



**PHILIPPINES**  
**CONFERENCE 2020**

*Seeing things Clearly*

**Warwick Smith**



**Seeing the generics market clearly:  
myths, realities and challenges**

# Structure

- Shape and operation of the generic medicines market
- Supply issues
- Challenges ahead



# Shape and operation of the generic medicines market

# Study

- What are the key drivers of strategic decisions including entry, supply and pricing, and of the overall competitiveness of supply?
- Analysis of the actual selling prices charged by manufacturers of generic medicines, where possible
  - How do these compare to prices of the branded product pre-entry?
  - Do prices of generic medicines increase and, if so, do existing market mechanisms limit or reverse such increases?
  - How do generic prices in the UK compare to those in other countries?
- Overall assessment of the existing regulatory framework for pricing in the UK

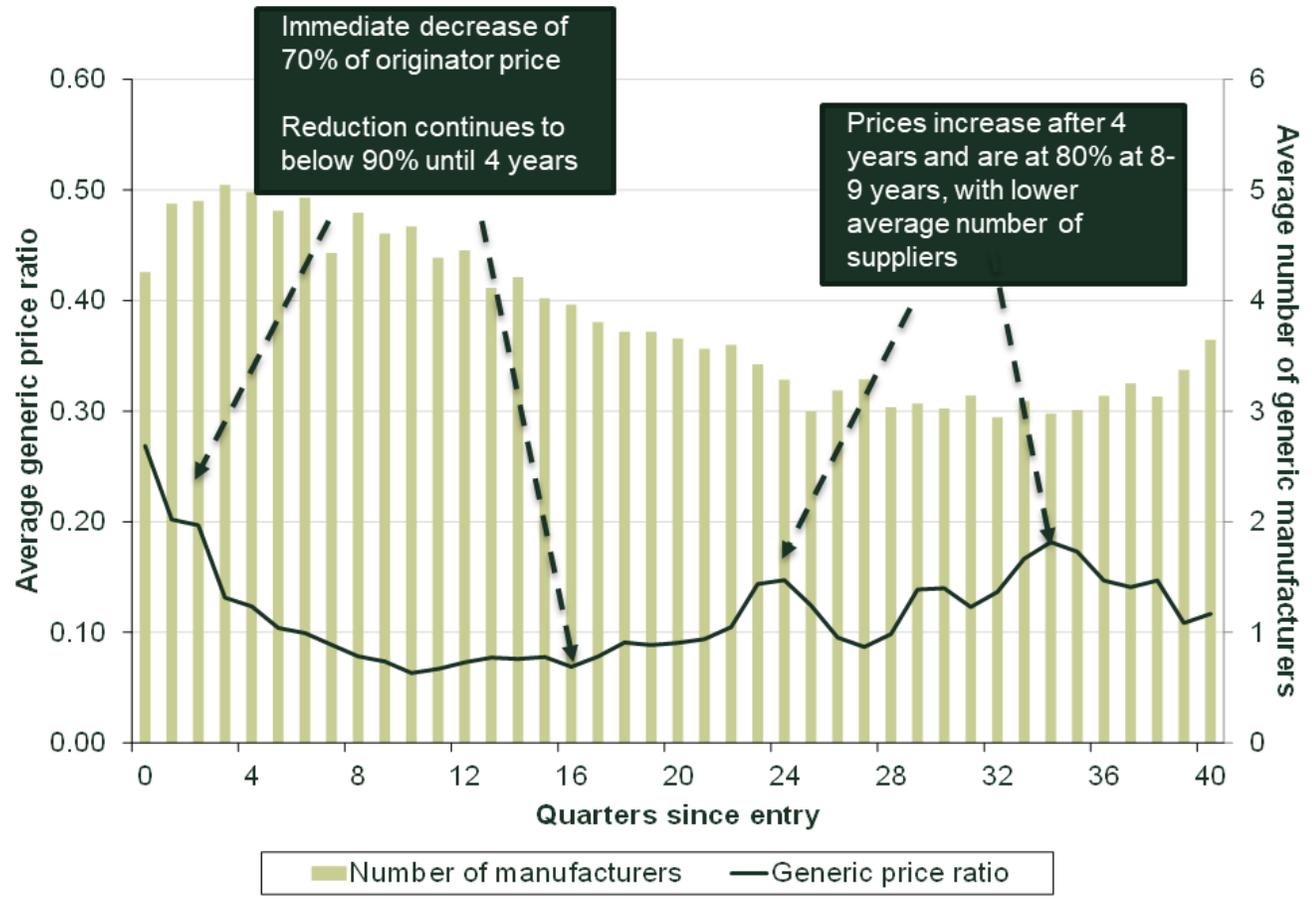


# Conclusions

- Overall, the supply of generic medicines in the UK is functioning well, delivering significant price reductions following widespread entry
- Manufacturers are generally able to respond effectively to price signals
- A comparison with five European countries suggests that UK prices are generally lower
- Freedom of pricing and low regulatory barriers in the UK are likely to be critical factors in driving this outcome
- Intervention may be warranted in specific cases;
  - should consider proportionality and **unintended consequences** in light of market features, long run dynamics and business model and strategy



Average actual selling price of generic medicines relative to pre-entry brand price



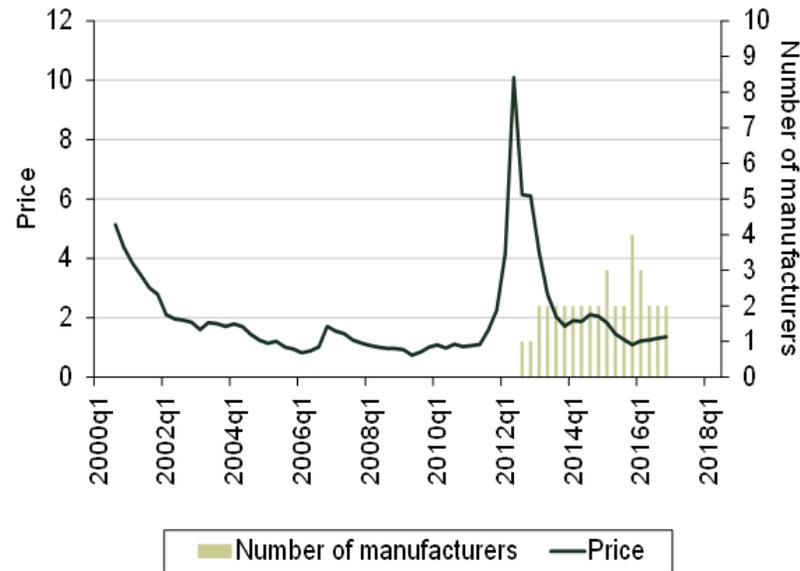
Source: Oxera analysis based on data from Scheme M, BGMA members and MPA.  
 Note: Based on 56 molecules. Originator price is measured as the average price of the product in the year prior to loss of exclusivity

# Analysis of observed price increases

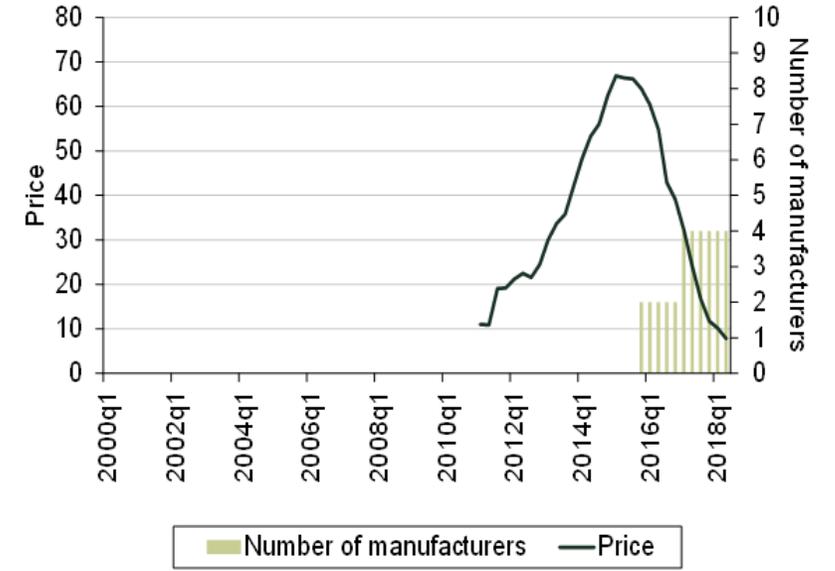
## Two types of price increases investigated

- price increases above 50% occurring over 1–12 months
- slower price increases, with small monthly increases over many years

37% monthly increase over 4 months followed by a reversal

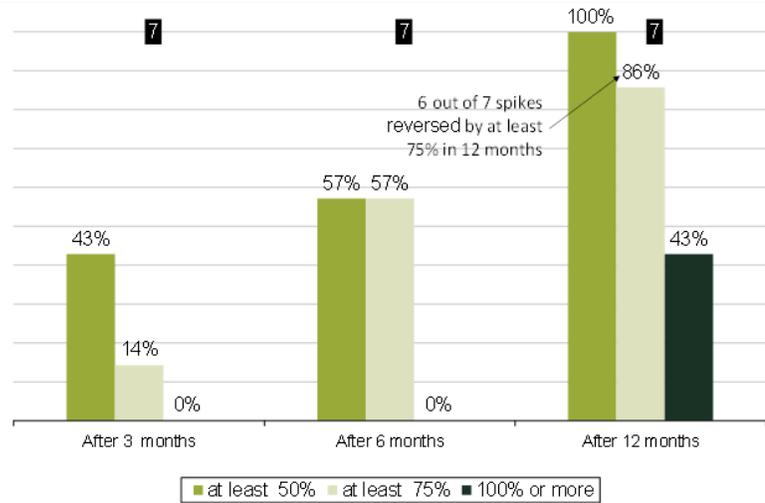


3% annual increase over 4.5 years



Source: Oxera analysis based on WaveData prices and no. of manufacturers from Scheme M returns (for products that entered Scheme M between 2012 and 2018).

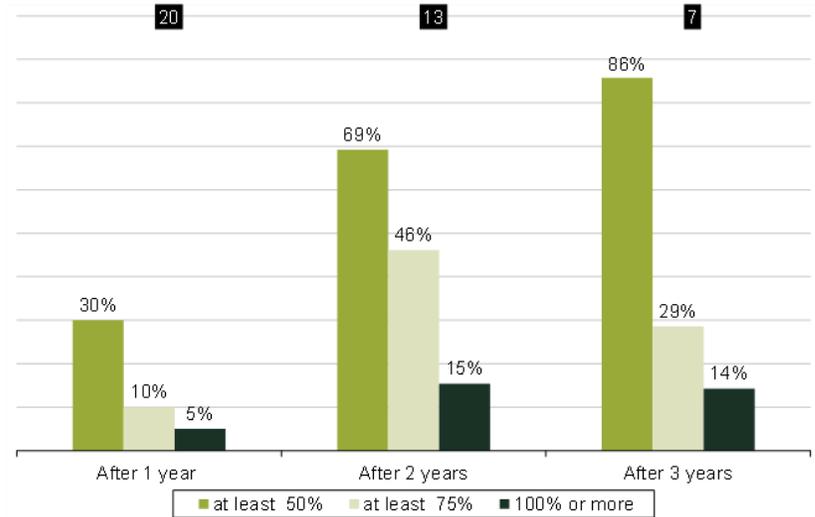
Analysis of observed price increases  
Extent and speed of reversals



**Slower price increases**

Longer and less complete reversal rate; majority still show 50% or greater reversal within three years  
Could indicate structural changes in supply

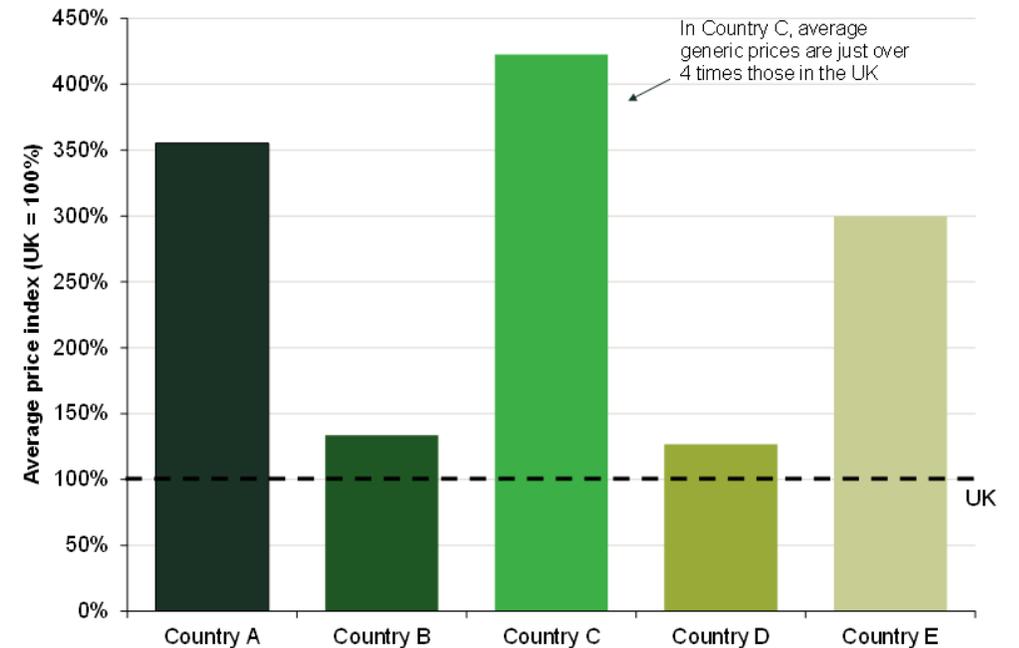
**Price spikes**  
Significant reversal of price 'spikes' within 6 months  
Majority of the price increases reversed within 12 months



Actual selling price of generic medicines relative to other countries

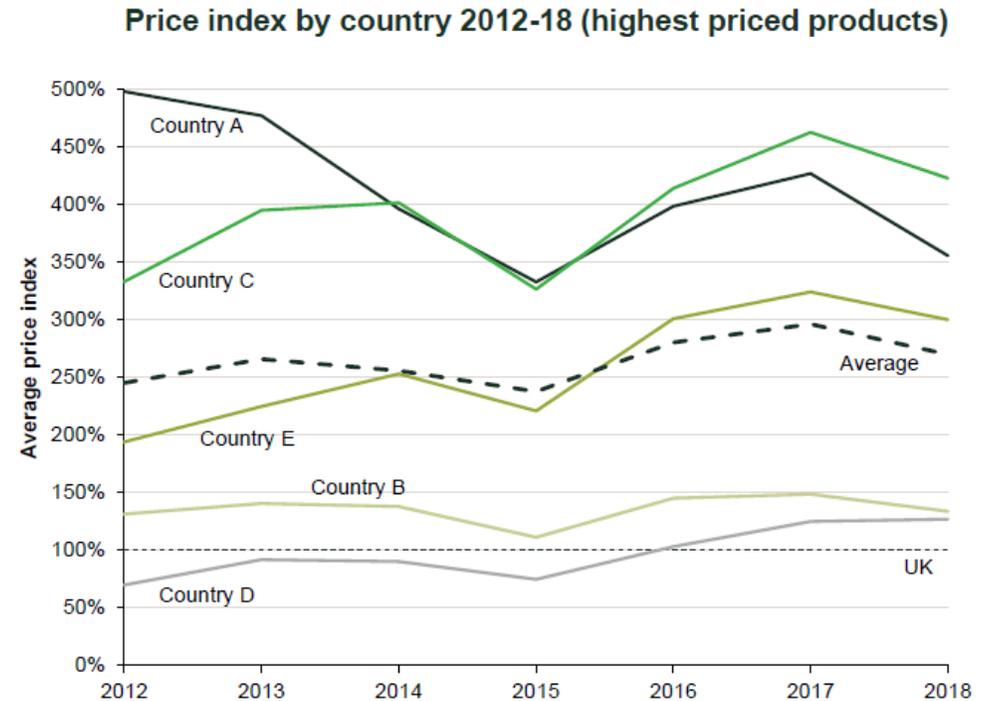
- IQVIA data on prices
  - including country-specific adjustment factors to estimate manufacturer actual selling prices
- price index of each country relative to the UK for products with two sets of products:
  - those with highest Tariff price
  - those with highest total expenditure
- UK prices are generally lower

Price index by country Q2 2018 (highest priced products)

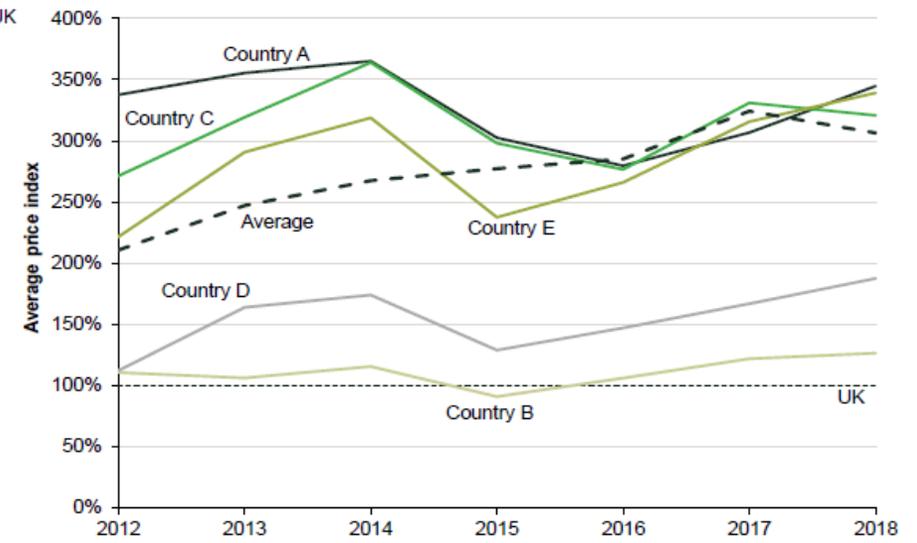
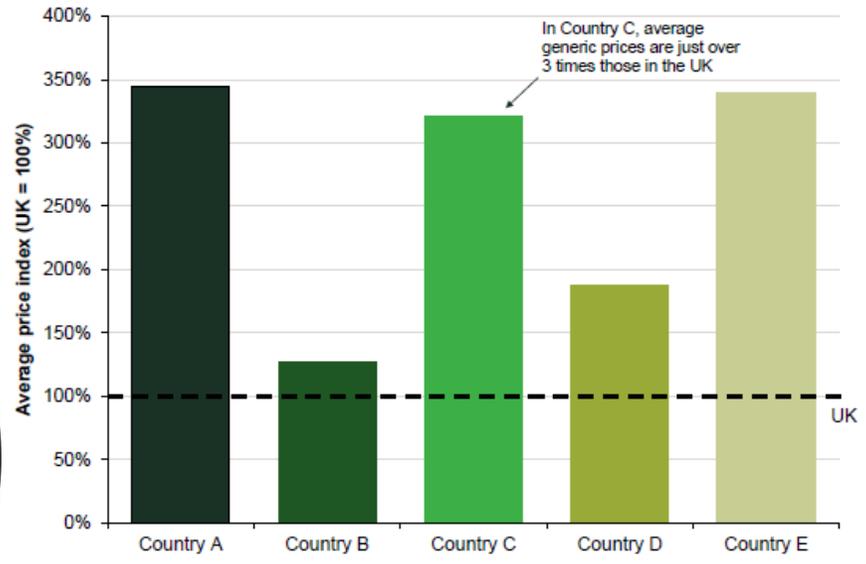


Actual selling price of generic medicines Relative to other countries

- IQVIA data on prices
  - including country-specific adjustment factors to estimate manufacturer actual selling prices
- price index of each country relative to the UK
- two sets of products
  - those with highest Tariff price
  - those with highest total expenditure
- UK prices are generally lower
- broadly consistent over time (prices in three countries are 3 to 4.5 times more expensive)



Actual selling price of generic medicines  
Results are similar for the set of most costly products



# Supply issues

# Pressure on supply



EASTWARD MOVE OF  
API AND OTHER RAW  
MATERIALS SUPPLY



CONSOLIDATION AT ALL  
LEVELS



LONGER, THINNER  
SUPPLY CHAINS



CHINESE  
ENVIRONMENTAL  
LEGISLATION



FALSIFIED MEDICINES  
DIRECTIVE

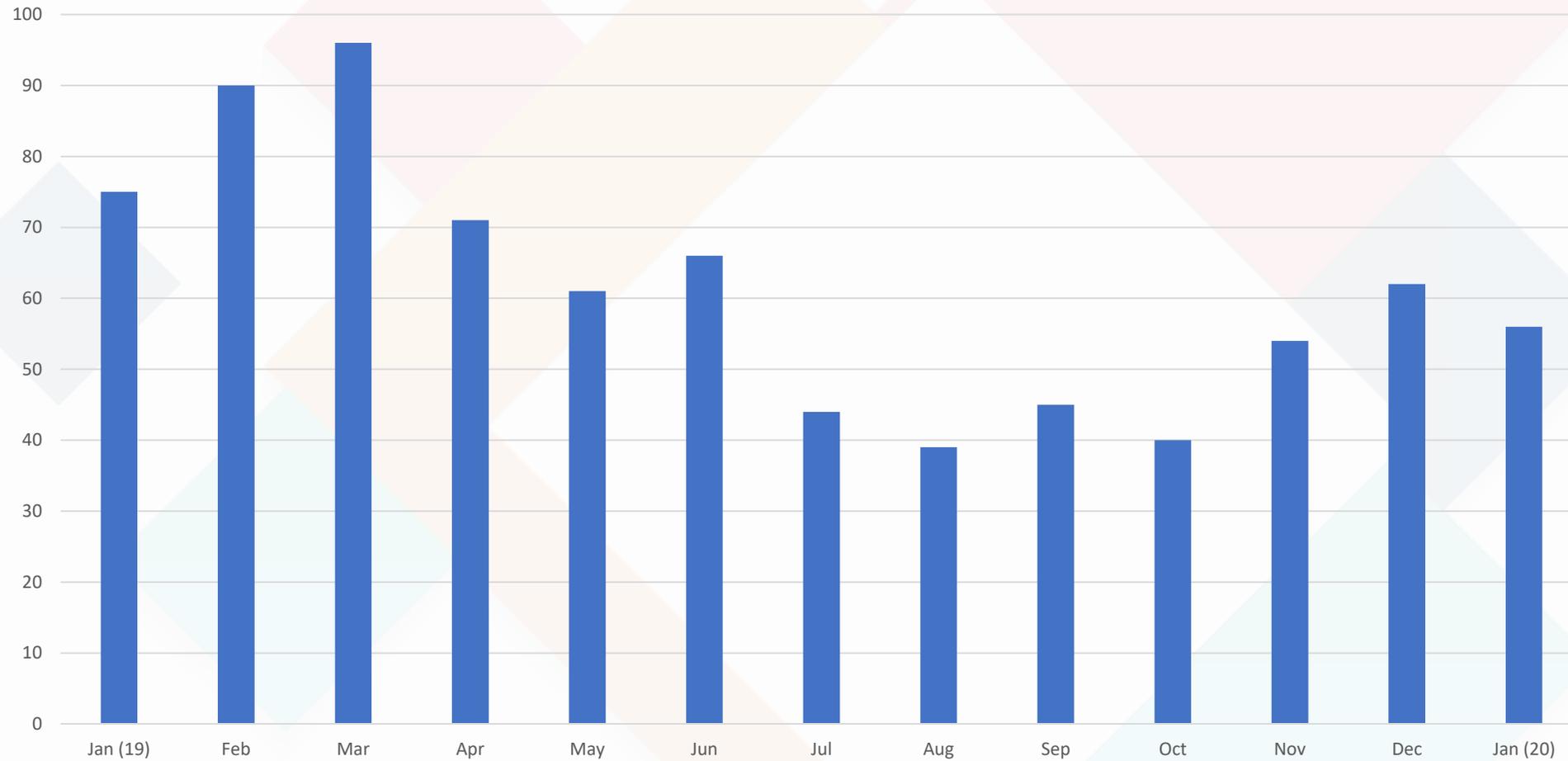


RETURN OF LICENCES



REDUCTION IN NUMBER  
OF SUPPLIERS ON  
LICENCES

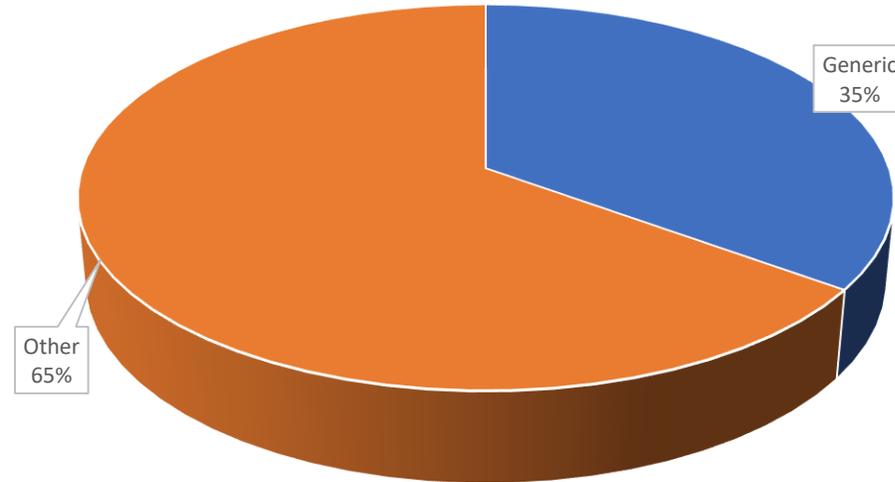
# Concession prices since Muscat



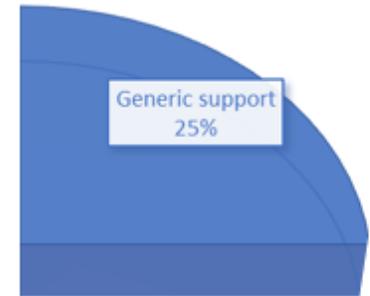
# Analysis of DHSC shortages list for November 2019

Not a just a generic issue

Excluding creams, eye drops, vaccines

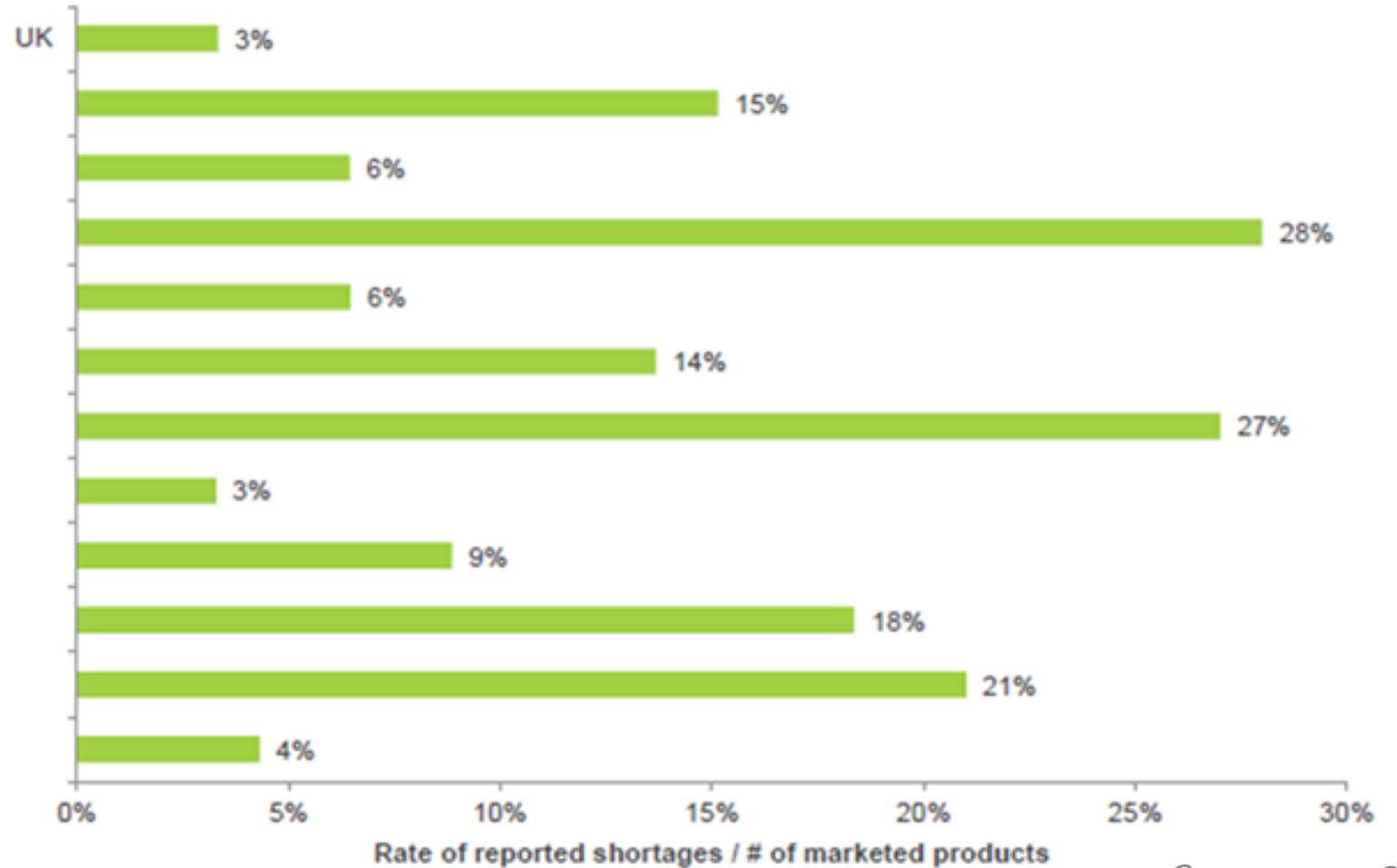


Shortages where generic alternatives are listed as able to fill the gap



# UK compared with other European countries

Reported shortages vs. listed products  
(average rate from top-10 companies / per market)



Not just a UK issue

# Medicines for Europe overview



## Medicines Shortages

### CAUSES

-  Consolidation of API suppliers
-  Price pressure on generic medicines
-  Less medicines manufacturers on the market
-  Burden of new regulation
-  Accidents or natural disasters

### RECOMMENDATIONS

-  EU cooperation on shortages
-  Pro competitive markets with price flexibility
-  Avoid cost containment measures
-  Allow for regulatory flexibility
-  Stimulate investment in manufacturing



*Seeing things Clearly*

And what  
now?



European Commission study  
into shortages



Possible UK  
strategic study into  
the supply chain

Identifying and  
dealing with  
causes

Not just trying to  
manage the issue



Improved information flows

# Challenges

# Brexit



Pharmaceutical companies tend to launch new products first in the EU and the US



EU membership offers manufacturers considerable economies of scale

Large market, with a single regulatory standard, and a single process



Different standards, or different processes—even if faster—may make the UK less attractive



Access to data is also needed: Withdrawal Agreement seems loaded in favour of the EU



Change may delay or deny generic and biosimilar launch



Too much uncertainty still remains

# UK / US Free Trade Agreement



USTR negotiating objectives:

“Seek provisions governing intellectual property rights that reflect a standard of protection similar to that found in U.S. law”



Radio 4 Today 28 November 2019: Justin Webb: “Do you entirely rule out, for instance, on patents, any change to the existing laws and regulations?”

Matt Hancock: “Yes”



Prime Minister’s 3 February 2020 speech:

“It goes without saying that of course the NHS is not on the table”



Secretary of State for International Trade, 6 February 2020”

“... the US FTA will secure provisions that support UK creative and innovative industries, whilst maintaining consumer access via an effective and balanced global framework”

# Downward pressure on price

Oxera study has confirmed that the UK has the lowest ex-manufacturer price in Europe

- “Freedom of pricing and low regulatory barriers in the UK are likely to be critical factors in driving this outcome”
- But concern and pressure remains on specific products

Drives behaviours that produce suboptimal outcomes

- API and finished form manufacture moves from the UK and Europe to Asia
- Manufacturers withdraw from products rather than invest in them
- Potential reduction in alternative sources of supply

# Conclusion

# Risks of unintended consequences



LOW LEVELS OF  
GOVERNMENT  
INTERVENTION



LOW BARRIERS TO  
ENTRY



ACCESS TO THE EU  
SINGLE MARKET



THE LOWEST PRICES IN  
EUROPE



FEWER SHORTAGES  
THAN MOST OTHER  
EUROPEAN COUNTRIES



VERY EARLY LAUNCH OF  
NEW PRODUCTS

Thank you



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