Mr Peter Sharott

NHS England

COMPETING INTEREST OF FINANCIAL VALUE ≥ £1,000:	
Speaker Name	**Statement**
Mr Peter Sharott	Peter Sharott has acted in a consultancy capacity for Bristol-Myers Squibb as a member of an advisory board held in March 2013 and also received financial support from Mylan Ltd for chairing and presenting at a satellite symposium at the European Hospital Pharmacists Congress in March 2013.
Date	**November 2013**

Generic antiretrovirals:
what will they mean for patients and HIV services?

Peter Sharott

BHIVA Conference 14th November 2013

THE NHS CONSTITUTION
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Role of generic medicines in healthcare

- Part of drug life cycle
- Bio-equivalence accepted as part of licensing arrangements
- Widely in use across NHS
- Generally no reason not to use generic immediate release formulations
- Use of generic medicines generates large savings for the NHS

NHS England

What's in the ARV generics pipeline?

Drug	UK Patent Expiry Date	Comments
Lamvudine	February 2011	National contracts from August 2012
AZT + Lamivudine	April 2013	National contracts from April 2013
Nevirapine immediate release	July 2012	National contracts from July 2013.
Efavirenz	November 2013	National contracts from December 2013.
Ritonavir	2013/14	Will impact on the cost of all protease inhibitor/ritonavir combinations
Abacavir	June 2014	Has implications for the combined price of generic abacavir and lamivudine with Kivexa, although generic versions of Kivexa should be available
Nevirapine prolonged release	2015	Currently around 75% of nevirapine use in the UK .
Lopinavir	December 2015	May create more price competitiveness across the protease inhibitor group
Darunavir	2018	
Abacavir + Lamivudine	2019	

Discounts range between 60 and 90%

Commissioner perspective 1: Safety

- Bio-equivalence for immediate-release formulations accepted as part of licensing arrangements
- Maintain robust, reliable supply chain
- Patient information and support
- Debate and partnership are keys to success

Commissioner perspective 2: Quality

- Quality assurance assessment for packaging, labelling and information leaflets as part of national tendering and contracting
- Managing change options:
  - automatic substitution
  - policies for switching
- Process for moving from branded medicines to generic versions
- Patient information and support
- HIV Pharmacy Association's guidance for homecare patients

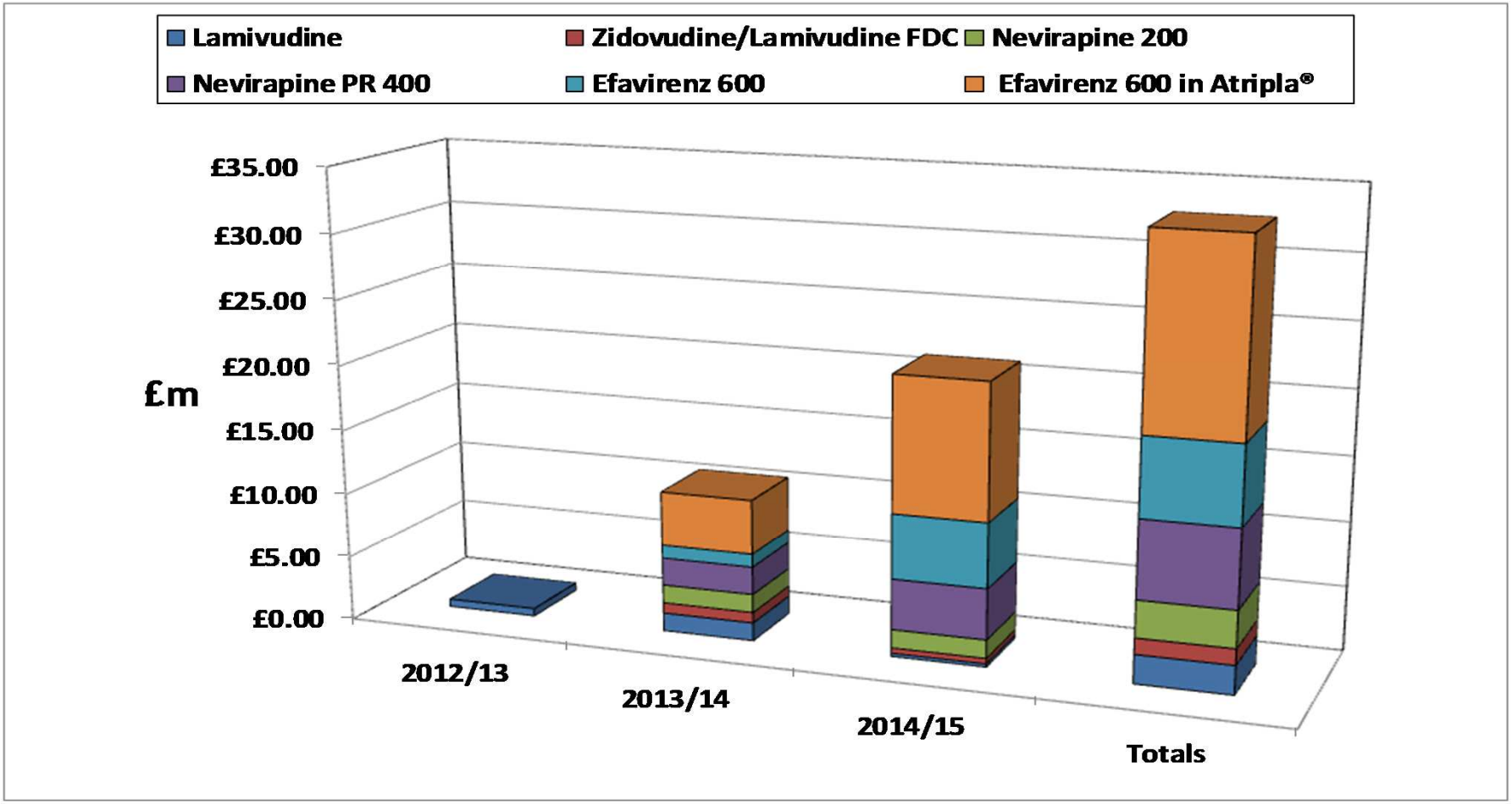
Commissioner perspective 3: Cost

- National process for tendering and contracting for generic medicines
- Market and price competitiveness
- Ensuring uptake occurs
- Generics contribute significantly to improved drug acquisition costs

Why we need generic ARVs now

- Growth in patient numbers: 9% per year in England
- Undiagnosed fraction remains at c. 25%
- Of those in care, almost 90% on ARVs and virally supressed
- Potential for expanded eligibility for ARVs (TasP?)
- NHS financial context - £50bn productivity challenge to 2020
- New ARV drugs pipeline

Estimated productivity gains in England



Opportunities and challenges

- Generic ARVs offer solution to increased demand in a financially constrained environment without compromising safety or quality
- Debate on switching medicines
- Debate on adherence support
- History of partnership working to solve challenges
- Patient engagement, information and support
- Role of the CRG and stakeholders

Thank you

Any questions?