<table>
<thead>
<tr>
<th>Speaker Name</th>
<th>Statement</th>
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<tbody>
<tr>
<td>Mr Peter Sharott</td>
<td>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.</td>
</tr>
<tr>
<td>Date</td>
<td>November 2013</td>
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Generic antiretrovirals: what will they mean for patients and HIV services?

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

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 suppressed
• 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?