

Generic HIV drugs in the UK



Regional Meeting on Access, Quality
and Pricing of HIV Drugs in SEE
Countries



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Simon Collins, HIV i-Base
www.i-Base.info

Disclosure

No personal financial conflict of interest

Outline

- Introduction
- Generics medicines on the NHS in the UK.
- Use of generic ARVs for HIV.
- Response of people living with HIV.
- Conclusions
- References

Introduction

- HIV+ advocate in the UK.
- Founded i-Base in 2000 and UK-CAB in 2002 (network of 700 advocates).
- Community rep on treatment guidelines and London drug commissioning group.
- Strongly support generics. I used generic ART for more than 10 years.



Generics in the UK



- Public health care depends on best value.
Budgets, by definition, are always limited. [1]
- 60 – 85% of medicines in the NHS are generic: they are just as effective, but cost far less.
- They have the same active ingredients and are made to the same high standards.

Refs: 1. NHS. <https://www.nhs.uk/conditions/medicines-information>.

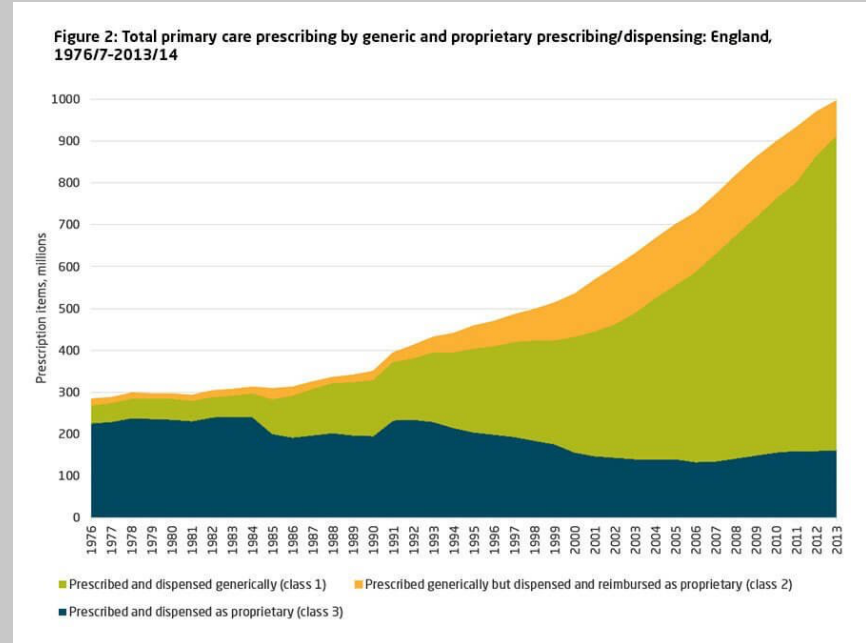
Generic approvals

- Generic HIV drugs are approved based on studies proving bioequivalence to original versions. [1]
- Can use different salts - ie tenofovir (Mylan) [2]
- This includes pharmacokinetic (PK) equivalence, usually based on meeting an 80% – 125% range. [3]
- Same guidelines for manufacturing and stability.

Refs: 1. EMA. <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines>. 2. <https://www.ema.europa.eu/en/medicines/human/EPAR/tenofovir-disoproxil-mylan..> 3. <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance>

Generics and value for money

- 1976 to 2013: generic use from 20% to 84%.
- Allowed 490 million more prescriptions at the same cost. *The NHS now gets better value for every pound it spends on medicines.* [1]
- Spending would need to have increased 8-fold otherwise. [2]

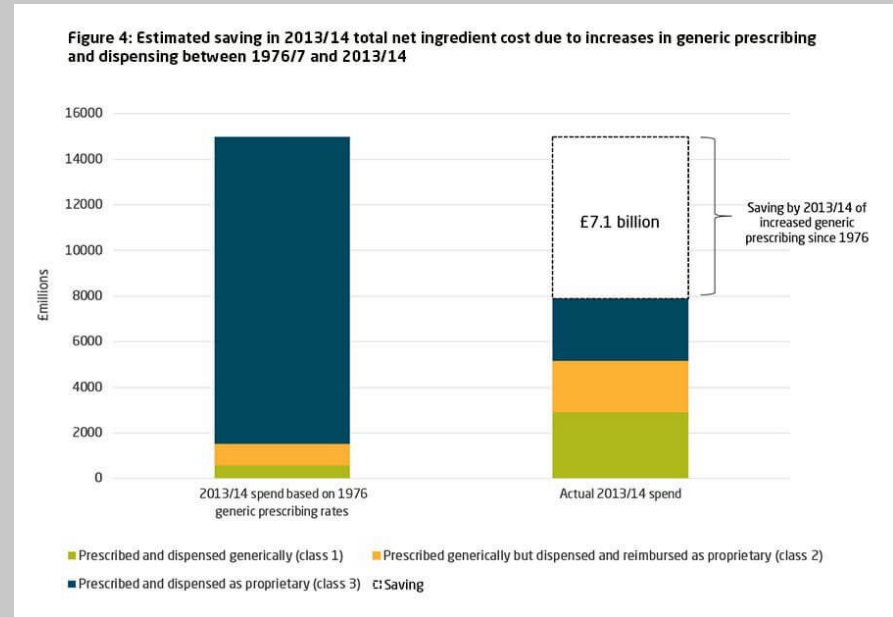


Refs: 1. NHS Blackpool prescribing statement , Dec 2017; 2. Kings Fund Report, August 2015.

Generics and value for money

- £7.1b savings, (2013/14).
- Exceptions include some medicines with low therapeutic window (some inhalers, lithium, epileptic drugs, immune suppressants, biosimilars and others) [3]

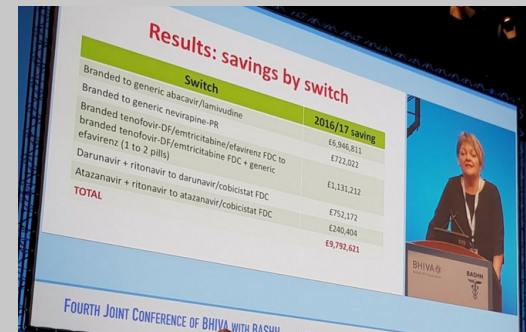
References: 1. Kings Fund Report, August 2015.
(<https://www.kingsfund.org.uk/blog/2015/07/how-much-has-generic-prescribing-and-dispensing-saved-nhs>); 2. UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals.



Generics for HIV

- ART is major part of the cost of HIV care.
- As generics became available, routine switching to save money was common. [1]
- Supported by both doctors and HIV+.
- HIV+ included in the process.
- £10 million savings in 2018. [2]

Refs: 1. BHIVA standards of HIV care, p31 (2018);
2. Waters L et al, BHIVA/BASHH 2018.
<https://i-base.info/htb/34003>.



Generics for HIV

“ART is a major component of the costs of treatment and care for HIV in the UK; this means that clinically effective and cost-effective prescribing is essential to make efficient use of NHS resources. As generic ARVs become increasingly available, treatment changes for reasons of cost saving are more frequent. Informed decision-making with the patient having a sense of control in this process is likely to increase the success of this strategy. The development of drug resistance and toxicity through inappropriate HIV prescribing might further increase costs so careful consideration of patient engagement and switch choice is important. Patient information and resources about generic medications are available from professional and third sector organisations.’

Refs: 1. BHIVA standards of HIV care (2018).



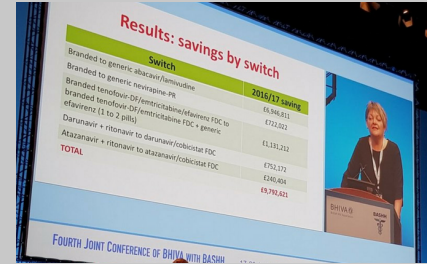
Examples in 2016

NOT about the cheapest combination.

- Splitting single pills ie from one pill a day to two pills (using generic dual NRTI).
- Switching from brand dual NRTIs to dual generic NRTIs.
- Switching for FDCs to use brand dual NRTIs + generic third component.
- In 2021 many more ARVs are now generic.

Refs: 1. Waters L et al, BHIVA/BASHH 2018.

<https://i-base.info/htb/34003>.



Community support

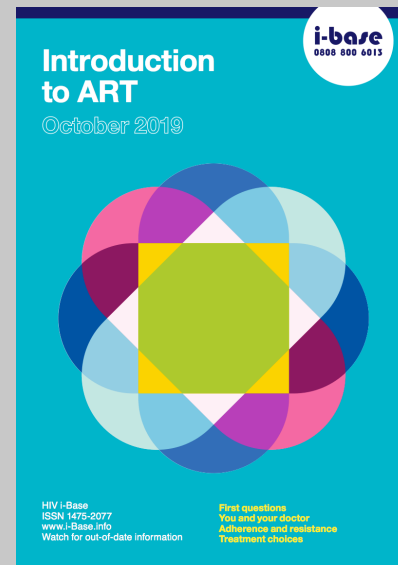


HIV positive people supported switch to generics.

- (i) 1 or 2 extra pills a day is okay.
- (ii) Not to increase daily doses – ie once-daily needs to stay once-daily.
- (iii) Changes from brand to generic is easy, especially if it saves NHS funding.

Ref: HIV i-Base. Generic HIV meds in the UK:

<https://i-base.info/guides/starting/nhs-changes-and-generic-drugs>



Cost effectiveness

- UK approach was NOT using the combinations.
- The UK does NOT recommend serious toxicities (AZT, nevirapine, lopinavir/r etc)
- Uses best clinical options and best combinations at the most competitive prices.



cascade with generics:
95%, 97%, 98%

Conclusions

- Generics are a central part of HIV care in the UK.
- Large cost savings without any loss of efficacy.
- Enables access to more expensive meds for those who need it.
- Strong community support – based on only changing brand version to a generic.
- Only switch treatment based on clinical reasons.
- Not switching number of daily doses.

References

NHS saves £10 million from use of HIV generics, BHIVA/BASHH 2018.

<https://i-base.info/htb/34003> (i-Base report)

<https://www.bhiva.org/Presentations180418> (PDF slides)

Info about use of generics in the UK:

<https://i-base.info/guides/starting/nhs-changes-and-generic-drugs>

Drug pricing and cost:

<https://i-base.info/qa/14461>

UK NHS website on generics

<https://www.nhs.uk/conditions/medicines-information/>

NHS prescribing guidelines (Manchester)

<http://gmmmg.nhs.uk/docs/guidance/Generic-Prescribing-Guidelines-Version-2-0-final.pdf>

Thank you

Questions?

www.i-Base.info

A vertical poster for i-base HIV treatment information service. The background is light blue with a large white pill shape in the center. The pill has an orange band around its middle. Text is arranged around and on the pill. At the top left is the i-base logo and service name. At the top right is a note about free calls. In the middle, on the pill, is the text 'ASK A QUESTION by phone, email or online'. Below that, on the pill, is the phone number '0808 800 6013', the email 'questions@i-base.org.uk', and the website 'www.i-base.info'. At the bottom is a small disclaimer and charity number. There are several small colored circles (yellow, green, pink) scattered around the pill.

i-base
HIV treatment
information
service

Calls are free from
land lines and most
mobile networks.
All calls are
confidential.

ASK A QUESTION
by phone, email or online

0808 800 6013
questions@i-base.org.uk
www.i-base.info

Information to be used in discussion with your doctor. Registered charity no: 1081905.