Department of Health
Consultation on the proposals to implement ‘Generic Substitution’ in primary care
Analysis of responses
For Department of Health & COI
By Greenstreet Berman Ltd
October 2010
Title | Department of Health Consultation on the proposals to implement ‘Generic Substitution’ in primary care
Analysis of responses

<table>
<thead>
<tr>
<th>Author</th>
<th>Beth Truesdale</th>
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<tbody>
<tr>
<td>Reviewer</td>
<td>Michael Wright</td>
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<tr>
<td>Date of publication</td>
<td>October 2010</td>
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1 EXECUTIVE SUMMARY

1.1 Introduction

From January to March 2010, the Department of Health (DH) carried out a consultation on ‘The proposals to implement “Generic Substitution” in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009’. ¹

The PPRS, a scheme agreed by the DH and the Association of the British Pharmaceutical Industry (ABPI), provided for a generic substitution scheme under which items prescribed by brand but available as a generic (representing some 5% of prescription items in 2008) could be dispensed as a generic, subject to the approval of the prescriber. Stakeholders were asked to consider three options:

- Option 1: to do nothing
- Option 2: to introduce dispensing flexibility but with specific exclusions, so that the arrangements do not apply to a selected group of products on an exempt list
- Option 3: to introduce dispensing flexibility but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list – the DH’s preferred option.

In total, 423 organisations and individuals submitted written responses. In addition, 107 delegates attended DH listening events, and their comments were recorded as part of the consultation. Respondents from organisations included representatives of NHS organisations, pharmaceutical companies, local pharmaceutical committees (LPCs), third sector organisations, community pharmacies, trade bodies, and professional and regulatory bodies. Individual respondents included doctors, pharmacists, academics, patients and carers.

Responses to the written consultation included 269 individually developed responses and 154 responses using two different campaign templates.

Greenstreet Berman, an independent social research company, analysed the responses to the consultation on behalf of the Department of Health.

1.2 Overall findings

1.2.1 Agreement and disagreement with Option 3

The DH’s consultation response template asked whether respondents agreed with Option 3, the DH’s preferred option. Among all responses, 64% disagreed with Option 3, as shown in Table 1. If we treat campaign letters as a single response, there were almost the same number of respondents who agreed with Option 3 and those who disagreed, as shown in the ‘Individually developed responses’ row in Table 1.

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All responses</td>
<td>112</td>
<td>271</td>
<td>40</td>
<td>423</td>
</tr>
<tr>
<td>Individually developed responses</td>
<td>112</td>
<td>117</td>
<td>40</td>
<td>269</td>
</tr>
</tbody>
</table>

Table 1: Do you think the preferable implementation approach is Option 3?

By respondent type, the majority views were:

- Against Option 3: LPCs; individual pharmacists; trade bodies representing pharmacists and pharmacies; patients and carers
- For Option 3: NHS organisations and individual doctors.

There was a much closer balance of opinion among pharmaceutical companies, trade bodies representing pharmaceutical companies, third sector organisations (such as charities focused on various medical conditions), professional and regulatory bodies, and community pharmacies.

1.2.2 Agreement and disagreement with Options 1 and 2

Respondents who disagreed with Option 3 were asked to state whether they preferred Option 1 or Option 2. The results are shown in Table 2, along with the proportion who agreed with Option 3. No one option was agreed with by a majority of respondents.

The relatively large number of responses (18% of all responses and 29% of individually formulated responses) that were categorised as ‘Other / None’ included alternative proposals for saving money as well as responses that offered observations or questions but did not comment on any of the three options.

Comments recorded at the listening events were generally most favourable in response to Option 1, although a number of positive comments were recorded about Option 3.

<table>
<thead>
<tr>
<th></th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Other / None</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>All respondents</td>
<td>154</td>
<td>79</td>
<td>112</td>
<td>78</td>
<td>423</td>
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<tr>
<td>Individually developed responses</td>
<td>51</td>
<td>28</td>
<td>112</td>
<td>78</td>
<td>269</td>
</tr>
</tbody>
</table>

Table 2: Agreement with the three options

1.3 Key issues

1.3.1 Patient issues: safety, confusion and compliance

Although the DH consultation document said that ‘drugs where there are any general clinical or patient safety concerns with regard to interchange between different manufacturers’ products could be specifically not included in the list,’ many respondents were not reassured by this, and were concerned that some substituted generic medicines might not be ‘true’ equivalents of the branded medicine.

Both individuals and organisations said that many patients would be worried or confused about a change in the appearance of their medication and might fail to take substituted drugs as prescribed. It was also observed that patients on long-standing renewable prescriptions might be prescribed a branded drug at a time when that drug was not on the select list. If the drug was later added to the select list, the patient could be dispensed a generic when their prescription was refilled – without their doctor’s awareness.

A large group of respondents, including patients, carers and epilepsy charities, were specifically concerned about the potential effects of substitution of anti-epileptic drugs (AEDs). The DH’s consultation document mentioned AEDs as not suitable for substitution, but respondents were concerned that AEDs could be added to a generic substitution scheme in future unless they were legally protected by being placed on a list of drugs that were permanently excluded from substitution. Many of these responses were very personal, and
respondents shared stories of situations in which a change in brand precipitated a negative reaction that had ‘devastating effects’ on their life or that of a family member.

1.3.2 Practitioner issues: workload, control and relationships

The principal issue identified for practitioners was the time required by prescribers and dispensers to counsel and advise patients who were worried or confused by the change in their medication. There were also concerns about the time required for practitioners to familiarise themselves with a changing list and to assess whether patients should be opted out of generic substitution. Many respondents were not reassured by what the DH had to say in the consultation documents about achieving a balance that would not create a significant increase in workload, and many said that the DH had significantly under-estimated the burden.

It was suggested that additional issues for practitioners would include:

- Prescriber control: a generic substitution scheme, even with mechanisms to safeguard prescriber autonomy, would undermine the prescriber’s control over patient treatment;
- Relationships and communication: generic substitution would cause a general loss of trust among patients, doctors and pharmacists;
- Human error: GPs might not always remember to opt patients out of generic substitution when they intended to, leading to inappropriate substitution.

1.3.3 Industry and business issues: generic appearance, innovation and stock control

Many respondents noted that patient compliance with substituted medicines can be improved if the substituted drug is similar in appearance – size, shape, colour, smell, texture, packaging – to the original drug. It was suggested that a generic substitution scheme would be more acceptable if manufacturers were required to make their products similar in appearance to the branded drugs they were emulating.

A number of professional bodies and pharmaceutical companies expressed concern that generic substitution would decrease the viability of the UK pharmaceutical industry and reduce the level of innovation in new or improved medicines.

Generally, there was a concern about how the timing of updates to the select list would affect manufacturers’ production and stock lists. If the timing was too short, some suggested, manufacturers might be caught with a large amount of un-sellable stock. Alternatively, they might reduce production in anticipation of a medicine being added to the select list – resulting in market shortages if it was not then added to the list.

1.4 Implementation and impact: Questions 2-9

1.4.1 Overview

Many respondents did not address Questions 2-9, which asked for respondents’ opinions about the implementation and impact of Option 3. 169 respondents (62% of individually formulated responses and 40% of all responses) specifically addressed one or more of these questions.

However, a larger number wrote about costs and benefits in response to questions across the consultation, and not only in response to Question 8. In total, 192 individually formulated responses, and 103 responses using a campaign template, addressed the issue of costs and benefits.
1.4.2 Views on the select list (Questions 2-6)

a. Identifying products for generic substitution

62% of those who answered Question 2 agreed that using rINNs and BANs and requiring the generic to be in the same pharmaceutical form as the named product was the best way to identify products that would be subject to generic substitution, although some suggested that clarification was needed about pharmaceutical form and product strength.

In Question 3a, the proposed definition of ‘generic equivalent’ was largely supported by NHS organisations and LPCs and opposed by the pharmaceutical industry and trade and professional bodies. Overall, 48% of those who answered the question agreed with the proposed definition. Opinion was divided on the question of what drugs could be shown to be ‘truly’ equivalent, and on whether salts should be substitutable.

Question 3b asked whether the proposed wording for the rubric of NHS prescriptions delivered the definition effectively. 55% of those who answered agreed that it did, though concerns were raised about the perceived complexity, ambiguity and length of the wording.

b. Creation and maintenance of a select list

In Question 4a, opinion was divided on whether a select list of just under 40 rINNs and BANs, amended no more than four times a year, was the right balance between flexibility and workability: 36% agreed and 32% disagreed. Opinion was much more unified among those who answered Question 4b, where 77% agreed that a list and its amendments should be published in the Drug Tariff.

In answer to Questions 5 and 6 on the criteria for the select list and the proposed contents of the initial select list, many respondents suggested that generic substitution would be acceptable only with two restrictions. First, there was a strong feeling that any generic substitution plans should include a list of drug types that could never be added to a substitution list. Second, many types of stakeholders suggested that any changes to the select list should be subject to consultation – either open-ended public consultation, or consultation with specific interested parties including patient groups and charities, manufacturers, GPs, and pharmacists.

1.4.3 Exclusion of dispensing doctors and appliance contractors (Question 7)

64% of those who answered this question disagreed with excluding dispensing doctors. Respondents cited three main reasons for their disagreement:

- Patients of dispensing doctors would be at an unfair advantage in their access to branded drugs
- Community pharmacies would be disadvantaged because patients would seek out dispensing doctors
- Excluding dispensing doctors would erode the cost savings of a generic substitution scheme.

1.4.4 Cost effectiveness (Question 8)

There was considerable scepticism from all types of respondents about the cost-benefit calculations presented in the DH’s Partial Impact Assessment. Of those who answered the question, 55% disagreed with the DH assessment of costs and benefits, while 11% agreed. 12% said they were not able to assess the DH’s calculations. 22% of responses were marked as ‘other,’ including a number who agreed with the principle of cost savings, as long as they could be made without harming patients. Specific concerns included:

- **Savings will be smaller than the DH assessment:** Many respondents asserted that the generic prescribing rate in the UK is already very high and that almost all the prescribing of brands is done intentionally. Some specifically disagreed with the statement in the DH Partial Impact Assessment that savings from generic substitution could increase as more branded medicines come off patent, saying that efforts by PCTs’ Medicine Management teams to promote generic prescribing could save just as much money as a generic substitution scheme.
• **Costs will be higher than the DH assessment:** Many also disagreed with the DH estimate of costs, saying that the costs of additional GP and pharmacist time, PCT involvement, ineffective treatments, wasted medicines, changes to IT systems, and potential market shortages of particular drugs had not been adequately assessed.

• **Cost of adverse reactions:** Both individual and organisational respondents noted that if a patient had an adverse reaction as a result of generic substitution, the additional cost could far outweigh the savings of generic substitution. A large number of respondents queried whether the prescriber or the dispenser would bear legal liability for adverse reactions.

• **More evidence required:** Some respondents said more evidence was needed to support the DH’s estimate of costs and benefits, including evidence that the opt-out rate would indeed be around 50%, and evidence about what portion of the ‘missing 5%’ (the 5% of prescriptions written for brands when a generic was available) was truly suitable for substitution.

There was considerable debate and confusion over what should be supplied when a brand or ‘branded generic’ medicine is cheaper than the related brand. The DH Partial Impact Assessment said that a generic may actually be cheaper for the NHS in the long run even if its reimbursement price is higher, as a result of the mechanism for the community pharmacy contractual framework funding. However, tension was apparent between the local level, where prescribing cheaper brands can make significant savings for individual PCT budgets, and the national level, where prescribing ‘more expensive’ generics can actually result in savings for the NHS as a whole. About twice as many respondents argued for branded prescribing on cost grounds as those who argued against it.

1.4.5 **Equality risks and opportunities (Question 9)**

Question 9 asked about risks to equality and opportunities to promote equality. 76% of those who answered said that generic substitution did pose equality risks to groups including:

• Those who might be confused about drug changes, including the elderly, learning disabled, mental health patients, non-English speaking patients, and those with low levels of ‘health literacy’

• Those who would find certain excipients unacceptable, including vegetarians, vegans and members of some faith groups.

Very few respondents said there were opportunities to promote equality in any of the options.

1.4.6 **Alternative proposals for cost savings**

a. **Generic prescribing: Medicines Management and software-driven solutions**

A number of organisations noted that generic prescribing has risen over the last several years, and said that this showed how effective the current approach was in promoting the cost-effective use of generic medicines. They suggested that continuing to encourage generic prescribing through PCTs’ Medicine Management teams and through the use of GP IT systems would result in all the cost savings of a generic substitution scheme, with none of the risks to patient health, practitioner workload, or costs of implementation.

b. **Other alternative plans**

Other proposals for cost savings included:

• Limiting the degree to which prescribers could opt patients out of generic substitution, and requiring patients to pay a top-up fee if they wished to receive a branded medicine without clinical need

• Making an 0.4% decrease via PPRS of the price paid by the NHS for branded medicines, or cancelling the price increases scheduled under the PPRS for 2011-2013
• Using pharmacies to provide a ‘prescribing intervention service’ to alert GPs about generics that become available.

1.4.7 Responses about the consultation

Some respondents, especially private individuals, noted that they found the DH consultation on generic substitution difficult to understand, because of the technical nature of the questions. A few suggested that separate consultations should be held for interested laypeople, including patients and patient representatives, and for medical practitioners and the pharmaceutical industry.

There were some suggestions that the consultation was not ‘fair’ because the questions were geared toward the DH’s preferred Option 3, and this made it difficult for respondents to comment fully on Options 1 or 2.
2 INTRODUCTION

2.1 Generic Substitution: the policy background

The NHS expects to be required to identify £15-20bn of efficiency savings by the end of the 2013-14 year in order to deliver improvements in quality of care. One of the areas in which the DH hopes to find savings is in spending on branded prescription medicines, which costs the NHS around £9bn a year. As the number of prescriptions increased consistently over the last decade, this expenditure is expected to increase if no steps are taken to change the trend.

The Department of Health is working to target spending on pharmaceuticals through, among other initiatives, the Pharmaceutical Price Regulation Scheme (PPRS) 2009, a voluntary scheme negotiated between the DH and the Association of the British Pharmaceutical Industry (ABPI). The PPRS aims to reduce NHS expenditure on branded medicines by an average of 5% each year over the next five years. In addition to setting price levels for branded medicines, the PPRS makes provision for introducing generic substitution, subject to discussion with affected parties.

In making its case for generic substitution, the DH said that generic prescribing not only saves money, it also increases flexibility for dispensers and, by using drug names rather than proprietary brand names, it helps health professionals to understand their patients’ treatment needs better.

In 2008, 83% of prescription items were prescribed generically, but 5% were prescribed by brand where the drug concerned was available as a generic. This 5% is the key target for generic substitution.

The proposed generic substitution scheme would apply in England, though not in Wales, Scotland or Northern Ireland.

2.2 About the Department of Health Generic Substitution consultation

Between January – March 2010, the DH consulted stakeholders on the proposed changes. It asked stakeholders to respond to three options:

- Option 1: to do nothing
- Option 2: to introduce dispensing flexibility but with specific exclusions, so that the arrangements do not apply to a selected group of products on an exempt list
- Option 3: to introduce dispensing flexibility but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list.

The DH’s preferred option was Option 3, on the grounds that it provided the best balance between cost savings and manageability.

The DH provided a consultation document giving information about the three options, plus a Partial Impact Assessment on the costs, benefits and equality issues.

2.2.1 Written consultation

In the written consultation, stakeholders were asked to complete a questionnaire of 10 questions, comprised of five sections:

- Question 1 asked if the respondent agreed with the DH that Option 3 was the preferred option; if so, to comment on workability; and if not, to state a different preferred option.
- Questions 2-6 dealt with the options for implementation of Option 3.
- Question 7 dealt with the scope of the proposals.
• Questions 8-9 discussed the costs, benefits, and equality issues that were presented by the DH in the Impact Assessment.

• Question 10 asked for any further comments.

The DH also accepted written responses in the form of letters or submissions that did not use the questionnaire format.

2.2.2 Listening events

The DH conducted five listening events in March, which were attended by patients, patient representatives, PCT staff, pharmacy contractors, the pharmaceutical industry and media personnel. Delegates were asked to undertake two tasks: an options analysis and preferences on implementation.

In the first task, each table group of 4-8 people produced a flip chart divided into six sections for each of the three options, where the six sections related to the ‘six thinking hats’ of facts, feelings, critical judgment, optimism, creativity, and the big picture. In the second task, each table produced one flip chart sheet in response to a series of questions on what implementation might look like.

All the comments recorded on the flip charts were compiled in a report on the listening events.

2.3 Respondents

2.3.1 Types of respondents

423 organisations and individuals responded in writing to the consultation. The majority of written responses to the consultation came from private individuals, many of whom responded with specific concerns about the effect of generic substitution on their own treatment or that of a family member.

Many of the responses from private individuals came from two identifiable campaigns:

• 51 responses used a template for a campaign initiated by Epilepsy Action, and more responses clearly drew on the issues raised by the Epilepsy Action campaign, although they did not use the same template.

• 103 responses used a template for a campaign initiated by LIVErNORTH.

Other individuals responded based on professional expertise, including doctors, community and hospital pharmacists, and academics.

Organisations responding to the consultation included pharmaceutical companies, NHS organisations, patient groups, third sector organisations, and professional bodies.

269 responses were individually developed rather than using a campaign template. Of these, 170 were submitted by organisations and 99 by individuals.
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<thead>
<tr>
<th>Respondent type – written responses</th>
<th>Number of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical company</td>
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</tr>
<tr>
<td>NHS organisations</td>
<td>33</td>
</tr>
<tr>
<td>Local pharmaceutical committee (LPC)</td>
<td>26</td>
</tr>
<tr>
<td>Third sector</td>
<td>21</td>
</tr>
<tr>
<td>Professional and/or regulatory body</td>
<td>15</td>
</tr>
<tr>
<td>Community pharmacy</td>
<td>12</td>
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<tr>
<td>Trade body</td>
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</tr>
<tr>
<td>Other organisation</td>
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</tr>
<tr>
<td>Epilepsy patient or carer</td>
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</tr>
<tr>
<td>Doctor</td>
<td>15</td>
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<tr>
<td>Individual pharmacist</td>
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</tr>
<tr>
<td>Other individual</td>
<td>34</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>269</strong></td>
</tr>
</tbody>
</table>

**Table 3: Respondent types among individually developed responses**

**a. Detail on organisation types**

Among the categories listed in the table above:

- **Third sector organisations** included charities focused on medical conditions including epilepsy, stroke, incontinence, cancer, brain injury, asthma and respiratory conditions, diabetes, renal conditions, liver conditions, and heart conditions. It also included charities working for the elderly and for mental health patients.

- **Professional and regulatory bodies** included medical royal colleges and organisations representing and regulating practitioners in dentistry, transplantation, dermatology, general practice and pharmacy, among others.

- Most of the **trade bodies** represented pharmaceutical companies or community pharmacists.

- Pharmacists and pharmacies contributed to the consultation as three different respondent types:
  - **Local Pharmaceutical Committees (LPCs)** were groups that represented all NHS pharmacy contractors in a particular area
  - **Community pharmacies** included both large pharmacy multiples with regional or national presence, and smaller community pharmacies
  - **Individual pharmacists** identified themselves as pharmacists, but made it clear they were responding as individuals, not as representatives of organisations. Some of these individuals worked as advisors within PCTs, some within NHS hospitals, some in community pharmacies, and some did not identify an employer.

- **NHS organisations** included PCTs, NHS hospital trusts, and specialist NHS divisions such as Prescription Services, Primary Care Commissioning and the Counter Fraud and Security Management Service.
A complete list of organisations that contributed to the consultation, through written responses or listening events or both, is included in an appendix. To protect privacy, individual respondents have not been identified by name in this report.

2.3.2 Response types

Of the individually developed written responses, 176 were submitted using only the questionnaire developed by the DH. An additional 22 used the questionnaire but also sent their own letters or accompanying documentation. 71 respondents did not use the DH’s questionnaire for their response, submitting ‘free form’ letters, emails, or documentation. 208 were sent via email, and 61 in hard copy.

The 51 Epilepsy Action campaign responses and the 103 LIVErNORTH campaign responses were all submitted by hard copy, and both followed their own format rather than the DH’s questionnaire format.

2.3.3 Level of detail of responses

Written responses ranged from emails of one or two short paragraphs to extensive and detailed documentation. It should be noted that respondents engaged with the DH’s consultation document and Partial Impact Assessment to widely varying degrees. These documents were 27 pages and 14 pages long, respectively, and the consultation document says they were written for a target audience of ‘PCT CEs [Primary Care Trust Chief Executives], SHA CEs [Strategic Health Authority Chief Executives], Medical Directors, Directors of Finance, Patients, Prescribers and Dispensers in primary care, Pharmaceutical industry, Voluntary groups representing patients.’

Some stakeholder organisations had clearly read and studied them closely, and responded in extensive detail, point by point, frequently quoting from the DH documents. Equally, many respondents, including some organisations and most individual respondents, made comments and raised concerns about generic substitution in general, or about the potential impact of generic substitution on a particular medical condition, without referring to the consultation documents.

2.3.4 Listening events

The listening events were attended by 107 people, representing 81 organisations and nine individuals. (Some organisations were represented by more than one delegate.)

<table>
<thead>
<tr>
<th>Respondent type – listening events</th>
<th>Number of respondents</th>
<th>81 organisations (some represented by more than one delegate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical company</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Community pharmacy</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Trade body</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Media and PR companies</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Patient groups and third sector</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Local pharmaceutical committee (LPC)</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Other organisation</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Individuals</td>
<td>10</td>
<td>9 individuals</td>
</tr>
<tr>
<td>Total</td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Respondent types among delegates to the listening events
2.4 Analysis of responses: methodology

Greenstreet Berman, an independent social research company, was appointed to analyse the responses on behalf of the DH following a competitive tender process run by the Central Office of Information (COI) in April 2010. The analysis was undertaken between May and July 2010. Briefly, the methodology used was as follows:

- We read all the responses and broke them into ‘representations,’ where each representation is a comment on a different theme or issue. Each representation was tagged with a theme and a sub-theme, such as ‘Theme = Patient Issues; sub-theme = Patient Non-compliance’ or ‘Theme = Practitioner issues; sub-theme = Workload’.

- The list of themes and sub-themes was developed and revised across the period of analysis in order to best reflect the actual content of the responses. We created a codebook and database to help our team of analysts work consistently.

- Each response, broken into its component representations, was entered into the database. A daily process of quality control helped to ensure accuracy.

- All the comments from the listening events were entered into a similar database and tagged with themes and sub-themes.

- After all the responses were entered in the database, we carried out counts and read all the comments on each theme in order to create this report.

Throughout this document, numbers of respondents or numbers of comments relate to individually developed written responses to the consultation. The responses of delegates at the listening events and the campaign responses are represented in the text. Where relevant, we have contextualised responses so that it is clear where respondents stood in relation to the DH’s consultation document and Partial Impact Assessment.
3 VIEWS ON THE IMPLEMENTATION OPTIONS

3.1 Question 1: Is the preferable implementation approach Option 3?

<table>
<thead>
<tr>
<th>Question 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) In general do you think that the preferable implementation approach is indeed Option 3, with opt-out endorsement, i.e. allowing the dispenser flexibility as to which manufacturer’s product to supply if a product is listed unless the prescriber specifically opts out?</td>
</tr>
<tr>
<td>(b) If so, do you have any particular comments regarding its workability for patients, prescribers and dispensers?</td>
</tr>
<tr>
<td>(c) If not, why not – what is your preferred approach – Option 1/2/3, opt-in/opt-out, tickbox / endorsement or other?</td>
</tr>
</tbody>
</table>

3.2 Question 1a: Views on Option 3

3.2.1 Overview

The majority of responses to the written consultation disagreed that the DH’s preferred option – Option 3 with opt-out endorsement – was the preferred implementation approach. This is shown in the ‘All responses’ row of Table 5.

If we distinguish (in the bottom row of Table 5) between individually developed responses and those that are duplicate or near-duplicate campaign letters – treating each campaign template as a single response – there were almost the same number of respondents who agreed with Option 3 and those who disagreed.

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
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<td>112</td>
<td>117</td>
<td>40</td>
<td>269</td>
</tr>
</tbody>
</table>

Table 5: Do you think the preferable implementation approach is Option 3?

3.2.2 Points of view on Question 1 by respondent type

Table 6 shows the number of respondents of each type and their points of view on Question 1 of the consultation, ‘In general do you think that the preferable implementation approach is indeed Option 3, with opt-out endorsement, i.e. allowing the dispenser flexibility as to which manufacturer’s product to supply if a product is listed unless the prescriber specifically opts out?’

Where more than half of respondents were in favour of Option 3, this is shaded in green; where more than half were opposed, this is shaded in orange; and where opinion was balanced this is shaded in yellow.
Table 6: Respondent types and points of view on Option 3 among individually developed responses

In general, then, Option 3 was supported by NHS organisations, individual doctors, and a number of other organisations. It was generally opposed by LPCs, individual pharmacists, trade bodies, and epilepsy patients and carers. Across other types of respondents, opinion was more evenly divided.

### 3.3 Questions 1b and 1c: Views on Options 1 and 2

Among those who disagreed with Option 3, some said they preferred Option 2 or Option 1. Among all respondents, the largest number agreed with Option 1. Among individually developed responses, the largest number preferred Option 3.

Table 7: Agreement with the three options

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2 Among trade bodies representing pharmacists and pharmacies, the majority of opinion was against Option 3. Among trade bodies representing pharmaceutical companies, opinion was more evenly divided.
The responses categorised as ‘other’ did not choose any of the three options. They included responses requesting that particular drugs be excluded from any substitution scheme, detailing personal stories about bad experiences with substitution of drugs, questions of clarification, and lists of concerns the respondents felt would need to be addressed if a generic substitution scheme were to go ahead.

3.4 Agreement with Option 1 – do nothing

3.4.1 Broad-based responses

Among the 51 individually developed responses that agreed with Option 1 were many different types of respondents, including pharmaceutical companies, pharmacists and community pharmacies, professional associations, NHS organisations and private individuals. Reasons given for promoting Option 1 included:

- The savings to be achieved by generic substitution would be small, and would be outweighed by negative impacts on patient wellbeing, additional workload on prescribers and dispensers, and the cost and inconvenience of implementation and ongoing maintenance of the scheme
- A preference for using the existing infrastructure: ‘Increases in generic prescribing would be better achieved through a continuation of the current initiatives designed to promote generic prescribing,’ in the words of the British Medical Association
- Patients would be confused by generic substitution, which could result in an increase in non-compliance with treatment
- The risk of error associated with generic substitution was too high.

3.4.2 LIVErNORTH campaign

103 responses that used the LIVErNORTH campaign template objected to automatic generic substitution in any form. Although they did not use the phrase “Option 1”, that option was clearly the preference for this group of respondents. Their objections were four-fold: that the cost of adverse patient reactions would outweigh any savings; that generic substitution was not in the best interest of patients; that implementation would be problematic; and that it was unclear who would bear legal liability for errors.

3.4.3 Listening events

At the listening events, 226 comments were recorded on Option 1, with a large number of positive comments. Supportive delegate comments included:

- If it ain’t broke, why fix it?
- Prescribers can prescribe generic already
- Only option that is patient focused
- Stakeholder satisfaction
- No risk to patients, prescribers, dispensers
- Clinical freedom remains without inventing a new system to complicate things
- It works.
3.5 Agreement with Option 2 – generic substitution with an exempt list

3.5.1 Epilepsy Action campaign

Those respondents who drew on an Epilepsy Action campaign letter suggested Option 2 as the preferred option. This included 51 responses that followed the campaign template very closely. In addition, 14 of the 28 individually developed responses that supported Option 2 expressed concern about the substitution of anti-epileptic drugs (AEDs).

However, this group’s support for Option 2 was not based on a desire to see generic substitution widely implemented; quite the opposite. These respondents strongly opposed generic substitution of AEDs and thought that the best way to ensure that AEDs were exempt from generic substitution was to specify these drugs on an exempt list.

3.5.2 Broad-based responses

A smaller group of respondents who supported Option 2 on other grounds felt that it would be the best way to move large numbers of patients from branded to generic medicines and to avoid patient pressure on GPs to opt out of substitution and dispense the brand. Some also felt that Option 2 would be a more straightforward approach than Option 3 and would not require practitioners to explain why some drugs can be substituted while others cannot.

3.5.3 Listening events

At the listening events, 253 comments were recorded on Option 2. Many of these were questions of clarification about how the list would be created and maintained. Of the very few positive comments that were made about Option 2, almost all of them were about the savings that could be achieved through a broad generic substitution scheme.

3.6 Agreement with Option 3 – generic substitution with a select list

Many of those who supported the DH’s preferred option, Option 3 – generic substitution using a select list with prescriber opt-out – were NHS organisations and individual doctors. Option 3 was also supported by some pharmaceutical companies, professional bodies, charities and other individuals.

Much of the support for Option 3 was on the grounds that it was a good balance between making cost savings and being workable. There was a strong feeling among a number of medical professionals that many brand prescriptions are written because of patient pressure to prescribe the brand (which patients may perceive as being of higher quality), and not because of clinical need – and that generic substitution would help.

Many of those who agreed with Option 3 did so with reservations. These included:

- A concern about which medicines are acceptable for generic substitution
- A desire that a patient who is moved onto a generic drug should receive that same generic brand for any long-term treatment
- A need for prescribers and pharmacists to allay patient concerns about switching to a generic.

Very few respondents engaged with the question of whether the opt-out should take the form of a tick-box or an endorsement; almost without exception, those who did address this question said that it should be an endorsement in order to make it difficult to tamper with the prescription.
3.6.1 Listening events

350 comments were recorded at the listening events about Option 3. Although most comments on Option 3 were negative or sceptical, there was some support for this option. Positive comments included:

- Easier to administer than Option 2
- Potentially save money for NHS
- Support pharmacists being seen as healthcare professionals
- List gives greater clarity for all provided it doesn’t change too often
- Would achieve savings in a targeted way and a workable system.
4 KEY ISSUES

Across the consultation and across all points of view, respondents raised concerns about the following seven issues. Those who disagreed with Option 3 cited these issues as the reasons for their disagreement; those who agreed often qualified their response with a comment such as, ‘We agree with Option 3, but we have concerns about…’

The key issues were:

- Patient issues: The impact of generic substitution on patient safety and wellbeing
- Cost: The cost effectiveness of generic substitution in the model of Option 3
- Practitioner issues: The effects of generic substitution on GP and pharmacist workloads and relationships
- Implementation: Drugs to exclude or include; administration of the list and consultation on the list; how to publicise and monitor the scheme
- Industry and business issues: Impact on the pharmaceutical industry or actions to be taken by the industry
- Legal and ethical concerns: Legal liability and similar issues
- Alternative proposals.

These themes are discussed here, except cost effectiveness, which is discussed under Question 8; and implementation, which is discussed under Questions 2-6.\(^3\)

\(^3\) Although the DH’s consultation questionnaire provided a separate question for ‘further comments,’ many respondents discussed wide-ranging issues, including issues outside the immediate scope of the consultation, under Question 1. In addition, respondents who did not use the DH’s consultation questionnaire but instead wrote ‘free form’ comments did not assign their comments to any particular question. For these reasons, in this Key Issues section of the report we have made a single tally of comments on these issues, including comments made specifically in response to Question 1, comments made specifically in response to Question 10, and comments made as part of a ‘free form’ response.

All the tables in this Key Issues section count comments from individually formulated responses, treating campaign letters as a single response. Where the campaign letters touch on a particular issue, this is discussed in the text.
4.1 Patient issues

4.1.1 Overview

The number of comments by theme is noted in Table 8.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient safety and wellbeing</td>
<td>83</td>
</tr>
<tr>
<td>Epilepsy drug patient safety concerns</td>
<td>53</td>
</tr>
<tr>
<td>Patient confusion, anxiety and non-compliance</td>
<td>51</td>
</tr>
<tr>
<td>Consistency of dispensed medicines and repeat prescriptions</td>
<td>22</td>
</tr>
<tr>
<td>Other</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>225</td>
</tr>
</tbody>
</table>

Table 8: Comments on patient issues

4.1.2 Patient safety and wellbeing

The overall issue of patient safety was one of the most frequently addressed in the course of the consultation. The DH consultation document said, with regard to Option 3, ‘Drugs where there are any general clinical or patient safety concerns with regard to interchange between different manufacturer’s products could be specifically not included in the list.’ However, many respondents said that generic substitution, even with a limited list, posed a threat to patient safety.

The comments categorised under the theme ‘patient safety and wellbeing’ were general and wide-ranging. Many of these comments simply said that drug substitution would put patients at unnecessary risk. Some refined their concerns by saying that substitution of particular categories of drug, substitution for certain indications or substitution for certain vulnerable groups of patients would be risky. Comments about the risks of confusion, non-compliance, repeat prescriptions and multiple medications were categorised separately. The risks associated with substitution of anti-epileptic drugs (AEDs) were also categorised separately.

4.1.3 Epilepsy drug patient safety concerns

A large group of respondents wanted to ensure that anti-epileptic drugs (AEDs) would be excluded from generic substitution. The DH’s consultation document twice briefly mentioned AEDs as being unsuitable for generic substitution, and did not include AEDs in the initial ‘proposed list of products for which substitution arrangements are permissible.’ However, several epilepsy organisations and many individuals were not reassured by this. They expressed strong concern that AEDs might become subject to generic substitution in the future, even if they were not included in the select list at the start of the scheme. They cited the DH’s consultation document, which said, ‘It is not intended that the Department will publicly consult on the amendments to the list in order that it can quickly be amended to reflect the market,’ as evidence for their concern that ‘AEDs could be added to a substitution list without warning or further discussion’.

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Respondents who were concerned about AEDs spoke of the serious threat to patient safety they believed was posed by changing from one AED to another. Small differences in absorption between one brand and another, for example, can have significant effects. Three epilepsy charities – Epilepsy Action, the Joint Epilepsy Council and National Society for Epilepsy – provided detailed evidence for the danger of substituting AEDs, while many people with epilepsy and carers of people with epilepsy spoke in the strongest terms about the potentially ‘terrible’, ‘life changing’ and ‘catastrophic’ effects of changing from one AED to another. They noted that loss of seizure control can result in short-term emergency hospitalisation, and in the longer term, a loss of job and driving license, disability and even death.

In addition to the individually formulated comments, the 51 respondents who used the Epilepsy Action campaign template said, ‘I am concerned that anti-epileptic drugs would be allowed to be substituted. There is strong evidence that brand switching for many people with epilepsy has caused breakthrough seizures, worsening of their seizure control or worsening of side-effects.’

Respondents called for a formal commitment to exempt AEDs permanently from generic substitution, and a mechanism for consultation on any additions to the list.

4.1.4 Patient confusion, anxiety and non-compliance

A large number of respondents said broadly that generic substitution would cause confusion and anxiety for many patients, especially the elderly, those with learning disabilities, and those whose first language was not English. (Other vulnerable groups are discussed in relation to Question 9). It was said that patient confusion would lead to a significant additional workload for GPs and pharmacists who would need to reassure patients and explain the changes, and that it would lead to non-compliance.

Many noted the importance of consistency of colour, shape, size and packaging in helping prevent confusion over drug changes. For example, the Royal College of General Practitioners said, ‘We feel there is a potential issue that generic substitution may have an impact on patient compliance – we know that many patients complain when the colour and shape of their medicines change. There should be research into this before government takes steps that may increase this tendency.’ The topic of generic appearance is discussed further in Industry and Business Issues, below.

A small number of pharmaceutical companies who produce topical medicines said that compliance with topical is often affected by the smell, texture, and means of application of the medicines, which differs from one manufacturer’s product to another.

4.1.5 Consistency of dispensed medicines and repeat prescriptions

A number of respondents noted that the problems associated with changing from brand to generic or changing from one generic to another were particularly acute for patients with long-term conditions. They said that the real issue was consistency of provision of a particular manufacturer’s product. The National Pharmacy Association said, ‘Some patients suffer from either an increase in side-effects or a decrease in effect with some brands. Even if these are only perceived effects they are very real to the patient and may lead to reduced compliance.’

Similarly, NHS Derbyshire County said, ‘Changing a patient’s medication without full consideration of all factors can significantly affect their concordance. Under Option 2 and 3 patients are likely to be changed on an ad hoc basis and this may differ from one prescription to the next.’

It was also observed that patients on long-standing renewable prescriptions might be prescribed a branded drug at a time when that drug was not on the select list. If the drug was later added to the select list, the patient could be dispensed a generic when their prescription was refilled – without their doctor’s awareness. They said that, if the select list changed on a quarterly basis while many medicine reviews are held annually, it would be almost impossible to identify and intercept repeat prescriptions where substitution might be an issue. They said this could lead to accidental and inappropriate substitution.
4.1.6 Other patient issues

a. Multiple drugs

Patients taking multiple medications were felt to be particularly at risk from generic substitution, since excipients in one drug could interact unexpectedly with another. This could mean that even drugs that are normally suitable for individual substitution are not suitable to be substituted as part of a regime of medicines.

As an example, the National Kidney Foundation said, ‘The management of the drug cocktail for all renal patients is critical. Every day drugs can cause serious side affects for individuals, e.g. antibiotics, blood pressure tablets, and statins can in some cases require careful selection and change for a variety of side effects and interactions.’

It was noted that elderly and disabled patients are particularly likely to be taking multiple medications, and that these groups of patients could be disproportionately affected by generic substitution.

b. Patient records

A small number of respondents said that generic substitution could pose a problem for the accuracy of patient records. For example, Norgine Pharmaceuticals said:

Under the proposals, the prescriber will not know what medicine their patient has received. Currently the prescriber can be confident the patient will receive the medication they have been prescribed. This is important in a situation where, for example, a patient experiences poorer control of his or her illness, or new adverse events. The prescriber would not be aware that they need to consider differences in the bioavailability of a generic as the potentially being the cause of the patient’s problem.
4.2 Practitioner issues

4.2.1 Overview

The majority of individual doctors and NHS organisations supported Option 3, while the majority of LPCs and individual pharmacists opposed it. However, respondents of all types – both those in favour of Option 3 and those against – raised concerns about the potential impact of a generic substitution scheme on prescribers and dispensers. An overview of comments by theme is noted in Table 9.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workload</td>
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<tr>
<td>Prescriber control</td>
<td>44</td>
</tr>
<tr>
<td>Relationships and communication</td>
<td>31</td>
</tr>
<tr>
<td>Human error</td>
<td>26</td>
</tr>
<tr>
<td>Pharmacist flexibility</td>
<td>15</td>
</tr>
<tr>
<td>Prescriber non-compliance</td>
<td>12</td>
</tr>
<tr>
<td>Pressure on prescriber</td>
<td>11</td>
</tr>
<tr>
<td>Other</td>
<td>17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>225</strong></td>
</tr>
</tbody>
</table>

Table 9: Comments on practitioner issues

4.2.2 Workload

The issue of the time required for GPs and pharmacists to implement generic substitution was seen as one of the major issues in the consultation. Respondents said additional time would be needed:

- By both GPs and pharmacists to familiarise themselves with changes in the list
- By GPs to assess whether particular patients should be opted out of generic substitution
- By GPs to physically endorse prescriptions
- By both GPs and pharmacists to explain changes to patients
- By both GPs and pharmacists to communicate with each other to clarify particular cases, such as situations in which a prescriber intended to opt out but forgot to endorse the prescription
- By GPs to see patients who were worried about the changes or were not satisfied with the substituted drugs
- By pharmacists to fill replacement prescriptions

Dermal Laboratories quantified some of these effects on GPs:

These allocations of time, multiplied by millions of GP/Patient interactions, may be hard to quantify, but they are certainly not “expected to be negligible” as asserted in the Impact Assessment. At an assumed rate of 50% of the estimated 3.5 million affected scripts, they could be highly significant. If only 1 minute of extra time were needed per consultation/prescription, this would equate to more than 29,000 GP hours (or more than £2m, using a very conservative
estimate of £70 per hour). More likely, given the need to give careful consideration to patients’ histories and sensitivities, this might be nearer to 5 minutes, on average, equating to 146,000 GP hours (or £10m). Furthermore, these estimates completely ignore the fact that in practice prescribers will have to consider these issues for a much larger proportion of their patients than the actual percentage that they determine to opt-out (estimated for the above calculations as 50%). In any event, these figures are in stark contrast with the Impact Assessment’s assertion that the time devoted would be “negligible”, for which reason it “has not been monetised”.

4.2.3 Prescriber control

The importance of prescriber control and autonomy was cited both in favour of and against Option 3. Within the larger group of respondents who agreed with Option 3, a few respondents specifically noted that they were satisfied that the opt-out mechanism was sufficient to maintain prescriber control.

On the other hand, other respondents voiced concerns that generic substitution would undermine prescriber control by making it possible for pharmacists to change patients’ drugs without the prescriber’s knowledge.

The BMA said:

Whilst the BMA supports generic prescribing, we do not support the Department of Health’s proposals to introduce generic substitution. A continuation of the efforts to increase generic prescribing would be preferable, as it would enable prescribers to retain full control of the prescribing decision.

If a doctor has prescribed a branded drug, it is because he / she has made a conscious and deliberate decision to choose the branded product to be prescribed to the patient. For those patients who have been on a repeat prescription for a branded drug for a long period of time, the possibility of switching them to a generic version of their drug should be explored by a Medicines Use Review rather than imposed by generic substitution.

4.2.4 Relationships and communication

Across the consultation, respondents were concerned that generic substitution would negatively affect the relationships among GPs, pharmacists and patients. The National Pharmacy Association said, ‘Generic substitution will have a deleterious effect on pharmacist, doctor and patient relationships. If a GP reviews medication without the patient present or neglects to mention the change the patient is likely to blame the pharmacist for giving them the “wrong” medicine, even when they have had a careful explanation of the process from the pharmacist.’

Similarly, the Royal Pharmaceutical Society of Great Britain said, ‘We are concerned that implementation of either option 2 or 3 could damage relations between general practitioners and pharmacists as pharmacists would be labelled as “accountants of the NHS”, and this at a time when we are encouraging collaboration between healthcare professionals.’

4.2.5 Human error

Respondents were concerned that GPs would forget to opt in or opt out, compromising patients’ treatment or causing an extra burden for GPs, pharmacists and patients to sort out the error.

‘On a practical level, there may be occasions where the intention is to opt-out but the prescriber has not endorsed the prescription. This could lead to inappropriate substitution by the dispenser, confusion and inconvenience for the patient,’ said NHS Westminster.
4.2.6 Other practitioner issues

a. Pharmacist flexibility

A number of respondents were unclear about whether, under Option 3, pharmacists would be required to dispense a generic drug if it was listed on the select list, or if they simply had the option to dispense a generic drug. The suggested prescription rubric in the DH’s consultation documents said, ‘If the drug mentioned in this prescription is referred to by a brand name and the drug is listed in Part VXIID of the Drug Tariff, the prescriber intends that either it or a generic equivalent may be dispensed.’

However, respondents of many different types were unclear on this issue. Boots UK said, ‘As currently outlined, it is unclear whether “dispensing flexibility” is something that community pharmacists will have to do or something they can choose to do. It is not clear whether pharmacies will be penalised financially if they do not make a generic substitution where this might be possible.’

Some believed that under Option 3, pharmacists would be required to dispense the generic. For example, the LIVERNORTH campaign invited supporters to visit the website www.genericsubstitution.com, sponsored by Norgine Pharmaceuticals, which said, ‘Automatic Generic Substitution is a scheme proposed by the Department of Health (DH) whereby pharmacists could be obliged to substitute a generic version… of a medication even if the doctor had written the prescription for a specific brand.’ Similarly, some pharmacists said that generic substitution would put them in an invidious position, as they believed they would be required to dispense the generic instead of the brand.

Based on this belief, some respondents suggested that generic substitution would only be workable if pharmacists could ‘opt out’ as well as prescribers, so that they could provide branded medicines to patients who refused to accept the generic, or to patients for whom the pharmacist was aware the generic drug would be unsuitable.

b. Prescriber non-compliance

There was a risk that busy GPs would simply opt out all the time, a few respondents suggested, undermining any cost savings to be had from the scheme.
4.3 Industry and business issues

4.3.1 Overview

Many (though not all) of those who commented on issues affecting the pharmaceutical industry, pharmacy businesses and drug markets were representatives of these businesses. The main exception was the issue of generic appearance, which was raised as an issue by several types of respondents.

Among pharmaceutical companies, opinion was divided, with about as many agreeing with Option 3 as disagreeing.

An overview of comments by theme is shown in Table 10.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic appearance</td>
<td>22</td>
</tr>
<tr>
<td>Investment and innovation</td>
<td>19</td>
</tr>
<tr>
<td>Pharmacist pay and remuneration</td>
<td>16</td>
</tr>
<tr>
<td>Security of drug supplies</td>
<td>16</td>
</tr>
<tr>
<td>Concern for small pharmaceutical companies</td>
<td>8</td>
</tr>
<tr>
<td>Other</td>
<td>35</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>116</strong></td>
</tr>
</tbody>
</table>

Table 10: Comments on industry and business issues

4.3.2 Generic appearance

The issue of generic appearance is partly a patient issue and partly an industry issue. As one individual said:

There is a risk of confusion by anyone where generic substitution is used. (Eg) “painkiller B” is the generic name for a medicine. Depending on the manufacturer this could come as varied presentation, possibly even as varied as a blue capsule, a green flat tablet or a pink coated pill…

Most people identify their medicines as “the little blue pills for their breathing” or “the green capsules for their heart” with no reference to their name or formulation. If they always got “a little blue pill” or a “green capsule” and it did the job, the vast majority of people would not be bothered whether it was branded or generic.

Although strictly speaking the issue of generic appearance was beyond the scope of the consultation, respondents used the opportunity of the consultation to suggest that generic manufacturers should be required to emulate the appearance of branded medicines in size, shape, and colour and packaging in order to avoid patient and pharmacist confusion. Some were concerned that, unless manufacturers standardised the appearance of generic drugs, a generic substitution scheme would exacerbate the confusion of patients over the change in appearance of drugs that they said already existed with generic prescribing.

Researchers from the Centre for Nursing & Midwifery Research, University of Salford, said, ‘Drugs are made to British and European Pharmacopoeia standards but these do not specify colour, size and shape. The Directive 2001/83/EC of the European Parliament stated that medicines had to be of “essential similarity” but that does not include appearance. Many pharmacists believe that standardisation should not only include size, shape, colour but also packaging.’
4.3.3 Investment and innovation

A number of pharmaceutical companies, trade bodies and professional organisations expressed concern that generic substitution would have a negative impact on the viability of the UK pharmaceutical industry and on innovation in new or improved medicines. Some suggested that impacts could include:

- Reduced investment in R&D
- Companies relocating research facilities in other countries, leading to a loss of scientific skills in Britain
- Reduced viability of the UK pharmaceutical industry
- Companies increasing the cost of branded drugs during their patent period to compensate for reduced profits off-patent.

4.3.4 Pharmacist remuneration and reimbursement

Two distinct issues were raised with regard to pharmacist pay:

- There should be greater clarity on how reimbursement would work for pharmacists under generic substitution. This includes details such as how to deal with market shortages of particular generics
- Since pharmacists would have to invest additional time, energy and expertise into making the substitution, they should be paid an additional sum.

These issues were in addition to the perceived additional workload for pharmacists, which is discussed in the section above on Practitioner Issues.

4.3.5 Security of drug supplies

The current role of branded drugs in helping to ensure security of drug supplies would be undermined by generic substitution, respondents said. The ABPI said:

> The risk of stock shortages has not been addressed in the consultation... When a product is added to the list, it is likely that the branded manufacturer will reduce stock significantly. DH must be satisfied that there is ready-availability of generic equivalents on an ongoing basis to avoid risks of stock shortages. The original branded manufacturer cannot be expected to maintain sufficient supplies to serve the whole market, or to maintain production capacity, after a product has been added to the substitution list.

4.3.6 Concern for small pharmaceutical companies

Several pharmaceutical companies who identified themselves as small, UK-based companies affiliated with EMIG (the Ethical Medicines Industry Group), said that the effect on small pharma companies could be ‘catastrophic’ if a medicine they produced was targeted for substitution, given that a single drug may represent a relatively large portion of a small company’s revenue. They charged that the inclusion of generic substitution in PPRS 2009 suited the large, global pharmaceutical manufacturers represented by ABPI, but not small manufacturers.

An additional concern for several niche pharmaceutical companies was ‘incremental innovation’, the practice by which products are improved with better delivery mechanisms or versions with fewer side-effects. Often, these new products are not able to be patented because they are based on previously existing drugs, but ‘for many patients the benefits of these medicines represent a significant step change in their disease management,’ EMIG said:
Automatic generic substitution is certain to undermine the process of incremental innovation - the development of new, improved treatments by smaller companies, which specialise in niche areas - because incremental innovation so often relies on brands, rather than patents, to identify and protect products. If such companies believe that future prescriptions for their unpatented new formulations will automatically be filled by generics, it will make no sense to incur the risks and costs of development, clinical trials and licensing.
4.4 Legal and ethical concerns

4.4.1 Overview

57 comments were made about legal and ethical concerns, the majority about legal liability.

4.4.2 Liability

Respondents wanted to know who would be liable if generic substitution went wrong. In addition to the comments made in individually formulated responses, this question was raised by the 103 respondents who used the LIVErNORTH campaign template.

Two scenarios were envisioned:

- An error on the part of the prescriber (forgetting to endorse NGS) or dispenser (overlooking the opt-out endorsement) leading to a patient incorrectly receiving a substituted drug
- An unanticipated adverse reaction by a patient to a substituted drug.

The PSNC noted that this potential liability could have an impact on pharmacists’ professional indemnity insurance.

4.4.3 Other legal and ethical issues

a. Pharmacist fraud

The NHS Business Services Authority, Counter Fraud and Security Management Service (CFSMS) described a risk associated with fraudulent dispensing. ‘The main fraud issue in branded/generic prescribing is a risk that pharmacists may dispense a generic product whilst claiming remuneration for a branded one, thus inflating their profits. For this reason, the ‘opt in’ approach is preferable to ‘opt out’: an ‘opt out’ system carries a risk that dispensers may tamper with paper prescriptions, changing them to give the impression that the prescribed item is not to be substituted, then dispensing the generic and claiming reimbursement for the branded product.’

b. Prescription interference

The CFSMS was also among a small number of respondents who said they preferred endorsement to tick-box and agreed with the DH consultation document that a tick-box was more liable to interference either by patients or by pharmacists. The CFSMS said, ‘There is no mention in the consultation documentation of any accompanying counter-signature requirement for endorsements on paper prescriptions. CFSMS would recommend that counter-signatures are included in the process as a counter-fraud measure.’

c. Patient consent

A few respondents mentioned the issue of patient consent. If a patient consents to treatment with a particular medicine, and that medicine is then substituted, it raises the question of whether that patient can be said to have consented to treatment with the new medicine. The Patients Association suggested that the pharmacist would need to obtain the patient’s consent at the point of dispensing. They noted that the issue of consent may need particular consideration for patients who do not collect their own medicines.
4.5 Alternative proposals for cost savings

Some respondents suggested alternative plans for the DH to save money on branded medicines.

4.5.1 Generic prescribing: Medicines Management and software-driven solutions

The most popular alternative proposal was presented as a ‘positive take’ on Option 1: the option to avoid a formal generic substitution scheme and to take advantage of existing infrastructure, but not to ‘do nothing.’

A number of organisations noted that generic prescribing has risen over the last several years. They suggested that it would be most effective to continue to use a ‘carrot’ approach to persuade GPs to prescribe generically, rather than imposing the ‘stick’ approach of generic substitution – an approach that may not be supported by stakeholders.

For example, Discovery Pharmaceuticals said that around 1,000 NHS staff work on medicines management within PCTs, advising GP practices on prescribing, and that this network could effectively achieve a further increase in generic prescribing without the complex implementation required for generic substitution. They also noted that ScriptSwitch software, which is increasingly being used by PCTs, also helps to promote generic prescribing: ‘Within this intervention lay all of the items that GS proposes but without the difficulties and risks.’

Similarly, the BMA said, ‘The BMA would prefer that efforts to increase generic prescribing are focussed on educating prescribers in order to effect long term changes to prescribing behaviour, rather than targeting prescribing at the point of dispensing. One way of achieving this would be via GP IT systems, which could provide tools to educate prescribers by suggesting alternative drugs to GPs, allowing the GP to make the final prescribing decision.’

Some of those who promoted generic prescribing, assisted by prescribing IT systems, called it ‘Option 4.’

The response from the Company Chemists’ Association (CCA) and Association of Independent Multiple Pharmacies (AIMp), said:

The DH should work with the suppliers of prescribing IT systems to ensure that as many drugs as possible are prescribed by their drug name. It is possible to have the facility within a system to translate every branded product into its generic equivalent as it is entered by the prescriber. If a product is entered by its brand name the prescriber would be presented with a choice; prescribe by brand name or prescribe as generic. The prescriber would then be able to control whether the patient received a named brand or unbranded generic.

4.5.2 Limited opt-out and patient top-ups

A few respondents, mostly LPCs, suggested that the scope for opting out of generic substitution should be extremely limited in order to realise the maximum savings through the scheme. Prescribers should only be able to opt out for clinical need. If patients then wished to receive a branded medicine, they should be able to pay a top-up charge.

4.5.3 PPRS price decrease on branded medicines

A small number of respondents who identified themselves as small pharmaceutical companies affiliated with EMIG suggested that the savings could be more effectively gained through a decrease via PPRS of 0.4% in the prices paid by the NHS for branded medicines across the board, or alternatively by cancelling the scheduled price increases for 2011-2013.
4.5.4 A pharmacist prescribing intervention service

The PSNC proposed this alternative plan, in which pharmacists become the lynchpin in supporting and advising GPs:

Pharmacists are ideally placed to identify changes to prescribing practice that could offer benefits to the patient and offer cost savings to the wider NHS. As an alternative to generic substitution, pharmacies could be commissioned to provide a prescribing intervention service. This could involve pharmacies alerting GP practices that a generic is available and prompting GP practice staff to change repeat medication records so that any future prescriptions are issued using the product’s generic title. There is scope for such a support service to have a wider remit than just recommending brand to generic switches, for example in some cases an alternative formulation, a combination of strengths of a product or an alternative dosage regime may be more cost effective or have wider benefits to the health system for example through improved patient compliance and better health outcomes.

4.5.5 Additional cost-savings plans

A few respondents made suggestions of additional ‘simple changes’ they said could result in significant savings without the cost of a formal generic substitution plan. These included:

- Encouraging best purchasing
- ‘Blacklisting’ branded generics
- Repeat dispensing schemes to reduce the amount of medicines wasted.
5 QUESTIONS 2-9: IMPLEMENTATION AND IMPACT

5.1 Introduction

Many respondents did not address Questions 2-9, which asked for respondents’ opinions about the implementation and impact of Option 3. 169 respondents answered one or more of these questions, representing 62% of individually formulated responses and 40% of all responses.

It appeared that reasons for not answering Questions 2-9 included:

- The technical nature of the questions;
- The fact that some respondents wished to raise specific comments or questions only on a particular aspect of generic substitution, such as the potential impact of substitution on a particular medical condition;
- The fact that some respondents who disagreed with Option 3 thought that questions about the implementation and impact of Option 3 were irrelevant.

In addition, a number of respondents, both individuals and organisations, submitted ‘free form’ responses rather than using the DH’s consultation template, and most (though not all) of these responses did not address the issues in Questions 2-9.

The primary exception was the issue of cost effectiveness (Question 8). Many respondents wrote about costs and benefits even if they did not specifically attribute these comments to Question 8, and we have combined comments about cost effectiveness across the consultation in the discussion of Question 8 below.
6 VIEWS ON THE SELECT LIST

6.1 Overview

Questions 2-6 all dealt with aspects of the select list proposed under Option 3 – in particular, how to define generic equivalents and how to create and maintain the select list.

Across the series of questions, some respondents noted that, as they opposed Option 3, these questions were irrelevant. Many of those who answered these questions did so despite opposing Option 3.

Some noted, either in direct answer to these particular questions or in more general comments on the consultation, that these questions were complex and difficult for non-specialists to understand or answer. Most of those who said they lacked the expertise to answer identified themselves as people with epilepsy or carers of people with epilepsy. These responses are recorded below as ‘cannot answer.’ (Responses such as ‘no comment’ are not included in the count.)

6.2 Question 2: rINNs, BANs, and pharmaceutical form

<table>
<thead>
<tr>
<th>Question 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you agree that using rINNs and BANs, and requiring the generic to be in the same pharmaceutical form as the named product, is the best way to identify products that are subject to the arrangements?</td>
</tr>
</tbody>
</table>

6.2.1 Question 2: Overview

An overview is given in Table 11. There was strong agreement with this proposal, with 104 (62%) in accord and 22 (13%) against. Many of those who agreed in principle also expressed reservations or qualified their answers. In fact, many of the concerns were common to both those who agreed and those who disagreed.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
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<th>Total</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>104</td>
<td>22</td>
<td>36</td>
<td>7</td>
<td>169</td>
</tr>
</tbody>
</table>

| Percent            | 62% | 13% | 21%   | 4%            | 100%  |

Table 11: Question 2: Is it best to use rINNs and BANs and require the generic to be in the same pharmaceutical form?

6.2.2 Agreement and disagreement

The concerns expressed by respondents were often similar regardless of whether they said ‘yes’ or ‘no’ to Question 2, or expressed an opinion that was neither for nor against.

Of the 104 who agreed with this proposition, 67 (64%) simply said ‘Yes’ or expressed general support. Others qualified their support with discussion of the themes above.

22 disagreed with the definition. Some of those who said ‘no’ to Question 2 said that rINNs and BANs were too complex. ‘This is far too confusing to explain to patients what we are doing. They will think we are giving them “cheap drugs”’, said a community pharmacy.
The answers from 36 respondents were classed as ‘other,’ neither for nor against. These included:

- General concerns about consistency of medicines, whether branded or generic
- A statement that the question was not relevant, as the respondent opposed Option 3
- Concerns about the complexity of the arrangements and the potential for confusion.

6.2.3 Common areas of concern

a. Alternative pharmaceutical forms

Ten respondents, including six NHS organisations and the Royal Pharmaceutical Society of Great Britain (RPSGB), said that it should not be necessary to require the generic to be in the same pharmaceutical form. The UK Medicines Information Executive said, ‘it would be helpful to the NHS (and of no detriment to the appropriately counselled patient) for a pharmacist to be able to substitute the cheapest formulation (eg a generic capsule even though the branded drug is formulated as a tablet). In some circumstances the potential savings could be considerable.’

One NHS organisation said that specifying the same pharmaceutical form might enable manufacturers to work around the arrangements by creating an off-patent form that was only available under the brand name.

On the other hand, 13 respondents specifically emphasised that the substituted product must be the same formulation as the brand, among the 104 who said they agreed with the definition.

Points of clarification

The PSNC said it was necessary to clarify whether pharmacists would be able to substitute modifications to oral dosage forms including ‘the product being manufactured as colour, gluten, preservative or sugar-free’.

The definition of ‘pharmaceutical form’ itself needed to be clarified, a few respondents said. For example, modified release tablets were considered the same form under the dm+d, even if they released their medicine over a different time span, Cedegim Rx said. NHS Brighton and Hove noted that other aspects such as tablet size and shape, which have an impact on patient experience, would not be covered by the standard definition of pharmaceutical form.

b. Therapeutic equivalence and medicines to exclude

A number of respondents, including a number of private individuals, expressed unease about whether drugs identified by rINNs and BANs were truly therapeutically equivalent. ABPI and some pharmaceutical companies called for substitutable products to be ‘affirmed as therapeutically equivalent by the MHRA.’

Several respondents, both individuals and organisations, noted that AEDs should be excluded from generic substitution.

Some pharmaceutical companies, some charities, and the ABPI suggested additional drugs to exclude that they said were not adequately covered by the proposed method of identifying products subject to generic substitution, including immunosuppressive agents, biosimilars, modified release preparations, topicals, and devices such as inhalers. Asthma UK said that inhalers should be defined by device and drug name, not by rINN and BAN.

c. Additional areas of clarification

Strength

A few respondents asked whether, under Option 3, there would be a requirement for the generic substitute to be the same strength as the branded medicine.
Salts
The PSNC said, ‘If the Department’s third option is adopted, for clarity, the product listing should include the product name, strength and form, permissible salts and any permissible formulation modifications.’

By contrast, the British Generic Manufacturers Association (BGMA) and a number of generic pharmaceutical companies said, ‘Products should be described by rINN, but salts are legally and scientifically equivalent and thus should not be specifically referenced.’

Indications
A few organisations queried how substitution would be handled in cases in which a branded drug is licensed for multiple indications, while the related generic is not. This issue is discussed further under Question 3.

6.3 Question 3: Generic definitions and prescription rubrics

<table>
<thead>
<tr>
<th>Question 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Do you agree with the proposed scope of the definition of “generic equivalent”, to allow for different salts?</td>
</tr>
<tr>
<td>b) Do you think that the proposed wording (see paragraph 56b) to be included within the rubric of NHS prescriptions (electronic as well as manual) delivers the definition effectively?</td>
</tr>
</tbody>
</table>

6.4 Question 3a

6.4.1 Overview

An overview of responses is given in Table 12.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Cannot answer</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
<td>79</td>
<td>47</td>
<td>32</td>
<td>5</td>
<td>165</td>
</tr>
<tr>
<td>Percent</td>
<td>48%</td>
<td>28%</td>
<td>19%</td>
<td>3%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 12: Question 3a: Do you agree with the definition of ‘generic equivalent’?

The definition was largely supported by NHS organisations and LPCs and opposed by the pharmaceutical industry and trade and professional bodies. Those who agreed with the proposed definition included 24 NHS organisations, 18 LPCs, four third-sector organisations, three pharmaceutical companies, and 14 individuals (of whom six were doctors or individual pharmacists).

Those who disagreed with the proposed definition included three trade bodies representing pharmaceutical companies, 15 pharmaceutical companies, four NHS organisations, the Royal College of General Practitioners, the BMA, and four third-sector organisations. Nine individuals disagreed.

The members of the pharmaceutical industry who disagreed with the proposed definition did so for two completely different reasons, as discussed below.

An additional 23 comments on generic definitions were made in answer to other parts of the consultation, and those remarks are incorporated here.
6.4.2 Bioequivalence

Both those who agreed and disagreed with the definition tended to agree on one thing: that substitution was acceptable as long as bioequivalence could be shown. The difference was that those who disagreed with the definition tended to be sceptical that many generic drugs could truly be shown to be bioequivalent; those who agreed said that in many cases there was no meaningful difference in the effect of different salts.

In answer to Question 3, 35 respondents commented specifically on whether generics were ‘true’ equivalents – bioequivalent, therapeutically equivalent, and clinically equivalent. They were divided across the spectrum of opinion: 12 agreed with the proposed definition of ‘generic equivalent,’ 13 disagreed, and 10 neither agreed nor disagreed.

The concerns about bioequivalence are exemplified by these two quotes, one from the British Medical Association (BMA) and one from an individual pharmacist:

The BMA has serious concerns about the true bioequivalence of generics versus branded drugs, which can vary considerably. There are concerns that patients could experience side-effects or withdrawal symptoms because their drugs are substituted for others which are not sufficiently bioequivalent to those originally prescribed. When patients are taking a number of different drugs, there is a risk that a change to one of them could have an adverse impact on their other medicines. This could be a particular risk for epileptics being treated with anti-convulsants. We believe that this poses an unnecessary risk to patients. Patients could also suffer adverse reactions to variations in the non-active ingredients of generic drugs. (BMA)

The definition of generic equivalence should make reference not only to the same active but also provide the same bioequivalence or something closer to a reference standard that the current +/- 20% typically seen. On occasions this variability has a huge impact on patient outcomes and has a knock on effect in terms of compliance to their prescribed medicine regimes. (An individual pharmacist)

6.4.3 Substitution of salts

Similarly, there was significant debate over whether salts should be substitutable. The pharmaceutical trade bodies and pharmaceutical companies – who largely disagreed with the proposed definition – were divided on this question.

a. Salts should not be substitutable

The ABPI and a number of research pharmaceutical companies opposed the proposed definition on the grounds that different salts should not be substitutable. The ABPI raised the question of the National Prescribing Centre’s advice on patent restrictions for products formulated with different salts. Others noted that different salts are not necessarily bioequivalent.

b. Salts should be substitutable

By contrast, a number of generic pharmaceutical companies, led by the BGMA, disagreed with the proposed definition on the grounds that, as salts should generally be substitutable, referencing salts in the list was unnecessary. The BGMA said:

The current EU legislation defines a generic as such irrespective of the salt used. The concept of ‘equivalence’ harks back to previous legislation. The proposal should be based on the current definition of a generic medicine [Art 10.2(b) of Directive 2001/83/EC, as amended]…
“‘Generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy.”

This means that it should be made clear that, unless there are specific regulatory decisions to the contrary, the salt is irrelevant and approved generics are interchangeable with the original brand and other generics. Thus, the products to which the substitution arrangements are to apply should be listed solely by rINN without the current unnecessary and misleading list of salts.

A few respondents expressed concern that pharmaceutical manufacturers might manipulate salts in order to prevent their products from being substituted.

6.4.4 Licensing and indications

A number of respondents raised the question of multiple indications for a particular drug. MSD UK Ltd said, ‘Clarification is required before any scheme is introduced as to exactly how the DH proposes to manage the entry of generic products without an identical list of licensed indications. If a generic product does not have all the licensed indications of the original branded product, the dispenser should not be able to substitute the brand with a generic. The pharmacist will not know what the intended indication for the product is and therefore will not know whether the generic is actually licensed for the use intended by the prescriber. DH should indicate what measures it proposes to address this issue.’

The Paediatric Continence Forum (PCF) provided an example: ‘Many branded treatments used in treating paediatric continence problems are licensed for paediatric use, whereas generic versions usually are not and have not been tested in children… The use of non-licensed drugs in children is an issue of patient safety as it means that bioequivalence between the branded and generic versions has not been established in children.’

6.5 Question 3b

6.5.1 Overview

The majority of those who answered this question agreed with it. An overview is given in Table 13.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Cannot answer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respondent answers</td>
<td>62</td>
<td>25</td>
<td>18</td>
<td>7</td>
<td>112</td>
</tr>
<tr>
<td>Percent</td>
<td>55%</td>
<td>22%</td>
<td>16%</td>
<td>6%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Table 13: Question 3b: Does the proposed wording for NHS prescriptions deliver the definition effectively?**
6.5.2 Agreement
Relatively few respondents made substantive remarks in answer to this question. Of the 62 respondents who agreed with the rubric, 44 said ‘yes’ without making further comment. Of the remainder, several commented that the rubric was wordy or complex, but generally effective.

6.5.3 Disagreement
The main reasons for disagreement with the rubric included:

- It is too long
- It is too complex
- It would confuse and worry patients
- It is unnecessary because the respondent opposed Option 3
- It is ‘meaningless’ on repeat prescriptions (157)
- It should be printed elsewhere, such as in the Drug Tariff.

Two LPCs charged that that the wording (and indeed the intention of Option 3) was ambiguous. They said it was not clear from the rubric whether a generic ‘may’ be dispensed, ‘should’ be dispensed or ‘must’ be dispensed.

6.5.4 ‘Other’
Most respondents who did not specifically agree or disagree with the rubric raised one or more of the concerns listed above.

NHS Prescription Services noted, ‘The text is very long and although the front of the prescription is the most suitable place for this text, it will take up a lot of room and mean that fewer items will be able to be placed on each form. This may have issues for different strengths of the same drug ordered as separate prescriptions that overflow onto 2 forms when two charges would come into effect.’

6.6 Question 4: select list size, amendments, and publication

Question 4
a) Do you think a select list of just under 40 rINNs and BANs, plus permitted alternative salts, that is amended via additions and deletions, which in practice will be made no more than four times a year, is an appropriate balance between being flexible enough to reflect changes in the market, while still being workable for prescribers and dispensers?

b) Do you think it is appropriate for this list and the notice of its amendments to be published in the Drug Tariff?

6.7 Question 4a

6.7.1 Overview
As shown in Table 14, opinion on this question was fairly balanced, with 36% agreeing and 32% disagreeing. A further 40 responses (26%) were marked as ‘other,’ often because the respondent agreed with the select list but disagreed with the timescale for amendment or vice versa.
As in the answers to the previous question, many of the concerns raised were the same regardless of whether the respondent agreed or disagreed with the question: many responses took the form of ‘Yes, but…’ or ‘No, but…’. As a result, we have discussed the responses by topic rather than by a division between agreement and disagreement.

As with other questions in this section, a number of respondents who answered the question (including Yes, No, and Other responses) pointed out that they opposed Option 3.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>55</td>
<td>49</td>
<td>40</td>
<td>7</td>
<td>151</td>
</tr>
<tr>
<td>Percent</td>
<td>36%</td>
<td>32%</td>
<td>26%</td>
<td>5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Table 14: Question 4a: Is the select list as proposed, amended no more than four times a year, the right balance?**

6.7.2 Comments from other sections of the consultation

As shown in Table 15, a number of comments were made elsewhere in the consultation on topics about the administration of a select list. These are discussed in this section.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of the list (timing, size, creation and updating)</td>
<td>30</td>
</tr>
<tr>
<td>Publicity of generic substitution for patients</td>
<td>25</td>
</tr>
<tr>
<td>Updating IT systems</td>
<td>25</td>
</tr>
<tr>
<td>Monitoring of the scheme</td>
<td>15</td>
</tr>
<tr>
<td>Guidance for practitioners</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>108</strong></td>
</tr>
</tbody>
</table>

**Table 15: Comments about the administration of a select list**

6.7.3 Size of the list

a. **Agreement with 40 rINNs and BANs**

55 respondents agreed with the question as posed, with several commenting that the scheme would be ‘workable’ or ‘manageable’.

Nine respondents said that the list should not exceed 40 rINNs and BANs.

b. **List too short**

21 respondents said a list of 40 drugs was too short. This group includes a few who agreed with the question, saying that 40 was a good starting point but should then expand; and a larger number who disagreed with the question, saying that the list should be longer from the start.
The BGMA, in remarks echoed by five generic pharmaceutical companies, said, ‘All products for which a
generic is listed in Part VIII of the Drug Tariff could be included in the list to which the proposed substitution
arrangements shall apply, except where the MHRA has decided for clinical reasons that the products should
not be marketed solely by INN’.

Four NHS organisations and five LPCs also said the list was too short, often noting that greater savings could
result from a longer list.

c. Flexible size

A few LPCs queried why the list was set at 40. They said the eligibility of products, not an ‘arbitrary’
number, should determine the size of the list.

d. List too long

A small number of respondents said the list was too long. The PSNC pointed out: ‘Although a list of just
under 40 unique molecules has been proposed, this covers approximately 120 prescribable generic products
and 250 available brands.’ The PSNC said this would create ‘a significant workload burden’ for pharmacy
staff.

6.7.4 Timescale for amendment and notice period for changes

a. Less frequent change or a longer notice period

The DH’s consultation document said, ‘It is envisaged that the list would be changed a maximum of four
times a year and in reality is unlikely to need changing more than once or twice a year, with one or two
products being added and removed each time. This would strike a balance between achieving cost savings
and not creating a significant increase in workload for prescribers and dispensers.’ However, a number of
respondents thought that quarterly change was too frequent, and were not reassured by the DH’s statement
that the list would likely be changed less frequently than quarterly.

Several called for less frequent change or a longer notice period, to avoid patient confusion, minimise
prescriber and dispenser workload, and allow manufacturers and pharmacies time to control stock. An
individual pharmacist said, ‘I don’t want to tell patients every few months that another of their medicines is
“not allowed” any more.’

The BMA said that quarterly changes could pose problems for repeat prescriptions:

    We are concerned that this proposal suggests that the list of drugs could change every 3 months. In
many cases, GPs review patients with stable health conditions only on an annual basis, and
associated medications are re-authorised annually. Hence, shortly after a review, doctors and
patients could face the situation whereby a prescribed drug could move onto the generic
substitution list and further repeat prescriptions would not carry the necessary endorsement to
ensure that the drug was not substituted. Already, amendments to prescribing databases used by
prescribers lag several months behind changes to the lists of approved drugs.

b. More frequent change

A few respondents, mostly LPCs, said that the list should be updated monthly via the Drug Tariff.

6.7.5 Consultation on the list

Several respondents said, in answer to Question 4, that there should be a consultation before drugs are added
to or deleted from the list. The issue of consultation on the list is discussed further in the next section.
6.7.6 Additional issues

Four additional issues emerged about the administration of a select list and a generic substitution scheme. In some cases, these comments were made in answer to Question 1, Question 10 or in general remarks rather than specifically in answer to Question 4. However, since they all relate to the mechanics of implementing, administering and publicising a select list, they are discussed briefly here.

- **Publicity of generic substitution**: A number of respondents said that it would be helpful to have posters and leaflets about generic substitution available at doctors’ surgeries and at community pharmacies in order to help GPs and dispensers communicate the changes and reassure patients about why their drugs were being changed.

- **Updating IT systems**: Various types of respondents noted the importance of timely updates to prescribers’ and dispensers’ IT systems in managing a select list. Some of these believed that it was possible for such updates to be achieved in an efficient manner, as long as software providers had sufficient notice of changes. Concerns about the cost of changing and updating IT systems are included under Question 8.

- **Monitoring on the scheme**: Opinion on how much monitoring was needed was divided. Some respondents said that PCTs should carefully and closely monitor the opt-out rates by prescribers, and should take action to correct any where the rates were unusually high. Others said the opposite: they said they hoped that any monitoring of a generic substitution scheme would not be taken by PCTs as an opportunity to ‘interfere’ with prescribers’ decision-making.

- **Guidance for practitioners**: A few respondents said that, in order to make a select list work effectively, the DH would need to provide regular guidance for practitioners.

6.8 Question 4b

6.8.1 Overview

Responses to this question were strongly favourable. An overview is shown in Table 16.

<table>
<thead>
<tr>
<th>Response</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Cannot answer</th>
<th>Total</th>
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<tbody>
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<td>Respondent answers</td>
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</tr>
<tr>
<td>Percent</td>
<td>77%</td>
<td>9%</td>
<td>12%</td>
<td>2%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 16: Question 4b: Should the list and its amendments be published in the Drug Tariff?

A large majority of respondents who answered this question agreed that the list and its amendments should be published in the Drug Tariff. The majority of those who agreed simply said ‘Yes’ or offered general agreement such as, ‘The Drug Tariff is the appropriate vehicle for publishing.’

6.8.2 Alternative or additional publications

Several of those who agreed with the question, as well as a number of those who disagreed, said it should also be published or embedded elsewhere. Suggestions included:

- Electronic prescribing systems and pharmacy IT systems
- The BNF (the British National Formulary)
• Public websites such as NHS Direct
• Publications by other organisations such as the PSNC
• Pharmacy trade press
• Posters
• A machine-readable list
• Email.

A number of respondents said that pharmacists are more accustomed to using the Drug Tariff than doctors are. One LPC said, ‘Yes, the Drug Tariff is very important for the supply side; however prescribers have no idea what the Drug Tariff is or how it affects their prescriptions, so some additional method (possibly via their Medical Record IT supplier) must be found to inform them of these changes.’ Similarly, a GP said, ‘I am the only non-dispensing GP I know who opens the Drug Tariff – please send us the list by email.’ Several said that prescribers are most likely to refer to the BNF.

Several others said that the most practical information source was prescribing and dispensing software, and said it was ‘vital’ that electronic prescribing systems (EPS) and pharmacy systems were updated with alerts about recent changes.

First DataBank Europe Ltd noted that if the rules do not apply to Wales, this should be stated specifically in the Drug Tariff.

6.8.3 Timing of publication

A few respondents said that the Drug Tariff was the right place for publication because it ‘is now available before the start of the month online’. Others were concerned about how the timing of updates would work, since they said hard copies of the Drug Tariff are sometimes late in arriving and it would also take time to cascade updates through other publications and into prescribing and dispensing software.
6.9  Question 5: select list criteria

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient safety and bioequivalence</td>
<td>33</td>
</tr>
<tr>
<td>Cost savings and cost implications</td>
<td>31</td>
</tr>
<tr>
<td>Consultation on the list</td>
<td>23</td>
</tr>
<tr>
<td>Clarity of criteria and management of the list</td>
<td>23</td>
</tr>
<tr>
<td>Permanent exclusion list</td>
<td>23</td>
</tr>
<tr>
<td>Drugs to exclude (aside from AEDs)</td>
<td>22</td>
</tr>
<tr>
<td>Opposition to Option 3</td>
<td>13</td>
</tr>
<tr>
<td>Pharmacist remuneration and reimbursement</td>
<td>8</td>
</tr>
<tr>
<td>General agreement with the criteria</td>
<td>8</td>
</tr>
<tr>
<td>Security of drug supply</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>212</strong></td>
</tr>
</tbody>
</table>

Table 17: Question 5: Do you have any comments on the criteria for the select list?

In addition, in other parts of the consultation respondents made comments on the following topics:

- Permanent exclusion list: 48 comments
- Consultation on the list: 29 comments.

6.9.2  Patient safety and bioequivalence

The importance of patient safety and ‘true’ generic equivalence were among the most frequently addressed topics. Many respondents said that patient safety and bioequivalence should be the principal criteria by which drugs should be assessed for the list. The All Party Parliamentary Group on Skin said:

The list of inclusion criteria provided at para 57 seem to us to miss the point. The key factor is not the extent to which a product is generically prescribed, but whether it is being written by brand when a generic version would serve the patient as well. Equally, the extent of cost savings are immaterial if the patient is better served by receiving the branded medication.
A number of pharmaceutical companies called for the decision on interchangeability to be made by the MHRA.

Others noted more general patient safety concerns around generic substitution, such as those associated with multiple medications, long-term conditions, allergies to excipients, and medicines with narrow therapeutic indices.

6.9.3 Cost savings and cost implications

A variety of opinions were expressed on the cost saving criterion. Several respondents said that the criteria should be that potential savings should outweigh the cost of delivery.

A few people said that the select list would deliver cost savings and free up much-needed money for other NHS work. For example, one doctor commented, ‘It’s all finance driven and as such there’ll be more money to allow the hernia repairs you are currently not allowing my patients to have – so I am bound to approve.’

a. Cheaper brands and branded generics

A number of NHS organisations called for generics to be excluded from the substitution list when there was a cheaper brand available. Expressing the opposite view, several LPCs said that branded generics should be included on the substitution list to end the ‘distortion to the market’ caused by prescribing of branded generics. A number of generic pharmaceutical companies agreed, saying that ‘cost savings should be judged in terms of the impact on the drugs bill as a whole and not on the basis of the impact on the cost of specific products to the NHS.’

This topic was also addressed in the DH Partial Impact Assessment and is discussed in more detail in the section on cost and benefits.

b. Pharmacist remuneration and reimbursement: the Community Pharmacy Contractual Framework

In a topic related to the issue of the prescribing of branded generics, a group of LPCs and community pharmacies suggested that an additional criterion should be added: ‘The criteria to which products are selected for the substitution list should be extended to recognise the generic substitution list could help protect the community pharmacy contract, from PCTs enforcing branded prescribing strategies. Therefore a criteria such as, “products should be added to the list to help protect the negotiated purchase profits in the community pharmacy contract”.’

6.9.4 Consultation on the list

In answer to Question 5 and across the consultation, a large number of respondents called for a process of consultation on additions and deletions to the list. Those who wished to see a consultation on the list included respondents of many types, with a wide range of concerns, and included both respondents who supported Option 3 and respondents who disagreed.

In addition to the individually formulated responses, the 51 respondents who used the Epilepsy Action campaign template said, ‘I do not support the government's preferred choice (Option 3) unless it is changed so that there is a public consultation before a drug is added to a substitution list. I am worried that anti-epileptic drugs could be added to this list at any time without this process.’

It was suggested that parties to consultation on any changes to the list should include:

- Drug manufacturers
- MHRA
- The National Patient Safety Agency
A few respondents said that in addition to consultation, there should also be a process of appeal to remove unsuitable drugs if they were added to the list.

6.9.5 Clarity of criteria and management of the list

A number of respondents said the criteria for inclusion on the list were not clear. For example, the National Society for Epilepsy said, ‘The proposed criteria for addition and deletion are not clear from this proposal. If they are, as outlined in paragraph 30, “drugs that will yield the biggest financial savings, are commonly prescribed and are still subject to relatively high brand prescribing rates even though generic products are available” .... These criteria are too broad and could apply to anti-epileptic drugs (AEDs). The criteria need to be more robust.’

MSD UK Ltd suggested the following criteria: ‘A specific minimum value of sales of a product which results in it being considered for inclusion; a specific minimum savings value threshold expected to be realised before a product is considered for inclusion; clarification and agreement of what “ready availability of generic versions” means and how it would be monitored; “General clinical or patient safety concerns.” These should be agreed and specified from the outset.’

6.9.6 Drugs to exclude (aside from AEDs)

A number of specific drugs and categories of drugs were listed that respondents said should be excluded from a select list. Many of these respondents made similar representations in answer to Question 6, and their answers are discussed further in that section.

6.9.7 A permanent exclusion list

There was a strong suggestion that any generic substitution plans should include a list of drug types that could never be added to a substitution list. A number of organisations and individuals said that a list of drugs or categories of drugs that could never be substituted should be included as part of any legislation for generic substitution, in order to give GPs, patients and their representatives confidence that the select list could not grow to include inappropriate types of drugs in the future.

Many (though not all) of those who suggested a permanent exclusion list were concerned about AEDs. In addition to the comments from individually formulated responses, the 51 respondents who submitted letters using a template created by the charity Epilepsy Action said:

> As well as a process for adding drugs to the substitution list, I also think there should be a second list of drugs that can never be added to a substitution list, which should include anti-epileptic drugs.

It was also thought that many other types of drugs should also be permanently and formally excluded from the possibility of substitution.
6.9.8 Opposition to Option 3
Several respondents said that the select list – and its criteria – were not necessary, because they opposed Option 3. A number of these respondents suggested alternative plans for saving money on branded drugs that they said would be more cost effective, easier to implement or safer for patients – and in any event, would avoid the need for a select list.

6.9.9 General agreement with the criteria
A few respondents expressed general agreement with the criteria. ‘The criteria seem reasonable,’ said the UK Medicines Information Executive, whose brief comment was similar to the other responses on this theme.

6.9.10 Security of drug supply
A variety of concerns were raised on the issue of security of drug supply and supply shortages. NHS Prescription Services said, ‘What if a generic product is identified as being in short supply? Under current arrangements NCSO status might be granted. Would the same rule apply for branded products which are suitable for generic substitution? i.e. would an additional endorsement by the dispensing contractor allow the contractor to claim reimbursement of a branded product?’

6.10 Question 6: The proposed initial select list

| Question 6 |
| Do you have any comments on the proposed initial select list in Annex A? |

6.10.1 Overview
Table 18 provides comments by theme.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs to exclude (aside from AEDs)</td>
<td>54</td>
</tr>
<tr>
<td>Drugs to include</td>
<td>25</td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td>22</td>
</tr>
<tr>
<td>Creating and maintaining a select list – consultation, criteria and length</td>
<td>20</td>
</tr>
<tr>
<td>AEDs</td>
<td>18</td>
</tr>
<tr>
<td>Drugs to clarify</td>
<td>13</td>
</tr>
<tr>
<td>Agreement with the proposed initial list</td>
<td>11</td>
</tr>
<tr>
<td>Opposition to Option 3</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>33</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>206</strong></td>
</tr>
</tbody>
</table>

Table 18: Question 6: Do you have any comments on the proposed initial select list?
139 respondents gave answers to Question 6. Their responses were divided into 206 comments on different themes. In addition, 34 comments were made elsewhere in the consultation on drugs to include or exclude on a select list.

Responses to Question 6 were extremely varied. Slightly over half of the comments addressed the contents of the list directly by discussing drugs to exclude (including AEDs), drugs to include and drugs to clarify. The remainder covered a wide range of issues, many of which were also addressed in answer to other questions in the consultation.

A large number of respondents, including the ABPI, pharmaceutical companies, the PSNC, LPCs, NHS organisations, third sector organisations, pharmacies and individuals, included lists of individual drugs they said should be included, excluded or clarified.

6.10.2 Drugs to exclude

About a quarter of the responses in answer to this question indicated drugs to be excluded from generic substitution. These categories were suggested for exclusion or permanent exemption:

| Anti-epileptic drugs | Drugs for which there is no generic equivalent |
| Modified or sustained release preparations | Drugs that are no longer prescribed by brand |
| Different formulations | Items where the brand price is cheaper than the generic |
| Medicines with a narrow therapeutic index | Drugs that are already on the Drug Tariff Black List |
| Vaccines | Products not listed in Part VIII of the Drug Tariff |
| Biosimilars | Drugs outside the PPRS scheme or patent-protected |
| Controlled Drugs | Oral contraceptives |
| Alternate salts | Immunosuppressives |
| Devices and routes of administration, including inhalers | Anti-psychotic and other psychiatric medication |
| Nanotechnologies | Salbutamol inhalers |

**Table 19: Types of drugs respondents said should be excluded from substitution**

6.10.3 Drugs to include

Respondents who suggested drugs to include on an initial select list mostly listed specific drug names. However, a number of respondents, mostly LPCs, said that all branded generics should be included. As Berkshire LPC said:

*We are also concerned about the practice of prescribing branded generics and feel very strongly that the list should include all those drugs which are available as a branded generic. This consultation and the subsequent changes it introduces must bring an end to the practice of circumventing the national agreements on price and retained profit by prescribing branded generics.*

Further discussion on branded generics is included below under Question 8.
Other categories that respondents said should be included were:

- Conventional release, solid oral formulations
- Drugs listed in national prescribing metrics.
7 QUESTION 7: EXCLUDING DISPENSING DOCTORS AND APPLIANCE CONTRACTORS

Question 7
Do you have any comments on the proposed scope of the arrangements, namely that dispensing by both appliance contractors and dispensing doctors is out of scope?

7.1.1 Scope of the arrangements
Most of the respondents who answered this question said they disagreed with excluding dispensing doctors, as shown in Table 20. Most responses to this question addressed the issue of dispensing doctors. Very few addressed dispensing by appliance contractors.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Agree with exclusion</th>
<th>Disagree with exclusion</th>
<th>Other</th>
<th>Cannot answer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent</td>
<td>13%</td>
<td>64%</td>
<td>19%</td>
<td>4%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 20: Question 7: Should dispensing by appliance contractors and dispensing doctors be out of scope?

7.1.2 Disagree with exclusion

a. Fairness for patients
Excluding dispensing doctors from the scheme would create a ‘two-tier system’, some respondents said, in which patients of dispensing doctors would be at an advantage compared to other patients in their access to branded drugs. They said this could create ambiguity, confusion and inequality.

b. Fairness for pharmacies
A few respondents said that pharmacies would be put at a disadvantage if dispensing doctors were excluded from generic substitution, because patients would seek out dispensing doctors in order to get the branded prescriptions they wanted.

c. Reduced cost savings
There was concern that excluding dispensing doctors from the scheme would erode cost savings, since dispensing doctors are ‘usually high brand prescribers’. Some respondents asked whether the ‘13% of the market’ represented by dispensing doctors had been included in the DH calculations of potential cost savings.

Respondents expressed opposing views about whether dispensing doctors make prescribing choices based on the brands that provide the greatest profit for them. Several respondents asserted that choosing brands to maximise profit was a problem with dispensing practices; others said this was a ‘myth’. Respondents from both sides agreed that excluding dispensing doctors from the scheme at the very least risked creating the appearance of a division between dispensing and non-dispensing doctors. For example, an NHS organisation said:
This [the exclusion of dispensing doctors] makes this scheme very difficult to see the point of implementation in a PCT with a mixture of Dispensing and non-Dispensing practices. About one fifth of patients receive their medicines from a dispensing practice. The only practices in our area that are high users of branded products are dispensing practices. All the prescribing only practices achieve close to 80% generic prescribing. Occasional use by some practices of cheaper branded alternatives (eg. Ventolin) is the only thing that drops them below the 80% mark. The vast majority of GPs make appropriate changes to prescribing when advised by the PCT to save money and prescribe more cost-effectively.

The main objectors to generic prescribing are from those that have a financial interest in the prescribing of particular medicines where they have buying advantages and make additional income through increased margins on some drugs.

The NHS Business Services Authority, Counter Fraud and Security Management Service also raised the concern of fraud: ‘Confining the scope of the arrangements to drugs dispensed by pharmacies retains the risk that dispensing doctors and appliance contractors may substitute a generic item whilst claiming reimbursement for a branded item at a higher cost.’

7.1.3 Agree with exclusion

Most of those who said they agreed with the scope did not elaborate on their reasons for agreement.

Two respondents who agreed with the exclusion of dispensing doctors asked for further clarity or monitoring. The ABPI said, ‘Dispensing doctors do not necessarily dispense for all their patients, and do not stock all the medicines that they prescribe. Are they out of scope for all prescribing, or only for those patients for whom they also dispense?’

The Royal College of General Practitioners said, ‘We agree with the proposal to exclude dispensing doctors from the scope of these measures. However, we would suggest there should be some mechanism to ensure that dispensing by dispensing doctors is in line with reasonable costs as mapped against the usual costs for the PCT.’

7.1.4 ‘Other’ answers

A number of respondents neither agreed nor disagreed with the scope of the proposals. This group included several types of responses:

- The respondent opposed Option 3 and therefore thought this question was not relevant
- A statement that pharmacy dispensers would be disadvantaged compared to doctor dispensers (but not directly saying that dispensing doctors should be included in the scheme)
- An observation about the potential for conflict of interest with dispensing doctors (but again not directly calling for dispensing doctors to be included in the scheme)
- A mixed response, saying that appliance contractors should be excluded but dispensing doctors should not be excluded
- Answers not related to the question.
8 QUESTION 8: COSTS AND BENEFITS

Question 8
Do you agree with our estimate of the likely benefits and costs? If not, please indicate and provide evidence, where possible, of any areas of disagreement.

8.1.1 Costs and benefits: Overview
In answers to Question 8, more than four times as many respondents disagreed with the DH’s estimate of benefits and costs as agreed, as shown in Table 21. A further 20 said they did not know or were not able to assess. Among the group of responses marked ‘other’ were a number of individuals who agreed with the principle of cost savings, as long as they could be made without harming patients.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Don’t know</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>18</td>
<td>93</td>
<td>38</td>
<td>20</td>
<td>169</td>
</tr>
<tr>
<td>Percent</td>
<td>11%</td>
<td>55%</td>
<td>22%</td>
<td>12%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 21: Question 8: Do you agree with the DH estimate of benefits and costs?

Many respondents made comments about the cost-effectiveness of the proposals outside of answers to Question 8, particularly in answer to Question 1, Question 10, or general comments. In total, 192 individually formulated responses, and 103 responses using the LIVErNORTH campaign template, addressed the issue of costs and benefits. Almost without exception, comments made about cost effectiveness in answer to Question 1, Question 10 or in general comments were critical in tone. In this table we have combined comments made throughout the consultation on a number of topics related to cost effectiveness:

<table>
<thead>
<tr>
<th>Theme</th>
<th>Number of comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not cost effective – general comments</td>
<td>63</td>
</tr>
<tr>
<td>Savings (if any) would be small, or savings are already being made</td>
<td>51</td>
</tr>
<tr>
<td>Further details needed on cost-benefit calculations</td>
<td>42</td>
</tr>
<tr>
<td>Cost of adverse patient reactions</td>
<td>37</td>
</tr>
<tr>
<td>Some brands are cheaper than generics</td>
<td>35</td>
</tr>
<tr>
<td>Cost and inconvenience of change (including IT systems)</td>
<td>29</td>
</tr>
<tr>
<td>Generic prescribing is favoured (rather than generic substitution)</td>
<td>21</td>
</tr>
<tr>
<td>Option 3 will give savings</td>
<td>20</td>
</tr>
<tr>
<td>Problem of branded generics</td>
<td>18</td>
</tr>
<tr>
<td>Other</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>350</td>
</tr>
</tbody>
</table>

Table 22: Comments on cost effectiveness across the consultation
In addition to comments on the topics above in Table 22, which we compiled across the consultation, a number of topics were raised specifically in answer to Question 8 that are discussed more generally elsewhere in this report (Table 23):

<table>
<thead>
<tr>
<th>Further comments in answer to Question 8</th>
<th>Number of comments</th>
<th>Related comments across the consultation are discussed in…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs of the workload on GPs, pharmacists, and PCTs</td>
<td>22</td>
<td>Practitioner issues</td>
</tr>
<tr>
<td>Costs related to the pharmaceutical industry</td>
<td>21</td>
<td>Industry and business issues</td>
</tr>
<tr>
<td>Patient safety should come before cost</td>
<td>17</td>
<td>Patient issues</td>
</tr>
<tr>
<td>General agreement with the DH assessment of costs and benefits</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Remuneration and reimbursement for pharmacists</td>
<td>9</td>
<td>Industry and business issues</td>
</tr>
<tr>
<td>Dispensing doctors</td>
<td>4</td>
<td>Scope</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>88</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Table 23: Further comments on the topic of cost-effectiveness**

### 8.2 Overall cost effectiveness

Overall, respondents were sceptical about the DH assessment of costs and benefits presented in the Partial Impact Assessment. Many made general comments about the overall cost effectiveness, asserting that either the costs would be substantially higher than the DH anticipated, or that the benefits would be less, or both.

Several respondents said that the effort involved in implementing a formal generic substitution scheme was simply too great for the potential gain, as in this comment from Hampshire & IOW LPC:

> We have no robust evidence either way; however, the predicted financial gain of £50 million against a national spend in excess of £8 billion would indicate that this is a sledgehammer to crack a walnut.

Many of the comments categorised as ‘not cost effective’ in the table above were general comments, broadly touching on multiple issues discussed in this section.

#### a. Savings would be small, or savings are already being made

Several respondents said the UK’s generic prescribing rate, at 83% of all prescription items, is ‘one of the highest in Europe’ and questioned whether it was realistic to think that significant further savings could be made. Branded prescribing is generally intentional on the part of the clinician, said a number of respondents including trade bodies, pharmaceutical companies, professional bodies and PCTs, so prescribers would simply opt out and generic substitution would not release savings. Bayer HealthCare said:
There is no recognition that prescribers already make a brand / generic choice in their prescribing and that there is little further scope. Seventeen of the treatments on the proposed limited list already have generic prescription rates of 97% or greater. It is highly questionable as to whether a further increase in generic prescribing rates is possible for this group. It is fair to assume that branded prescribing in this group is taking place for a particular reason.

There was also disagreement about the projections for future levels of generic substitution. In the next few years, a large number of high-volume medicines are scheduled to come off patent. The DH Partial Impact Assessment said that the savings associated with generic substitution are likely to rise as further medicines are added to the scheme. However, some respondents said that PCTs and Medicines Management teams, strongly focused on saving money on drug budgets, were already able to inform prescribers about medications that are coming off patent so that savings could very quickly be made without a formal generic substitution process. They queried whether a generic substitution scheme could achieve greater savings than continued promotion of generic prescribing.

A few respondents talked about software tools already used in the NHS to promote generic prescribing. Several mentioned ScriptSwitch, a drug comparison software used by GPs at the point of prescribing, which they thought was an effective way to encourage GPs to prescribe generically and cost-effectively without the need for a generic substitution scheme.

It was also noted that there are additional mechanisms in place to control the cost of drugs to the NHS. Points included:

- The Drug Tariff includes a ‘blacklist’ of medicines that cannot be prescribed on the NHS
- NICE provides a ‘fourth hurdle’ for medicines to be available
- Clawback mechanisms are applied via the Drug Tariff to pharmacy reimbursement
- The price cuts included under the PPRS control the price of branded medicines.

It was thought that these mechanisms were both effective and sufficient.

### 8.3 Details needed on cost-benefit calculations

#### 8.3.1 Overview

A number of respondents said they needed more information and evidence to be able to assess the cost effectiveness of Option 3. The British Medical Association said, ‘The DH needs to explain in detail, with calculations, how the proposed savings projected for this initiative will be generated. We have strong concerns that the cost and inconvenience of introducing the proposals will outweigh any potential benefits.’

The charge was made that the calculations in the DH Partial Impact Assessment were not based in evidence, as in the response from Norgine Pharmaceuticals: ‘The public policy aspirations of the NHS are to be evidence-based and patient-centred. The proposal to implement AGS [Automatic Generic Substitution] appears to be neither.’

Several organisational respondents, including pharmaceutical companies and the PSNC, provided extensive details about their own cost-benefit calculations.

#### 8.3.2 The “missing 5%”

Several respondents asked for information on how much of the ‘missing 5%’ – the 5% of total prescribing in which a brand was prescribed although a generic was available – was really available for generic substitution.
For example, a GP said: ‘You have calculated that only 5% of total prescribing is possible to undergo a change from branded to generic in order to make savings. However, you haven’t worked out what percentage of these were reasonable or good branded prescriptions. For example, what percentage was for epilepsy medication, or for specific contraceptive pills being used for specific conditions, etc? Although I agree wholeheartedly with the idea that generic substitution will often be a good thing, it seems that you have underresearched the impact that your proposals might have and I am afraid that you may have overestimated them.’

Similarly, East Riding & Hull LPC said, ‘The Impact Assessment does not clarify whether this 5% was dispensed by Pharmacy Contractors or Dispensing Doctors. As these proposals only cover the dispensing of prescriptions by pharmacies we would ask for clarity on the percentage which is available to community pharmacy to accurately access the savings/cost benefit of delivering this proposal. What percentage of the 5% would be removed based on clinical reasons? What percentage of the suggested 40 drugs in the selected list contributes to this 5% savings?’

8.3.3 A 50% opt-out rate

A number of respondents queried how the DH had arrived at the figure of a 50% opt-out rate, and said it was not based in evidence.

Some said they expected the opt-out rate to be higher than 50%, for one of two reasons:

- A negative reason: prescribers would regularly opt out to avoid taking the time to assess individual cases for the acceptability of generic substitution
- A positive reason: prescribers are already aware of the generic options because of good work by Prescribing Management teams within PCTs, and have already exercised a clinical choice by prescribing a brand.

8.4 Costs to patient health and wellbeing

8.4.1 Adverse reactions

One of the major concerns of both individuals and organisations was the financial cost of a serious adverse reaction to a different medication. The DH’s consultation document said that drugs where there are patient safety concerns with regard to interchange ‘could be specifically not included in the list.’ Nonetheless, many respondents thought there was a risk that inappropriate drugs might at some stage be included in a generic substitution scheme, or that inappropriate substitutions might be made through human error.

In addition to individually formulated comments on adverse reactions, the 103 respondents who used the LIVErNORTH campaign template said, ‘This is a cost driven exercise unlikely to realise any savings in real terms. Possible litigation as a result of being given medication with an adverse effect could easily cost more than any perceived savings.’

The concern about adverse reactions was raised frequently by respondents who mentioned treatment of epilepsy. Even those who acknowledged that the DH consultation documents did not include AEDs among the potential drugs for substitution wanted to reinforce the point that AEDs should never be subject to substitution. They cited potential costs including:

- Hospital treatment due to adverse reactions
- Disability, unemployment, and even death due to epileptic seizures
- Additional visits to doctors and pharmacists to try to re-set the balance of medicines
- Legal challenges from patients who experience adverse effects after changing medicines.
Concerns about adverse reactions were also raised in relation to other conditions, as in this response from the Primary Care Respiratory Society UK: ‘Avoidable morbidity in asthma and COPD is not just a reason for avoidable suffering for patients but also very costly in terms of emergency service usage and hospital admissions.’

### 8.4.2 Ineffective treatments, non-compliance and wastage

Some respondents mentioned the cost of a treatment that is less effective for the patient, short of precipitating a serious adverse reaction. They said that ineffective treatments could result in patients returning to GPs to ask for new prescriptions, non-compliance with the treatment, and wasted medications. For example, one GP said, ‘It is possible that the “reject” rate of prescriptions by patients who cannot tolerate a generic substitute formulation will lead to a higher NHS expenditure on multiple prescriptions than saving money.’

### 8.5 The cost and inconvenience of change: changing IT systems

Many made general comments that the cost and inconvenience of change would outweigh any savings. In addition, a number of respondents specifically commented on the cost of changing IT systems. It was noted that both GPs’ systems and pharmacists’ systems would have to change to accommodate generic substitution. Respondents expected the DH to pay for these changes, including changes to pharmacy systems.

It was also noted that in addition to the ‘millions’ it would cost to change software to carry out generic substitution automatically, there would also be ongoing costs as systems would need to be updated every time the list changed. Some said that the DH Partial Impact Assessment did not sufficiently account for these costs.

Anticipated changes included:
- GPs’ EPS (Electronic Prescription Service) systems
- Pharmacists’ ETP (Electronic Transfer of Prescriptions) and PMR (Patient Medical Record) systems
- Processing systems at NHS Prescription Services
- CfH (NHS Connecting for Health) and NHSBSA (NHS Business Service Authority) systems.

A few respondents expressed scepticism about the NHS track record in implementing new IT systems. In the words of a LINk organisation, ‘If there is any element of IT involvement as part of the implementation and operation of the scheme, think of a number, multiply it by infinity and subtract it from any possible cost benefits and look to 2020 for project conclusion.’

### 8.6 Prescribing of brands and branded generics

There was considerable confusion and debate over what should be supplied when a brand or ‘branded generic’ medicine is cheaper than the related brand. The DH Partial Impact Assessment said:

There may be occasions when the reimbursement price of the brand may be lower than that for the associated generic. This does not necessarily mean that it is cheaper in the long run for the NHS if the brand is prescribed and dispensed. This is due to the fact that discounts offered to pharmacies… by generic manufacturers tend to be higher than the discounts offered by branded manufacturers. This margin [is]… counted as part of the community pharmacy contractual framework funding… it may therefore be appropriate to allow the arrangements to apply even where the brand has a cheaper list price than the generic.
However, it was clear that many respondents did not understand this mechanism. About twice as many respondents argued for branded prescribing on cost grounds as those who argued against it. A number of PCTs said that they made significant savings in their drug budgets – sometimes hundreds of thousands of pounds on a single medicine – by encouraging GPs to prescribe branded products instead of generics when the brands were cheaper.

On the other hand, the Pharmaceutical Services Negotiating Committee (PSNC) and several PCTs, community pharmacies and individual chemists acknowledged and agreed with the DH’s position in the Partial Impact Assessment, saying (in the words of the PSNC) that prescribing by brand when the brand list price undercuts the generic reimbursement price ‘damages the competitive generics market, undermines profoundly the basis for funding of community pharmacy and substantially drives up costs for the NHS.’ Some of these respondents called for all branded generics to be substituted with ‘true’ generics.

A few respondents acknowledged the tension between the local level, where prescribing cheaper brands can make significant savings for PCT budgets, and the national level, where prescribing ‘more expensive’ generics can actually result in savings for the NHS. NHS Derbyshire County suggested that, in the interest of long-term savings, the DH would have to support PCTs financially to facilitate a transition from ‘cheaper’ brands to ‘more expensive’ generics.

An example of the debate over branded generics is salbutamol, a drug used in inhalers for the treatment of asthma. It was mentioned frequently in the course of the consultation because it is marketed by brand as Ventolin at a cheaper list price. A few asthma charities said that salbutamol should not be substituted on clinical grounds, as a different manufacturer’s product may use a different inhaler device which the patient may be unaccustomed to use. However, most comments on salbutamol / Ventolin focused on cost. On one side, several PCTs said that prescribing branded Ventolin saved them hundreds of thousands of pounds; on the other, the PSNC and a few other organisations pointed to the ‘clawback’ mechanism used by the NHS that means the cost of salbutamol to the national drug budget is actually less than the cost of the brand, even though the brand appears cheaper to local PCT drug budgets.

8.7 Costs to practitioners and the pharmaceutical industry

A number of respondents said that the costs to GPs, PCTs, pharmacists and community pharmacies, other NHS organisations and the pharmaceutical industry had not adequately been accounted for in the proposals for Option 3. As we discuss these in greater detail in the sections above on Practitioner Issues and Industry Issues, we summarise them briefly here.

Practitioners:

- GP and pharmacist time to counsel patients on switching
- GP time to assess which patients may qualify to opt out
- Additional interactions between pharmacists and GPs
- Increased pharmacy workload in processing prescriptions

NHS:

- The impact on NHSBSA Prescription Services
- Time required for PCTs to monitor prescribing rates and investigate higher-than-average opt-out rates
Pharmaceutical industry:

- Security of supply when there are market shortages of generic drugs: If volumes of off-patent brand prescriptions decrease, manufacturers may choose not to make that brand available in the UK at all or to make it available only at a very high cost.
- Incremental innovation: Pharmaceutical companies will no longer seek to improve on medicines liable to generic substitution, resulting in uptake of more expensive New Chemical Entities (NCEs).
- Small Firm Impact: Small niche pharmaceutical companies would be disproportionately affected.

8.8 Support for Option 3 and the DH assessment of costs and benefits

Those who agreed with the DH assessment of costs and benefits included the ABPI, the British Generic Manufacturers Association (BGMA), eight pharmaceutical companies (predominately generic companies using the same phrasing as the BGMA response), four NHS organisations, and individual respondents.

Most of the positive responses simply said ‘Yes’ or expressed general agreement, such as ‘Our calculations of the likely benefit and costs of the proposals are consistent with the Department’s estimates,’ as the BGMA and several pharmaceutical companies said. Similarly, the ABPI said:

The ABPI reviewed the value of the medicines on the consultation list and calculated the benefit using PCA 2008 data. This analysis showed that, with 50% tick-out, the savings from the list of medicines in Annex A would be around £19m (compared to DH’s figure of £20.5m in the Impact Assessment). Both Assessments appear consistent with each other.

One pharmaceutical company, Janssen-Cilag Ltd, disagreed with the DH assessment because they said the cost savings would be greater than calculated: ‘In our view it is likely that if Option 3 with opt-out endorsement is adopted and restricted to a narrow list of medicines, then prescribers will use the opt-out less often than predicted and the savings to the NHS will be greater than calculated.’
9 QUESTION 9: EQUALITY RISKS AND OPPORTUNITIES

Question 9
a) Do you think any of the options present any risks to equality for particular groups of people, people from minority ethnic groups, disabled people, older people, men women and transgender people and people from different faith groups? If so, what are they and what do you think needs to be done to address these risks?
b) Do you think there are opportunities to promote equality in any of the three options? If so, what are these?

9.1 Risks to equality: overview

In answers to the question of whether any of the options present equality risks, respondents generally took the question to mean, ‘Does generic substitution present any risks to equality?’ Some addressed the legal categories for discrimination (age, disability, race, religion or belief, sex and sexuality). Others responded more generally about groups of people they thought would be disadvantaged by generic substitution. Overall perspectives are shown in Table 24.

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respondent answers</td>
<td>91</td>
<td>22</td>
<td>6</td>
<td>119</td>
</tr>
<tr>
<td>Percent</td>
<td>76%</td>
<td>18%</td>
<td>5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 24: Question 9a: Do any of the options present equality risks?

9.2 Four equality risk categories

More than four times as many respondents said that generic substitution posed risks to equality as said that it did not. The concerns about the risk of disadvantage fell into four categories: concerns about people who would be confused about drug changes, those who would find some excipients unacceptable, those who might suffer impaired health as a result of a drug change, and patients who would receive unequal treatment.

9.2.1 Confusion about drug changes

There was concern that confusion about drug changes would disproportionately impact vulnerable groups of patients including the elderly, learning disabled, mental health patients, non-English speaking patients, and those with low levels of ‘health literacy.’ The National Society for Epilepsy, for example, cited research showing that low health literacy is particularly prevalent among lower socioeconomic groups, ethnic minorities, the elderly, and people with chronic conditions or disabilities.

The mental health charity Rethink said, ‘Mental health service users are sensitive to any changes to their medication, even if it is only in appearance, and… non-adherence or overdose could result if any changes are not explained. We know of one case where a drug company changed the packaging of a drug, and a service user then took a deliberate large overdose, to “prove” that the drugs were counterfeit.’

Some respondents said that the practice of generic prescribing already gives rise to confusion. One individual said, ‘The use of generics is already a major threat to the elderly, disabled, mental health problems as the dispensing chemist is free to issue any manufacturer’s product and the resulting confusion that arises — last pack was red this blue it’s not the same or confusion between products — my heart pills are always red and my painkillers blue, when different generics are issued this changes and a dangerous situation arises.’
9.2.2 Unsuitable excipients

Some drugs use animal products or gluten. It was noted that vegetarians, vegans, members of some faith
groups and coelicaes would want to avoid drugs containing certain of these excipients.

9.2.3 Risk of adverse reaction

It was noted that people on multiple drugs may be more sensitive to a change in one or more of their
medications – if, for example, the excipients interacted in an unanticipated way. Respondents said that
people on multiple medications are disproportionately likely to be elderly or disabled.

Respondents who were concerned about generic substitution of anti-epileptic drugs said that substitution of
AEDs could discriminate against people with epilepsy who are classed as disabled under the Disability
Discrimination Act.

9.2.4 Unequal treatment

Some respondents said that generic substitution could introduce new inequalities or aggravate existing ones.
Several noted that patients who are more confident and articulate already have better health literacy and are
better placed to put pressure on a prescriber to prescribe certain medicines, and that the disparity between
those who are health literate and those who are not could be aggravated by an opt-out system. For example,
West Sussex LPC said, ‘Option 3 could advantage more affluent articulate groups who could argue the case
for a branded product with the prescriber.’

Patients of dispensing doctors were not generally felt to be disadvantaged by the introduction of generic
substitution. But because one set of rules would apply to most patients, and another to patients of dispensing
doctors, it was felt that there would be a ‘considerable inequality in service provision between patients who
receive medication via a community pharmacy and those who receive medicines via dispensing doctors’, as
South Staffordshire LPC said.
9.2.5 Disadvantaged groups

This table shows the groups respondents said could be disadvantaged by generic substitution.

<table>
<thead>
<tr>
<th>Group</th>
<th>Reasons given for discrimination or disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elderly</td>
<td>As elderly patients are more likely to be on long-term and multiple medications, there is more risk of confusion when the appearance of one or more of their medications changes</td>
</tr>
<tr>
<td>Physically disabled</td>
<td>Visually impaired people would have difficulty reading new packaging and information leaflets People with swallowing and dexterity problems would be disadvantaged by inappropriate shapes and sizes of pills, as well as blister packs or pill bottles that are difficult to open</td>
</tr>
<tr>
<td>Non-English speakers</td>
<td>People who are not fluent in English may not be able to discuss changes in their medication with their doctors or pharmacists</td>
</tr>
<tr>
<td>Faith groups</td>
<td>Some Jewish, Hindu, and Muslim patients would not wish to take drugs containing certain animal products</td>
</tr>
<tr>
<td>Learning disabled</td>
<td>Learning disabled people would be more likely to be confused by changes in medication</td>
</tr>
<tr>
<td>Epilepsy patients</td>
<td>Generic substitution that does not explicitly exclude AEDs could discriminate against people with epilepsy classed as disabled under the Disability Discrimination Act</td>
</tr>
<tr>
<td>Mental health patients</td>
<td>Mental health patients would be more likely to be confused or suspicious about changes in medication</td>
</tr>
<tr>
<td>Vegetarians</td>
<td>Vegetarians and vegans would not wish to take drugs containing animal products</td>
</tr>
<tr>
<td>Patients with long-term illnesses and patients on multiple medications</td>
<td>The risk of unanticipated interactions between different drugs, and the need for consistency in treatment, would be particularly important for these groups</td>
</tr>
<tr>
<td>Coeliacs</td>
<td>Coeliacs would be sensitive to gluten in any formulation</td>
</tr>
<tr>
<td>Children</td>
<td>Especially children with autism or sensory sensitivities may reject medicines that look or feel different</td>
</tr>
</tbody>
</table>

Table 25: Risks to equality and risks of disadvantage for various groups
9.3 Opportunities to promote equality: an overview

9.3.1 Overview

Responses are summarised in Table 26.

<table>
<thead>
<tr>
<th>Respondent answers</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>32</td>
<td>34</td>
<td>5</td>
<td>71</td>
</tr>
</tbody>
</table>

Table 26: Question 9b: Are there opportunities to promote equality in any of the three options?

9.3.2 Opportunities for equality – Option 1

A few respondents said that Option 1 was the only option that provided opportunities for equality, as in this response from Norgine Pharmaceuticals: ‘Only Option 1 allows for equality to be maintained, with the prescriber choosing which medication their patient receives on a case by case basis, without continual reference to selected lists which may be changed many times a year.’ These respondents included four LPCs, an NHS organisation, and members of the pharmaceutical industry.

9.3.3 Opportunities for equality – Option 2

A small number said that Option 2 would promote equality. Two very different reasons were proposed:

- Option 2 would make it clear that generic prescribing was the norm for all. NHS Camden said, ‘Option 1 and 3 both have potential for risks of equality, as those with louder voice and who can champion their cause for wanting branded products will be placed to do so. Option 2 allows all, regardless of advocacy issues, to be treated equally.’

- Option 2 – by virtue of having an exempt list – would provide clear messages for prescribers about which drugs were not suitable for generic prescribing, particularly AEDs. Epilepsy Action said, ‘Adopting Option 2 with anti-epileptic drugs on an exclusion list has the potential to improve the healthcare of some people with epilepsy. Currently many prescribers and pharmacists are ignorant to the problems that can occur when a patient switching between versions of an AED. Including AEDs on an exemption list would reinforce the message that consistently receiving the same AED is of clinical importance, and may lead to more secure treatment regimes for large numbers of people with epilepsy.’

9.3.4 Opportunities for equality – Option 3

Option 3 would promote equality, a few respondents said, by releasing funding for healthcare to be spread equitably across the NHS, or by ending the ‘postcode lottery’ in which some patients receive branded drugs and some receive generics.
Epilepsy charities said that Option 3 could promote equality and better health outcomes, not because of the nature of the option itself or the nature of generic substitution, but because it would give the opportunity to create a strategy of patient empowerment to improve health literacy: ‘Medicines adherence could be enhanced by focusing on ways to improve health literacy, and that this should be an important consideration for the outcome of the consultation. For example, improving patient information leaflets and supporting literature provided alongside medicines prescriptions,’ the National Society for Epilepsy said.
10 RESPONSES ABOUT THE CONSULTATION

10.1.1 Overview

Among the individually formulated responses, 42 comments were made about the DH consultation on generic substitution itself or about future consultation with the DH. In addition, the LIVErNORTH campaign (103 respondents) addressed the nature of the consultation.

10.1.2 Complexity

Some respondents, especially private individuals, noted that they found the DH consultation on generic substitution difficult to understand, because of the technical nature of the questions. Indeed, there was clearly confusion from some respondents on what the select list in Appendix A of the consultation document represented; some incorrectly thought that the list was a list of drugs that would be excluded from substitution. More than one individual who wanted to see their own drug excluded from generic substitution was very worried that their drug did not appear on the select list.

A few suggested that separate consultations should be held for interested laypeople, including patients and patient representatives, and for medical practitioners and the pharmaceutical industry.

10.1.3 Access: publicity and the internet

A number of individual respondents said that they only heard about the consultation through particular patient groups, and that it should have been publicised more widely in pharmacies and doctors’ surgeries.

Others questioned the ability of the public to engage via the internet. The LIVErNORTH campaign template, submitted by 103 respondents, said, ‘I am also aggrieved that I have been excluded from the consultation due to the complexity of this internet based process which discriminates against a large sector of the community – mainly the elderly and people who find concentrating difficult.’

The DH sent a letter to all individual respondents in response to this concern in which it made the following points:

- The DH adhered to the Code of Practice on Consultation
- The consultation was publicised to the National Association of LINks Members Steering Group and to other third sector organisations
- It was possible to respond by post, either using the questionnaire form or by writing a letter or making an individual submission
- The DH ran a number of listening events that included patients and their representatives.

10.1.4 Fairness

A few respondents said the questionnaire failed to allow a ‘fair’ exploration of all three options, since most of the questions asked about the details of the implementation of Option 3. ‘I feel that Option 1 will not be considered as too much has gone on to get to this stage and that Options 2 & 3 will be the only ones considered,’ said an individual pharmacist. Similarly, the pharmaceutical company ProStrakan said, ‘This questionnaire is written with option 3 in mind and does not allow the exploration of all options fairly.’
11 APPENDICES
11.1 List of organisational respondents

This list includes both those who submitted written responses and those who attended the DH listening events. For privacy, individual respondents are not named in this report.

AAH Pharmaceuticals Ltd
Abbaxis Bioscience
Actavis UK Ltd
Age Concern and Help the Aged
All Party Parliamentary Group on Skin
Association for Continence Advice
Association of Teaching Hospital Pharmacists
Association of the British Pharmaceutical Industry (ABPI)
Assura Pharmacy Ltd
Asthma Steering Group
Asthma UK
AstraZeneca UK Ltd
Avicenna plc
Avon Local Pharmaceutical Committee
Barry Shooter Pharmacy
Bayer HealthCare
Beacon Pharmaceuticals
Bedfordshire Local Involvement Network (LINK)
Berkshire LPC
Bolton LPC
BMA
Boots Pharmacists Association
Boots UK Ltd
Breast Cancer Care
British Association of Pharmaceutical Wholesalers
British Dental Association
British Dermatological Nursing Group
British Generic Manufacturers Association
British Renal Society and The Kidney Alliance
British Thoracic Society
British Transplantation Society
Burson-Marsteller
Cambridgeshire Local Medical Committee
Campbell Gentry
Cege
dRx
Centre for Nursing & Midwifery Research, University of Salford
Cerebra
Chiesi Ltd
Civil Service Pensioners Alliance
CMP Medica
Company Chemists’ Association (CCA) and Independent Multiple pharmacies (AIMp)
County Durham & Darlington Local Pharmaceutical Committee
Croydon LPC
Cumbria LPC
DE Pharmaceuticals
Denton Village Surgery
Dermal Laboratories Ltd
Devon Local Pharmaceutical Committee
Dexcel-Pharma Ltd
Diabetes UK
Discovery Pharmaceuticals
Dispensing Doctors’ Association (DDA)
Dispex Buying Group
Dorset Local Pharmaceutical Committee
Dudley LPC
Dudley PCT
Dunns Chemist
East Riding & Hull LPC
East Sussex Local Pharmaceutical Committee
Epilepsy Action
ESNA (Epilepsy Nurses Association)
ESPRIT (Efficacy and Safety of Prescribing in Transplantation) Group
Ethical Medicines Industry Group (EMIG)
European Medicines Group
Ferring Pharmaceuticals Ltd
First DataBank Europe Ltd
Focus Pharmaceuticals Ltd
FPA
Genus Pharmacy
GlaxoSmithKline
Goldshield Pharmaceuticals
GP Newspaper
Grunenthal Ltd
Hampshire & IOW Local Pharmaceutical Committee
Haymarket Medical Media
Healthy Scepticism UK
Heart UK
Herbert Smith LLP
H.I. Weldrick Ltd
Interchem
International Glaucoma Association
International Trademark Association
Janssen-Cilag Ltd
Joint Epilepsy Council (JEC)
Kalmak Chemists Ltd
Kent House
Kent LINK
Kent Local Pharmaceutical Committee
Kingston Richmond and Twickenham LPC
Kirkburton Health Centre
Leeds, Bradford and Calderdale & Kirklees LPC
Leicestershire LINk
Lincolnshire Local Pharmaceutical Committee
LIVERNORTH
Lloyds Pharmacy
Lundbeck Ltd
Lupin (Europe) Ltd
M.D. & A.G. Burdon Ltd
Medicines Management & Prescribing group at NHS Hounslow
Medicines Management Team, Plymouth NHS
MSD UK Ltd
Napp Pharmaceuticals
National Kidney Federation
National Pharmacy Association (NPA)
National Society for Epilepsy
National Voices
NHS Barnsley
NHS Bath and North East Somerset
NHS Berkshire West
NHS Bexley
NHS Blackpool
NHS Bolton
NHS Bournemouth & Poole
NHS Brent
NHS Brighton & Hove
NHS Business Services Authority, Counter Fraud and Security Management Service
NHS Camden
NHS Central Lancashire Medicines Management Committee
NHS Cornwall & IOS
NHS Derbyshire County
NHS Devon
NHS Dorset
NHS East and North Hertfordshire
NHS East Riding of Yorkshire
NHS East Sussex Downs and Weald
NHS Eastern and Coastal Kent
NHS Employers
NHS Enfield
NHS Gloucestershire
NHS Greater Glasgow & Clyde
NHS Greenwich
NHS Hampshire
NHS Havering
NHS Islington
NHS Milton Keynes
NHS Northamptonshire
NHS North East
NHS North East Essex
NHS North Tees
NHS Prescription Services
NHS Primary Care Commissioning
NHS Somerset
NHS South Gloucestershire
NHS Suffolk
NHS Walsall
NHS Waltham Forest
NHS Wandsworth
NHS West Kent
NHS Westminster
NHS Yorkshire and the Humber
Norgine Pharmaceuticals Ltd
North Tyne Local Pharmaceutical Committee
North Yorkshire LPC
Nottingham City PCT
Novo Nordisk Ltd
Paediatric Continence Forum (PCF)
Patients Association
PCT Healthcare Ltd
PDC Healthcare Ltd
Pfizer Ltd
Pharmaceutical Services Negotiating Committee (PSNC)
Pharmacy Direct
Primary Care Dermatology Society
Primary Care Respiratory Society UK
Professional Relationships Working Group
ProStrakan
Ranbaxy UK
Rethink
Rochdale User Carer Action Forum
Roche Products Limited
Rowlands Pharmacy
Royal College of General Practitioners
Royal College of Paediatrics and Child Health - Science and Research Department
Royal College of Paediatrics and Child Health
Royal Pharmaceutical Society of Great Britain
RX Systems.co.uk
Sandoz Limited
sanoﬁ-aventis
Servier Laboratories
Sheffield PCT
Shire Pharmaceuticals
Shires Pharmacies Ltd
Sigma Pharmaceuticals plc
Somerset Local Pharmaceutical Committee
South Cheshire Local Pharmaceutical Committee
South East Forum of Local Pharmaceutical Committees
South Staffordshire Local Pharmaceutical Committee
Sunderland LPC, Gateshead & South Tyneside LPC
Surrey LPC
Stroke Association
Taylor Wessing LLP
Teva UK Limited
The Co-operative Pharmacy
Theale Medical Centre K81077
UCB Pharma Ltd
UK Medicines Information Executive (UKMI Executive)
UK Renal Pharmacy Group and
British Renal Society
Unique Solutions for Pharma
United BioSource Corporation
United Commissioning
University of Salford
Veterinary Medicines Directorate
Victoria Road Patient Participation
Group
West Sussex LPC
Walford Mill Pharmacy
Walsall Local Pharmaceutical
Committee
Wellfoods Ltd of Barnsley
West Sussex LPC
Whitworth Chemists Ltd
Winterton Medical Practice
Wirral LPC
YOR Local Medical Committee Ltd,
North Yorkshire Branch
11.2 Text of the Epilepsy Action campaign letter

The following is the text of the Epilepsy Action campaign letter, submitted by 51 respondents in this form. Additional respondents drew on the points raised in this letter in formulating their own responses.

Dear consultation team,

Re: ‘Generic substitution in Primary Care’ consultation

I am writing to submit my thoughts regarding “The proposals to implement ‘generic substitution’ in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009” consultation document.

As a person with epilepsy, I am concerned that anti-epileptic drugs would be allowed to be substituted. There is strong evidence that brand switching for many people with epilepsy has caused breakthrough seizures, worsening of their seizure control or worsening of side-effects

Having read the document I do not feel able to respond to all the questions asked, but would like to put forward some points for consideration.

Question 1

I would like to see Option 2 adopted, provided anti-epileptic drugs are on the list of drugs not to be substituted. This option would be best to ensure that people with epilepsy are not put at unnecessary risk.

I do not support the government's preferred choice (Option 3) unless it is changed so that there is a public consultation before a drug is added to a substitution list. I am worried that anti-epileptic drugs could be added to this list at any time without this process.

Question 5

As well as a process for adding drugs to the substitution list, I also think there should be a second list of drugs that can never be added to a substitution list, which should include anti-epileptic drugs.

I hope you will take my comments into account when deciding which proposal to adopt.
11.3 Text of the LIVErNORTH campaign letter

The following is the text of the campaign letter distributed by LIVErNORTH and submitted by 103 respondents.

Dear Sirs,

**Automatic Generic Substitution**

I am extremely concerned about the intention of the Department of Health to introduce the automatic generic substitution of prescription drugs. I wish to register my objection for the following reasons:

1. This is a cost driven exercise unlikely to realise any savings in real terms. Possible litigation as a result of being given medication with an adverse effect could easily cost more than any perceived savings.

2. Patient care is not the priority – illustrated by the following:
   i. Unknown contra-indications of other prescribed drugs with the generic substitute.
   ii. Prescriber may not be aware of the substitution.
   iii. Patients would be unaware of any substitution until the time the drugs are actually dispensed.
   iv. Patient confusion and stress could be caused by changes in appearance of regular medications.

3. Implementation is potentially problematic.
   i. The proposed list of drugs which can or cannot be substituted needs to be constantly maintained.
   ii. A list, once implemented, could grow or shrink to suit budgetary pressures or requirements.
   iii. Repeat prescriptions can be written by someone with no knowledge of the patient.
   iv. Heavily reliant on the prescriber knowing when to use the tick box.

4. Who will take responsibility and therefore be liable when something goes wrong?

I am also aggrieved that I have been excluded from the consultation due to the complexity of this internet based process which discriminates against a large sector of the community – mainly the elderly and people who find concentrating difficult. This letter is therefore my response to the Public Consultation on Automatic Generic Substitution and I would appreciate an acknowledgement being sent to me at the above address.
### 11.4 Glossary of acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>AEDs</td>
<td>Anti-epileptic drugs</td>
</tr>
<tr>
<td>BANs</td>
<td>British Approved Names</td>
</tr>
<tr>
<td>BGMA</td>
<td>British Generic Manufacturers Association</td>
</tr>
<tr>
<td>BMA</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>BNF</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>EMIG</td>
<td>Ethical Medicines Industry Group</td>
</tr>
<tr>
<td>LPC</td>
<td>Local Pharmaceutical Committee</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
</tr>
<tr>
<td>PPRS</td>
<td>Pharmaceutical Price Regulation Scheme</td>
</tr>
<tr>
<td>PSNC</td>
<td>Pharmaceutical Services Negotiating Committee</td>
</tr>
<tr>
<td>rINNs</td>
<td>Recommended International Non-proprietary Names</td>
</tr>
<tr>
<td>RPSGB</td>
<td>Royal Pharmaceutical Society of Great Britain</td>
</tr>
</tbody>
</table>