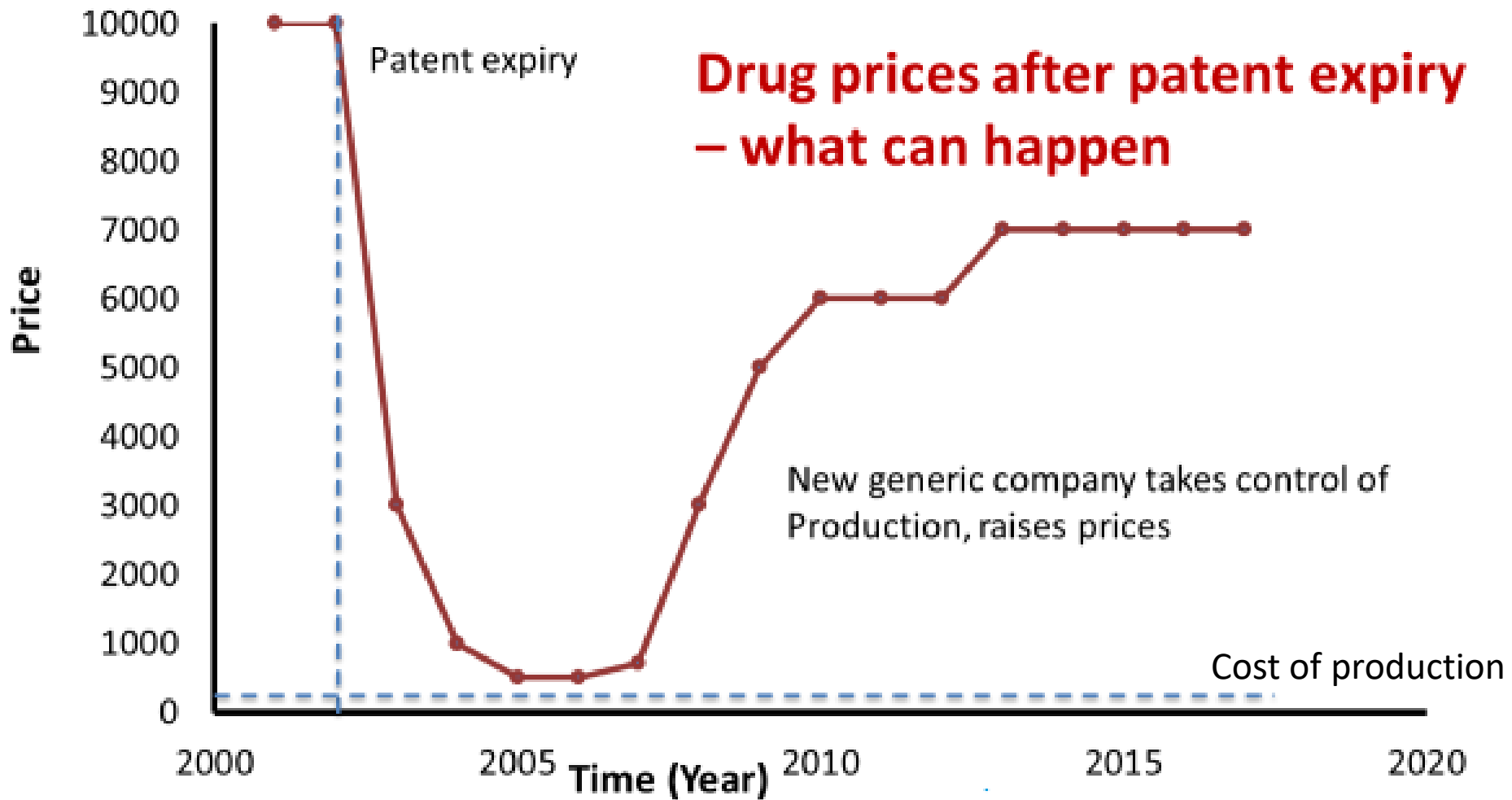
Generics can be cheap worldwide



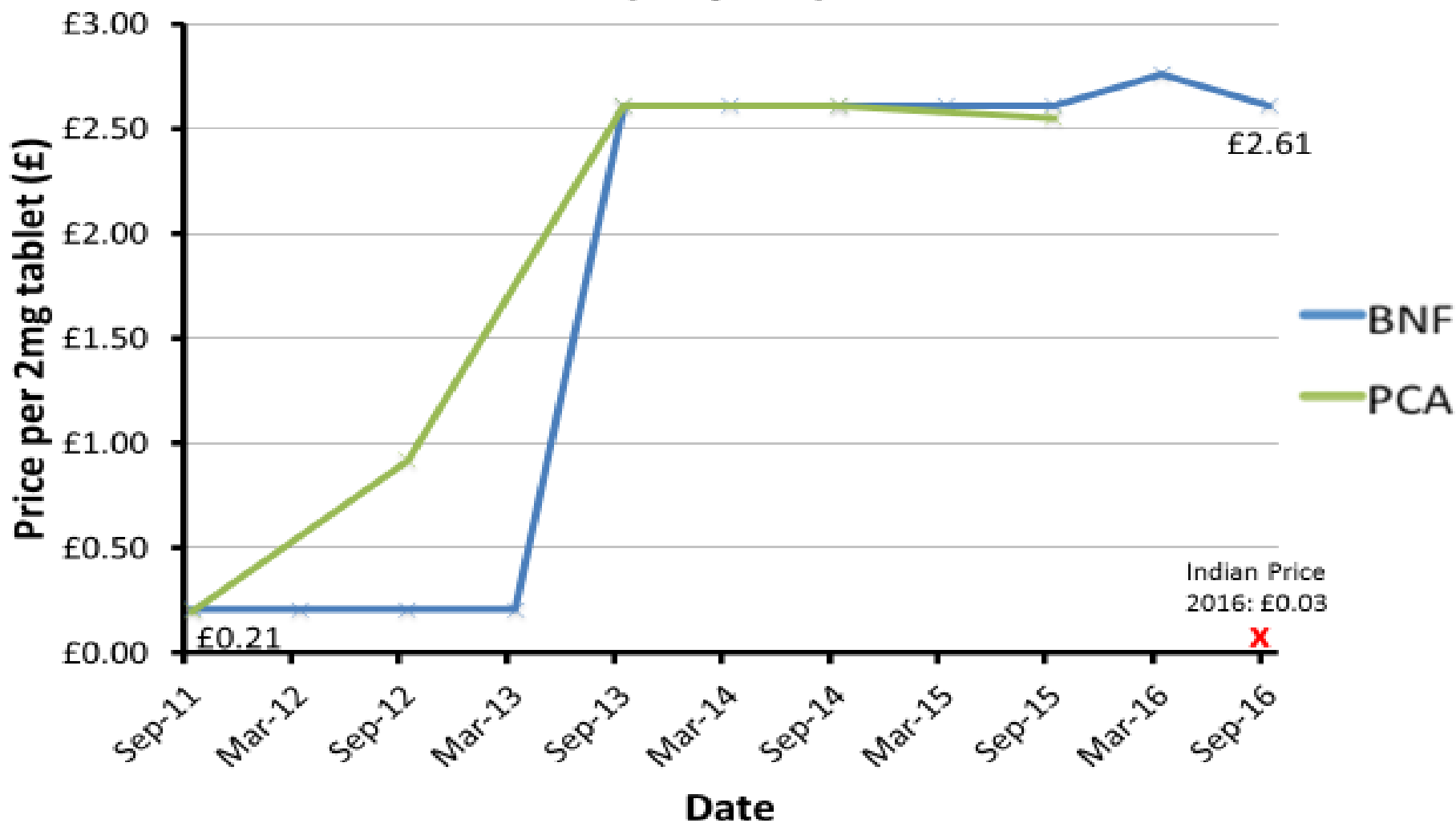
Prices and costs of drugs to treat **HIV**, **HBV**, **HCV** and **TB**

DRUG	USA PRICE	GLOBAL LOWEST PRICE	ESTIMATED COST	PATENT EXPIRY (US)
TDF/3TC/EFV	\$28,204*	\$107	\$82	Generic
TDF/FTC	\$17,258	\$67	\$54	Generic
Entecavir	\$5,915	\$409	\$36	Generic
SOF+LDV	\$91,207	\$307	\$79	2028-2032
SOF+DCV	\$142,710	\$78	\$47	2028-2031
TB: RHZE	\$945	\$27	\$38	Generic

*for TDF/FTC/EFV; HCV – per 12-week course, TB – per 6 month course, HIV and HBV – per year. Patent expiries from US FDA Orange Book (oral dosing)



Busulfan 2mg tablets for CML (Aspen)



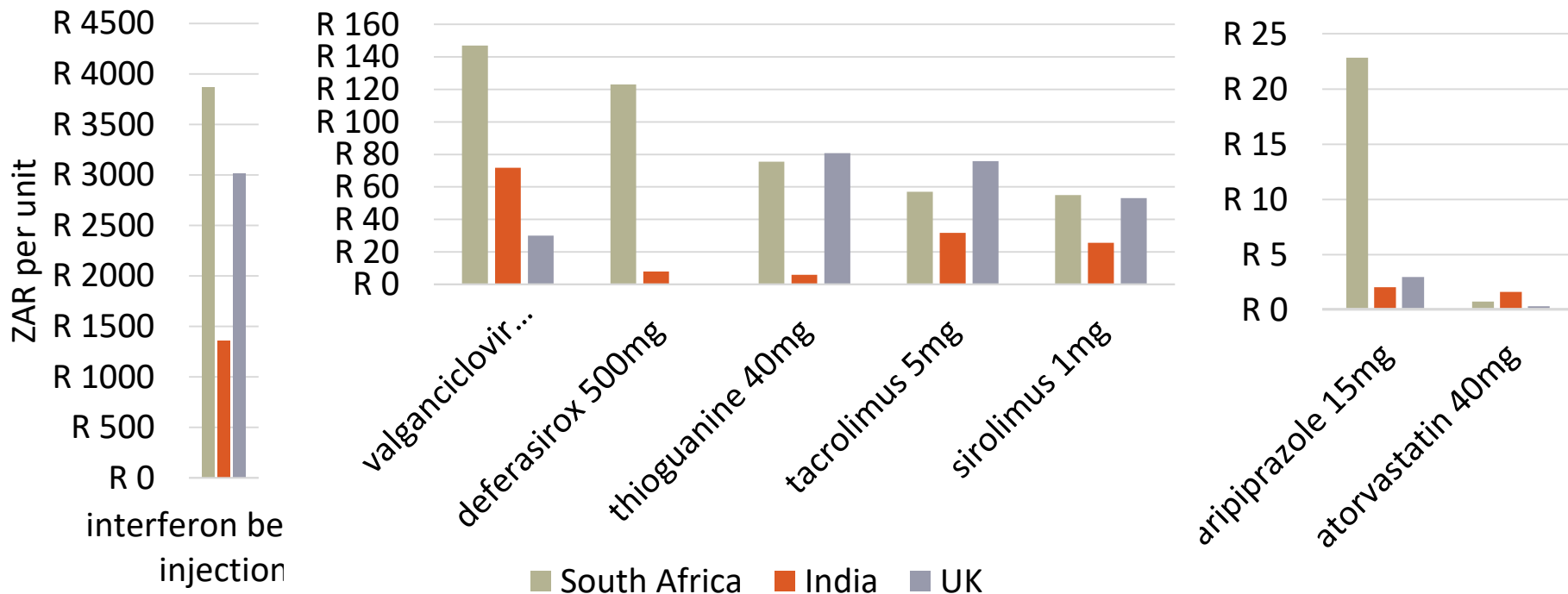
UK versus Indian prices for generic cancer drugs, 2016

Drug / dose	India	Company	UK	Company	% Increase
Melphalan 2mg	8p	GSK India	£1.82	Aspen**	+ 2,175%
Ifosfamide 2g vial	£6.95	Celon	£180	Alliance, Baxter	+ 2,490%
Chlorambucil 2mg	5p	GSK India	£1.71	Aspen**	+ 3,320%
Imatinib 400mg*	£1.71	Glenmark	£65	Novartis	+ 3,701%
Lomustine	£1.00	Samarth	£37	Medac UK	+ 3,600%
Cyclophosphamide 50mg	2p	Khandelwal	£1.39	Alliance	+ 6,850%
Mesna 1g vial	16p	Cipla	£13.41	Alliance	+ 8,281%
Busulfan 2mg	3p	GSK India	£2.76	Aspen**	+ 9,100%
Ethinylestradiol 1mg	3p	Bushnell	£7.14	AAH, Alliance	+ 23,700%

*Imatinib generic in USA, patent expires in Europe in 2017

** GSK had a large share-holding in Aspen from 2009 until late-2016

Selected examples of medicines for which South African prices are substantially higher than other countries’.



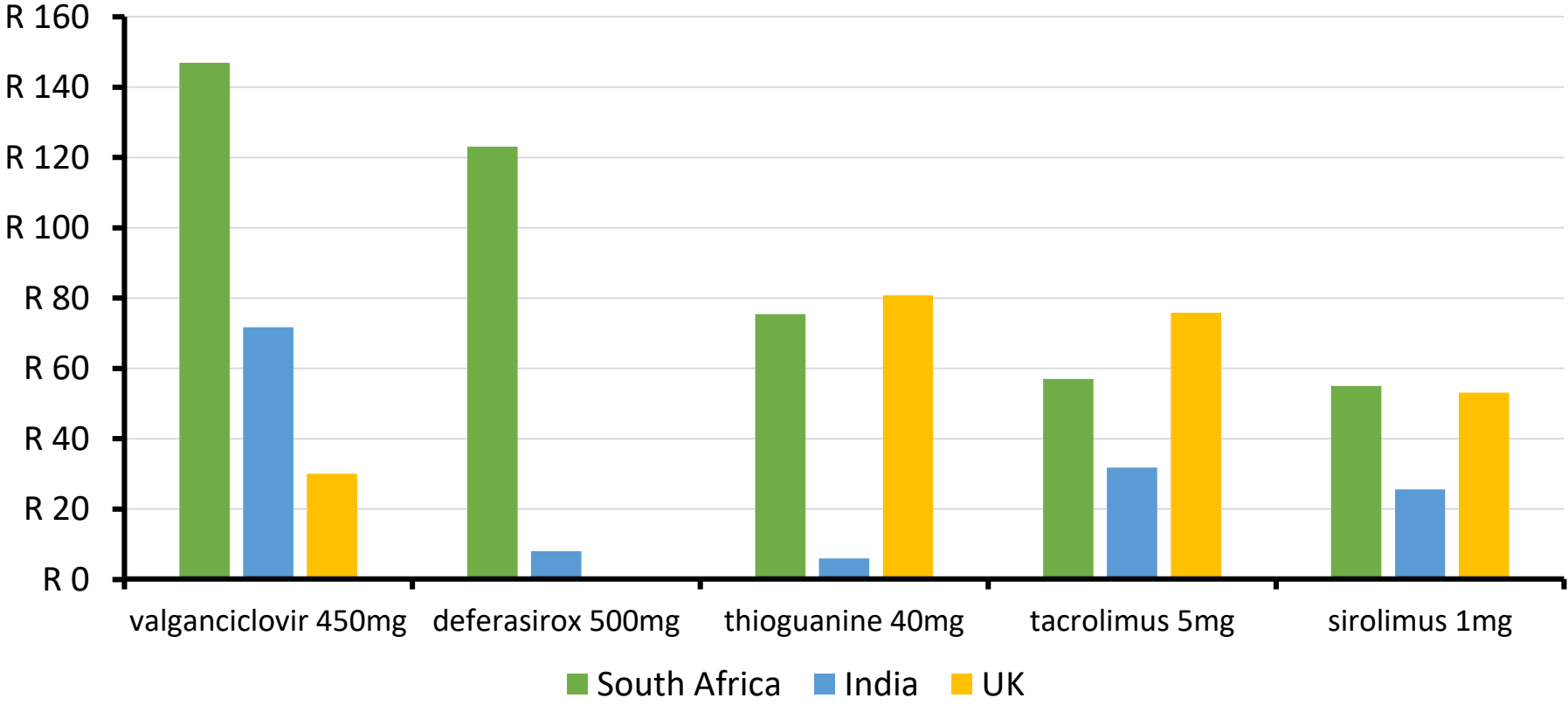
Note that these are selected examples and in general, for EML listed medicines, South African prices are lower than UK prices, and higher than Indian prices*.

*Hill A, Barber MJ, Gotham D. Estimated costs of production and potential prices for the WHO Essential Medicines List. *BMJ Global Health* 2018; 0: e000571.

Gotham D, Barber MJ, Hill A. Estimated cost-based prices for injectable medicines in the WHO Essential Medicines List (under review at BMJ Open).

All prices not inclusive of VAT. Sources: South Africa – Master Procurement Catalogue, March 2019. India – 1mg.com. UK – lower of British National Formulary and electronic Market Information Tool (eMIT).

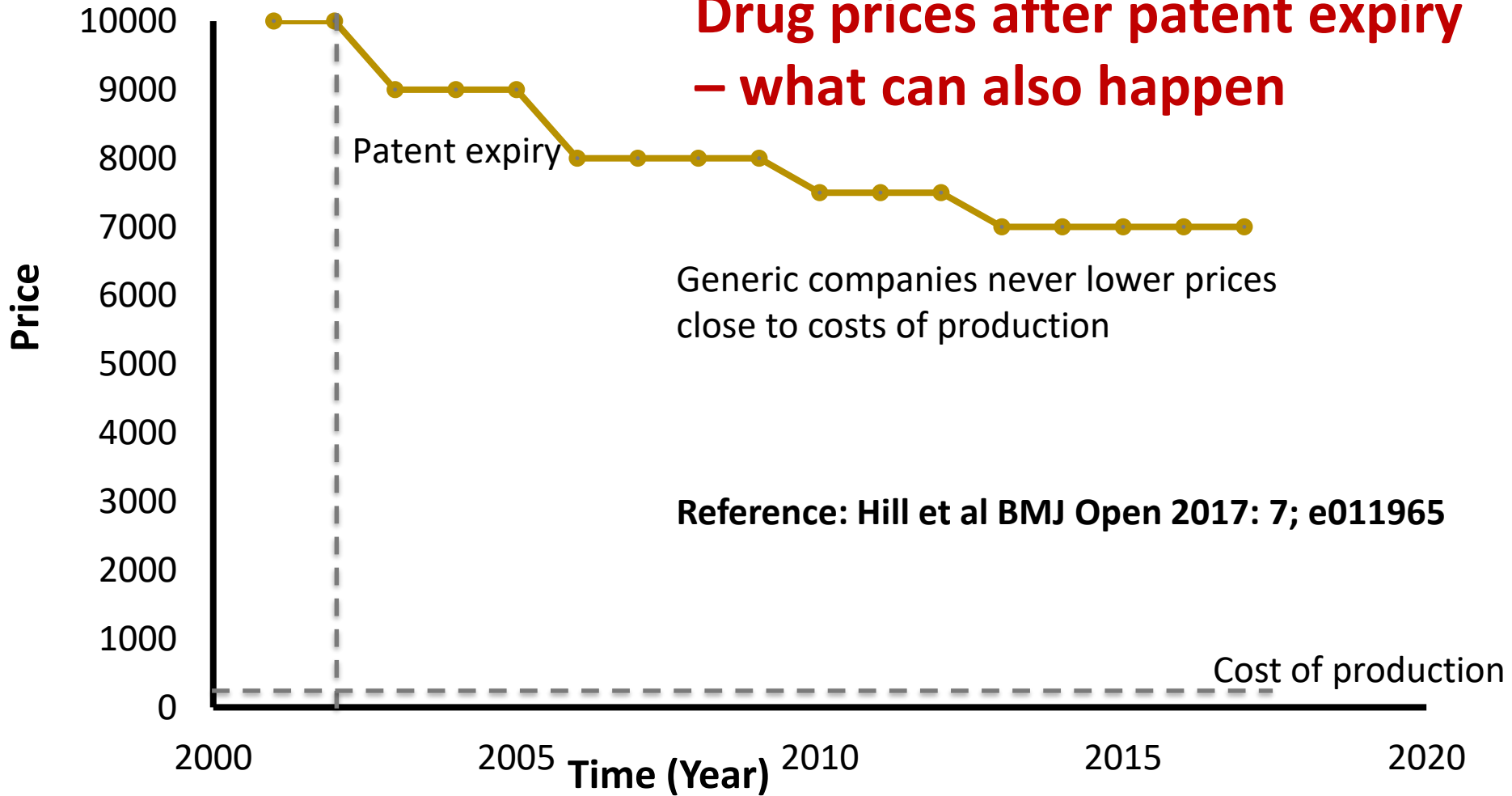
Examples of South African prices higher than India or UK.



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Drug prices after patent expiry – what can also happen



Insulin for diabetes

Discovered in 1923

**Global market:
\$28 billion**

**Cost price:
\$1 per vial**

**Sold for up to
\$240 per vial**



Generic Biosimilars need to be approved in Europe

Imatinib - generic

Price in USA for generic: \$30,000 per year

Price in India for generic: \$300 per year

Same company, same drug: Sun Pharmaceuticals

<https://www.goodrx.com/imatinib>

**If drug prices were lower,
could pharmaceutical
companies
still afford
to do R&D?**

Pharma profits and tax avoidance

Main tax havens: Bermuda, Cayman Islands, BVI, Bahamas, Luxembourg, Ireland

Company	Profits held offshore	US Taxes Avoided
Pfizer	\$69 billion	\$20 billion
Merck	\$57 billion	\$16 billion
Johnson & Johnson	\$51 billion	\$14 billion
Amgen	\$26 billion	\$9 billion
Abbott	\$24 billion	\$7 billion
BMS	\$24 billion	\$7 billion

Source: Citizens for Tax Justice, 2016. <http://gormanandjoneslaw.com/offshore-tax-havens/>
<http://america.aljazeera.com/articles/2015/3/12/obama-gambit-for-corporate-cayman-cash.html>²⁴

Universal Access to Essential Medicines

1. Show countries how much they could save from buying all generic drugs at close to cost prices
2. Maximise use of generics, in national treatment campaigns. Identify high quality generic suppliers
3. Re-evaluate the cost-effectiveness of all patented drugs, versus cheap generic alternatives – this should lead to a cascade of price reductions
4. If companies refuse to lower prices, use TRIPS flexibilities to ensure access – compulsory licenses, personal importation, patent challenges.