# The UK Lesson

**The impact of the regulatory environment on patient access to medicines**

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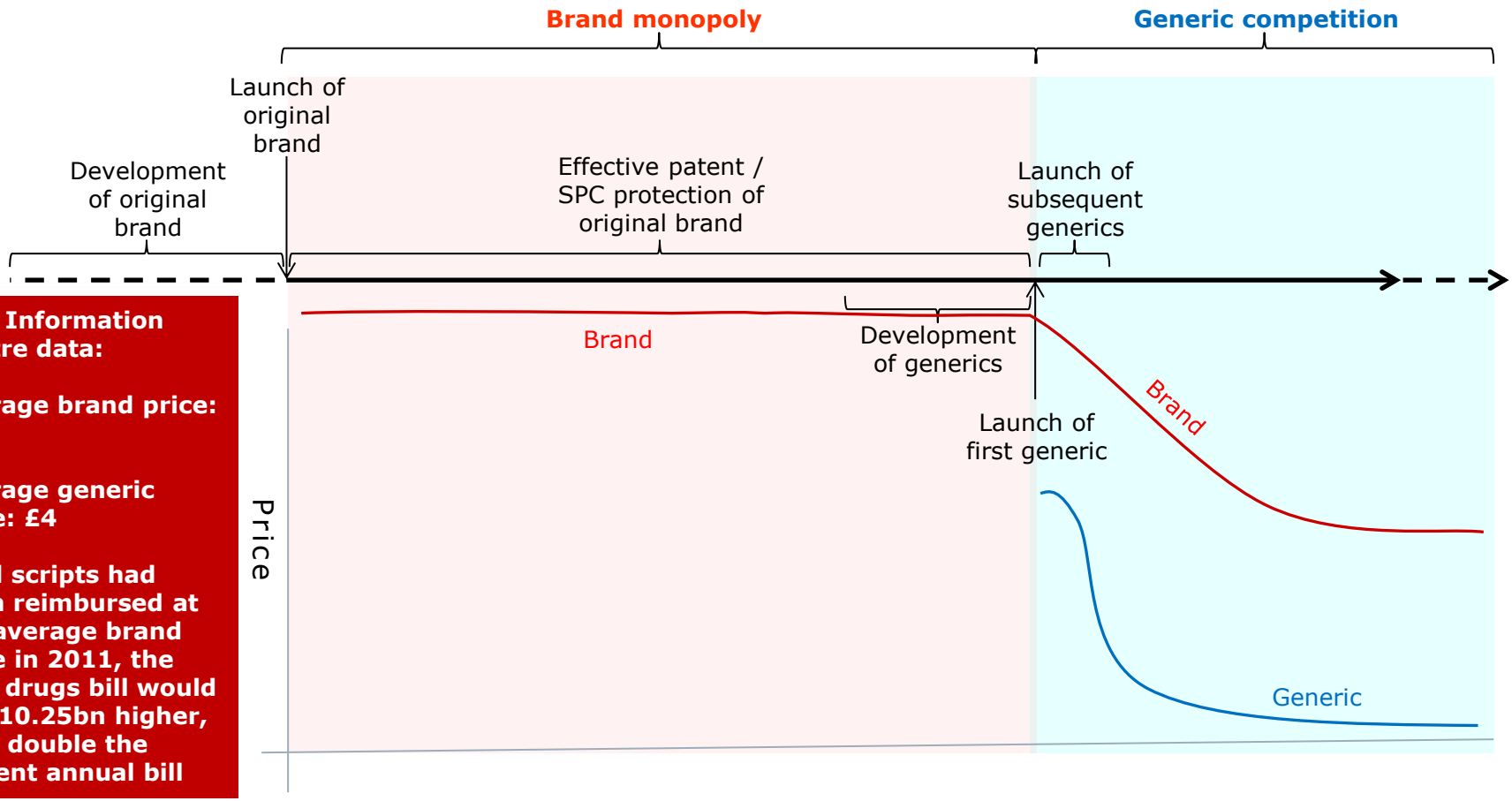
# About the BGMA

- The British Generic Manufacturers Association (BGMA) represents the interests of UK-based manufacturers and suppliers of generic medicines and promotes the development and understanding of the generic medicines industry in the United Kingdom
- The BGMA is made up of 26 members of the generic manufacturing industry, who between them account for nearly 90% of the UK generic market by volume
- The BGMA represent the views and interests of its members to the UK government, the devolved administrations, regulators, other relevant third parties, including where appropriate the Institutions of the European Union and the media
- A central point for UK generics industry communication

# Generic launch in the UK Market




**NHS Information Centre data:**

**Average brand price: £20**

**Average generic price: £4**

**If all scripts had been reimbursed at the average brand price in 2011, the NHS drugs bill would be £10.25bn higher, over double the current annual bill**



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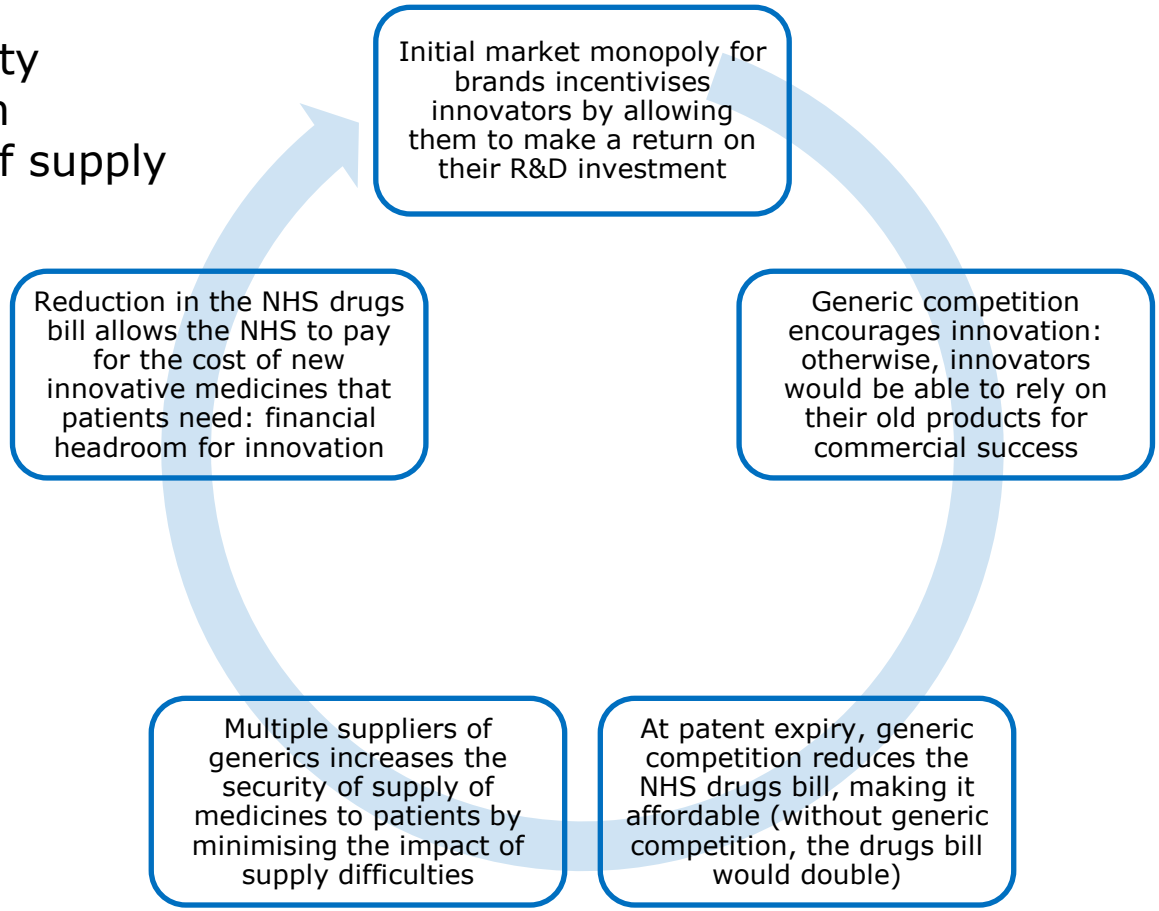
# The virtuous circle

- Affordability
- Innovation
- Security of supply



# The UK regulatory environment

The conditions for the generic industry create a highly efficient market to the benefit of the NHS and patients:

- a non-branded INN market – with Doctors trained to prescribe by INN in medical school
- freedom of pricing with prices constrained by competition
- BGMA members provide data, through Scheme M, that supports the Category M reimbursement mechanism
- no separate pricing or reimbursement approval
- generic medicines available as soon as marketing authorisation granted and patents expired.

The UK government developed the reimbursement "Scheme M" with the BGMA which supports the operation of the competitive market and avoids price regulation.

# Dispensing of Generic Medicines

- If a specific brand-name drug is prescribed in primary care, a pharmacist is obliged to dispense this even if an equivalent generic version is available. Reimbursement is made using the manufacturer's list price for the branded product.

- When the generic name is written then either a branded or generic version of the medicine can be dispensed, but the **pharmacist is reimbursed at the generic rate**.

- The reimbursement price to dispensers of generic medicines includes a significant margin to fund the UK pharmacy network, and encourage price competition between medicines suppliers.

# Medicines regulation by MHRA

- Up to 90% of generic medicines registered through DCP in 12 – 15 months.
- Marketing Authorisations usually granted within 30 days of procedure end.
- Same process being followed for national applications to meet local patient needs.
- Major participant in EU regulatory network.
- Popular reference member state for EU wide new product registrations.

# Saving from generic medicines continue to increase in UK

Recently published NHS 2012 data …..

- Saving due to generic competition is now £11 billion.
- A 1% swing to generics saves £151m.
- Significant leap in generic usage from 69% of scripts to 73% in 2012.
- Generic NIC (reimbursement cost per prescription item) £3.85 compared to the average brand NIC of £ 19.37.
- Average generic NIC now is 5.64% less than it was 10 years ago.

# Sustainability of the generic medicines industry

Government Health minister Lord Howe at the AGM of the BGMA on May 23, 2012 announcing a new programme exploring the long-term sustainability of the generics industry in the UK.

"The benefits of generic medicines are clear. Reducing the cost of medicines through generic prescribing and dispensing has been pivotal in controlling the NHS drugs bill. And of course reducing the cost of medicines allows more patients to be treated and frees up resources which are in turn invested in new and innovative treatments for patients."

# Members and Contact

























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