

Briefing Paper  
25 April 2008

**Subject: Pharmacy in England White Paper**

### **Purpose of briefing**

This policy briefing examines the market reforms outlined in *Pharmacy in England: Building on strengths – delivering the future* the White Paper published by the Department of Health on 3 April 2008.<sup>1</sup>

Detailed analyses of the practice, education, research and communications aspects of the White Paper will follow.

### **Issues**

Rather than announcing a series of policy initiatives, as might be expected from a traditional white paper, this White Paper outlines a framework of future actions, consultations and policy development.

This briefing provides an overview of the White Paper's proposals and examines the policies set out and their associated implementation plans.

### **Overview**

The White Paper is concerned with promoting a wider role for pharmacy in line with earlier government policy and in the light of policy documents including: *World Class Commissioning* (Department of Health, December 2007)<sup>2</sup>; *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21<sup>st</sup> Century* (Department of Health, February 2007)<sup>3</sup>; and *Our health, our care, our say: a new direction for community services* (Department of Health, 2006)<sup>4</sup>.

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<sup>1</sup> Department of Health. *Pharmacy in England: Building on strengths – delivering the future* (3 April 2008):  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_083815](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083815)

<sup>2</sup> Department of Health. *World Class Commissioning* (December 2007):  
<http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/index.htm>

<sup>3</sup> Department of Health. *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21<sup>st</sup> Century* (February 2007):  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_065946](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946)

<sup>4</sup> Department of Health. *Our health, our care, our say: a new direction for community services* (2006):  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4127453](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453)

Key proposals in the White Paper include:

<i>Practice</i>	The White Paper articulates a vision for pharmacy practice that can be summarised as: supporting healthy living and better care; expanding access to clinical services; and providing more support for people with long term conditions (LTCs). <sup>5</sup>
<i>Communication</i>	The White Paper outlines the communication task associated with these practice reforms, and the need to foster closer professional relationships between pharmacy and other healthcare professionals. <sup>6</sup>
<i>Research and Innovation</i>	The White Paper looks at the need to develop a sound evidence base to underpin decisions relating to the effectiveness, quality, and value of pharmacy service provision. <sup>7</sup>
<i>Education and Regulation</i>	The White Paper elaborates on the Government's intentions and expectations regarding: undergraduate and postgraduate education; continuing professional development; and advancing and regulating pharmacy practice. <sup>8</sup>

## Main proposals

### 1. Practice and Research

Chapter 4 of the White Paper articulates a vision for pharmacy practice that can be summarised as: supporting healthy living and better care; expanding access to clinical services; and providing more support for people with Long Term Conditions. Chapters 5 and 6 focus on the communication and organisational aspects of this task.

In order to promote pharmacies in communities as **'health living' centres that support self care**, the White Paper announces that the Public Health Leadership Forum for Pharmacy will identify a work programme for 2008-2010 to accelerate pharmacy's ongoing and expanding contribution to health; and to reduce health inequalities, with a particular focus on community leadership and sustainable development. (Paragraph 4.13, p.52)

The White Paper highlights a need for **clinical leadership** in the development of pharmaceutical services. In support of the development and promotion of pharmacists' clinical capabilities, the government has announced the appointment of two new clinical leaders who will focus on pharmaceutical service

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<sup>5</sup> Department of Health. *Pharmacy in England: Building on strengths – delivering the future*, April 2008, Chapter 4, pp.46-69

<sup>6</sup> Department of Health. *Pharmacy in England: Building on strengths – delivering the future*, April 2008, Chapter 5, pp.70-74

<sup>7</sup> *ibid*, Chapter 6, pp.75-84

<sup>8</sup> *ibid*, Chapter 7, pp.85-100

delivery in the community and primary care, and in hospital pharmacy respectively. These leaders will work directly to the Chief Pharmaceutical Officer. (Paragraph 4.64, p.68)

The government seems likely to deliver on its commitment in *Our health, our care, our say* (2006) to provide more support for **people with long term conditions** (LTCs). The White Paper outlines roles for pharmacists at three levels: supported self care – where people monitor their own conditions with periodic support and advice; disease management – supporting people on multiple, complex medicines regimes; and case management – working alongside other primary care providers supporting high risk patients. (Paragraph 4.51, p.62)

In support of the aforementioned healthy living, clinical and LTC agendas, the White Paper also notes the government's intention to implement a **communications programme** to identify and target the recipients of these services. (Paragraph 5.7, p.72)

To encourage the commissioning of pharmacy services, the White Paper notes the need to improve the evidence base in relation to the outcomes of clinical pharmacy. To this end, the White Paper announces the government's intention to convene an expert panel under the Chief Pharmaceutical Officer to provide advice on priorities for **health service research in pharmacy**. The panel will feed into the government's National Institute for Health Research prioritisation process. (Paragraph 6.24, p.80) The White Paper also indicates the government's intention to conduct research on the availability and contribution of **specialist pharmacy services** across England. (Paragraph 6.36, p.82)

The White Paper notes the release of stage 2 of the Electronic Prescription Service and signals the government's intention to develop further the **use of information in community pharmacy**. For example, working with early adopter PCTs the government is considering the benefits and the governance and practical implications of giving community pharmacists access to patient Summary Care Records. (Paragraph 6.45, p.84)

## *2. Education and Professional Development*

Chapter 7 of the White Paper elaborates on the government's intentions and expectations regarding: undergraduate and postgraduate education, continuing professional development, and advancing and regulating pharmacy practice.

The actions outlined in the White Paper show that the government intends to build on work initiated by the RPSGB in **undergraduate pharmacy education**. The government indicates its intention to ensure 'a meaningful clinical context and experience throughout the undergraduate programme'. The government will test whether undergraduate education outcomes are optimised by the integration

of undergraduate degree course with the pre-registration training year.  
(Paragraph 7.17, p.90)

The White Paper also commits the government to ensuring: '**an appropriate funding framework**' to support academia and clinical practice in delivering these new programme arrangements; and sufficient capacity and infrastructure in the relevant academic and clinical institutions to provide high quality education.  
(Paragraph 7.17, p.90)

The government set out proposals for the introduction of a new system of **revalidation** in *Trust, Assurance and Safety: The Regulation of Health Professionals in the 21<sup>st</sup> Century*. Consistent with this framework, the White Paper notes the scheduled introduction of a statutory **continuing professional development** (CPD) scheme when the GPhC assumes regulatory responsibility for pharmacy in 2010. (Paragraph 7.25, p.92) The White Paper also notes that the government will look to the RPSGB to work with the profession, employers and education providers to support pharmacists and pharmacy technicians in the regular recording of CPD. (Paragraph 7.28, p.90) Importantly, under transitional arrangements to regulation by the GPhC, CPD records created in the period before 2010 may form part of the assessment process by the GPhC. (Paragraph 7.27, p.92)

The government acknowledges the important dual contribution of **pharmacy expertise in the pharmaceutical industry** as both a science based and clinically informed profession. The White Paper stresses the need to maintain this balance of expertise as pharmacy takes on a more clinical role, and it is noted that the government has asked the RPSGB to identify the unique competencies that should remain within the profession as it undertakes this transition. (Paragraph 7.41, p.97)

The government wants to markedly accelerate the deployment of advanced practitioner pharmacists but acknowledges that regulation of **advanced and specialist roles** must be put on a more consistent footing to ensure patient safety. (Paragraph 7.39, pp.95-96) The RPSGB's current statutory role as the regulator of prescribing pharmacists is also noted alongside the government's expectation that the GPhC will seek early on in its existence to regulate advanced and specialist practice. (Paragraph 7.39, pp.95-96)

On improving the utilisation of the pharmacy workforce, the White Paper advises that the government will publish a summary of the outcome of the consultation on **the responsible pharmacist** in spring 2008, and that the next stage will be consultation on the proposed content of regulations on the supervision requirements. The regulations will be laid later in 2008 for commencement in 2009. (Paragraph 7.54, p.100)

### 3. The Galbraith Report

Alongside the White Paper, the government has also published the *Review of NHS pharmaceutical contractual arrangements* by Anne Galbraith.<sup>9</sup> The following table summarises the government's response to the Galbraith recommendations.<sup>10</sup>

Galbraith recommendations	Government's response
1. Strengthen PCT's commissioning role to stimulate competition and ensure quality.	<ul style="list-style-type: none"> <li>• Endorses recommendation, as part of World Class Commissioning programme</li> <li>• But PCTs' commissioning capability and capacity has been assessed as 'less mature' in primary care</li> </ul>
2. Commissioning of pharmacy services should be against PCT assessments of local pharmaceutical needs.	<ul style="list-style-type: none"> <li>• This is a valuable part of the commissioning process</li> </ul>
3. PCTs will set out requirements for all contractors to meet, with enough flexibility to ensure prompt access to medicines and appliances.	<ul style="list-style-type: none"> <li>• [Endorsement is implied]</li> </ul>
4. PCTs will be able to terminate contracts with underperforming/poorly performing pharmacy contractors.	<ul style="list-style-type: none"> <li>• PCTs should have effective powers where contractors are underperforming/poorly performing</li> </ul>
5. Two alternative options proposed to achieve these goals, replacing current 'control of entry' system: <ul style="list-style-type: none"> <li>• Complete devolution of contracting responsibilities to PCTs</li> <li>• Essential services provision would be open to 'any willing provider'; increased contestability for local enhanced services.</li> </ul>	<ul style="list-style-type: none"> <li>• Commissioning systems and structures need to be strengthened before PCTs can take full responsibility for contracting</li> </ul>

### Analysis

In the context of the aforementioned initiatives, this analysis focuses on the structural reforms outlined in the White Paper, and how the government intends to create an environment in which pharmacy will be incentivised to deliver its objectives for the primary healthcare sector.

Chapter 8 of the White Paper, *Structural enablers and levers*, outlines how the government intends to expand and embed the role of pharmacy as a clinical service provider in the primary care sector.<sup>11</sup> The government believes that, in

<sup>9</sup> Galbraith A. *Review of NHS pharmaceutical contractual arrangements* (April 2008): [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_083815?IdcService=GET\\_FILE&dID=163048&Rendition=Web](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083815?IdcService=GET_FILE&dID=163048&Rendition=Web)

<sup>10</sup> *ibid*, pp.102-103

<sup>11</sup> *ibid*, pp.101-116

order to create innovative responses to local primary and secondary health service requirements, the commissioners of these services (PCTs and practice-based commissioners (PBCs)) need to encourage diverse and flexible health services markets, and recognise the role that pharmacy can and does play in these markets.

To achieve this outcome, the government is relying on a number of measures to address shortcomings in the current service framework. Key areas targeted in the White Paper include commissioning, contracting arrangements, payment mechanisms, and quality and safety assurance.

### 1. Commissioning for local needs

The White Paper notes that, while the 2005 market entry reforms have resulted in increased access to pharmacies, a number of 'control of entry' problems have emerged:

- The opening of exempt 100 hours per week pharmacies: a lack of PCT control as to where these pharmacies are located, and no match between access and need has resulted in clustering of new pharmacies close to income sources; and, for some PCTs, the incursion of unbudgeted additional expenditure.<sup>12</sup>
- Consent for dispensing doctors: under the current regulatory system access to dispensing services from a GP is dictated by the distance between a person's home and the nearest community pharmacy, leading to inequality of access to dispensing services at dispensing GP practices.<sup>13</sup>
- Market entry for appliance contractors: under the current regulatory system appliance contractors are effectively frozen out of local markets.<sup>14</sup>

The White Paper outlines a series of remedies to these 'control of entry' problems<sup>15</sup>, but acknowledges that the more fundamental issues of market entry being driven primarily by providers and the lack of pharmacy confidence regarding the levels of enhanced service commissioning from PCTs require a different kind of response.

The key issue in relation to the government's proposed initiative is the nature of the 'appropriate support programme for PCTs'. For PCTs to be able to continuously improve their PNA processes clear standards for these assessments need to be established and performance against these standards monitored and reported. The White Paper provides no detail as to possible arrangements for the ongoing quality assurance and performance assessment of PNAs.

<sup>12</sup> *ibid*, paras. 8.59 and 8.60, p.113

<sup>13</sup> *ibid*, paras, 8.68 and 8.69, p.115

<sup>14</sup> *ibid*, para. 8.75, p.116

<sup>15</sup> *ibid*, paras. 8.64, 8.74 and 8.77, pp.114-116

On the execution of PBC: the White Paper places responsibility for improvement firmly at the feet of PCTs. While recognition of PCTs as the ultimate owner and driver of PBC is important, the role and responsibility of community pharmacists as active participants in the PBC process is an important one and should not be discounted.

It has been noted in the literature that pharmacists' level of engagement with PBC has not been high.<sup>16</sup> By overlooking the importance of an engaged community pharmacy sector, equipped with the requisite skills to proactively participate in PBC, the government is potentially undermining its objectives for the reform of clinical service provision. It is in the government's interest to ensure that the profession is supported by appropriate training and information resources.

Finally, the White Paper provides little detail as to the role that pharmacists could play within PCTs in relation to the planning of PNA and PBC processes. As expert medicines managers, pharmacists are well equipped to provide not only end-point clinical services, but also input to PNA and PBC programming in relation to care pathways and drug delivery. If pharmacists are excluded from these processes then PCTs and practice based commissioners risk missing out on the value pharmacists can add in relation to clinical service innovation.

## 2. Contracting arrangements

The White Paper identifies Local Pharmaceutical Services (LPS) arrangements as a means by which all services outlined in the White Paper could be contracted.<sup>17</sup> However, in response to recommendations by the All-Party Pharmacy Group in their 2007 inquiry into pharmacy services, the White Paper acknowledges the limitations of delivering national priority responses through LPS arrangements,

The White Paper therefore identifies a need for a new category of service – directed enhanced services. The government will use Directions in consultation with NHS Employers and PSNC to direct PCTs to commission certain services from pharmacy contractors according to local needs they identify and subject to suitable accreditation requirements and service quality standards.<sup>18</sup>

The ability of government to direct services like the proposed national minor ailments scheme, or to support people newly prescribed a medicine for an LTC

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<sup>16</sup> Blenkinsopp, A. *National evaluation of the new community pharmacy contract*, June 2007: [http://www.pprt.org.uk/Documents/Publications/National\\_evaluation\\_of\\_the\\_new\\_pharmacy\\_contract.pdf](http://www.pprt.org.uk/Documents/Publications/National_evaluation_of_the_new_pharmacy_contract.pdf)

<sup>17</sup> LPS Permanence allows PCTs to enter into LPS contracts without requiring prior approval of the Secretary of State for Health and provides PCTs with flexibility to make LPS arrangements in response to local needs within timetables of their own choosing.

<sup>18</sup> Department of Health. *Pharmacy in England: Building on strengths – delivering the future*, April 2008, para. 8.34, p.109

will be dependant on the quality of PNAs and the ability of the commissioned bodies to meet accreditation and service standards.

Without a reliable evidence base created through rigorous PNAs, the government will be unable to guarantee that the funding it directs to national priorities is appropriately targeted. Furthermore, the government will need to ensure that 'suitable service quality standards' are applied equally to the PNA and PBC processes, and to the end-point enhanced services. As it stands, the White Paper addresses neither of these issues.

### 3. *Payment mechanisms*

The White Paper notes the importance of payment mechanisms as a means for PCTs to 'own' the new services and a range of possible payment mechanisms are suggested including: fees set nationally; fees set within a band range by PCTs; and fees set locally (presumably by PCTs and unconstrained).

A consultation on future payment mechanisms is flagged for summer 2008.<sup>19</sup>

From a structural perspective, the advantage of the first option, 'fees set nationally', is that payment equality is preserved across PCTs creating certainty for new entrants. The disadvantage is that PCTs and pharmacy service providers are denied the flexibility to innovate and to negotiate fees in the context of local needs and conditions. The second and third options for setting fees raise the question of how the level of the fee, whether it be 'set within a band' or 'set locally', will be determined.

The relative benefits and implications of the proposed payment mechanisms are not explored in the White Paper. The summer 2008 consultation will need to address issues including which payment mechanisms are appropriate, and under what circumstances. Perhaps more importantly the consultation will need to examine how the performance of these payment mechanisms will be reviewed once implemented.

### 4. *Quality and safety assurance*

The White Paper identifies three areas through which improvements in quality and safety assurance can be secured: standard setting and harmonisation, financial incentives and penalties, and sanctions.

On performance management, the government indicates that it will work with the PSNC and NHS Employers to devise proposals to ensure effective arrangements are in place to address unwarranted variations in standards and quality of service delivery.<sup>20</sup>

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<sup>19</sup> *ibid*, para 8.39, p.109

<sup>20</sup> *ibid*, para.8.46, p.111,

On standard setting and harmonisation, the government signals its intention to work with the NHS and professional bodies to develop a set of pragmatic, easily measurable metrics or indicators that will serve to demonstrate the quality and outcomes of pharmacy service provision.<sup>21</sup> With an increasing emphasis on pharmacy provision of clinical services, the government also highlights a need for clinical audits to ensure that pharmacy services and systems are safe and effective.<sup>22</sup>

In the absence of detail on the proposed 'effective arrangements' to address unwarranted variations in standards and quality of service delivery, it is difficult to speculate on how these arrangements might operate.

Whatever levers are applied, be they in the form of incentives or sanctions, they will be based on the performance 'metrics and indicators', making the ownership of these performance measures and the regulation of the ownership body a critical issue. The White Paper does not identify who will own the performance measures.

Finally, the White Paper states that the performance measures will be pragmatic and easily measurable. To ensure community pharmacy is not unreasonably burdened by new performance assessment arrangements, the government will need to substantiate this assurance with some form of regulatory impact assessment.

##### *5. Access to patient information*

The issue of access to patient information is not addressed in relation to commissioning and the pharmacy market. However, the government's position on this issue will have a bearing on the ability of pharmacy to deliver safe and high quality services to patients.

The White Paper advises that the government will be undertaking further work with an early-adopter PCT to consider the benefits, governance and practical arrangements of community pharmacists having access to patient Summary Care Records (SCR).<sup>23</sup>

As demonstrated by its support for the NHS Connecting for Health programme, the government accepts the principle of information sharing as a means to deliver better and safer care to patients. However, in the case of pharmacy, the government has not as yet extended the SCR system to include community pharmacists. The White Paper mentions two areas of concern: patient consent to pharmacists accessing their records and the maintenance of patient

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<sup>21</sup> *ibid*, para. 8.47, p.111

<sup>22</sup> *ibid*, para. 8.56, pp.112-113

<sup>23</sup> *ibid*, para. 6.45, p.84

confidentiality, and a perceived conflict of interest between access to patient information and the commercial aspect of community pharmacy.

One important safeguard in relation to both these areas of concern is pharmacy's own commitments regarding the use of patient information as contained within its Code of Ethics; specifically the Professional Standards and Guidance for Patient Confidentiality. A written undertaking to comply with the Code of Ethics is a requirement of the RPSGB's current registration and renewal processes. However, it is recognized that a range of measures, of which the Code of Ethics is one, will be needed to enable community pharmacists to meet the requirements for access to the SCR.

## **Conclusion**

While the White Paper indicates the government's good intentions and aspirations with regard the future of pharmacy in England, there is a lack of important detail around a number of key issues including assurance frameworks, incentives and support for clinical reform, patient information sharing, and funding commitments.

*Assurance frameworks* – the White Paper provides no detail on arrangements for the quality assurance and performance assessment of PNAs, PBC systems, and - integral to PBC - of contracting arrangements and payment mechanisms. There is also a lack of clarity on who will own and be responsible for these quality assurance and performance assessment processes.

*Incentives and support for clinical reform* – the White Paper does not acknowledge the value that pharmacy can add as an active participant in the PBC process; and this has the potential to undermine the participation of PCTs and pharmacists in PBC if not addressed.

*Patient information sharing* – the government's apparent reticence in the White Paper around the issue of the community pharmacy's ability to manage patient information without being compromised by their commercial interests betrays a lack of trust that may deter the profession from engaging with the wider reform process.

*Funding commitments* – except in the case of the appointment of the two new clinical leaders, the lack of clearly identified funding for the measures outlined in the White Paper risks bringing into question the government's commitment to pharmacy beyond the establishment of the GPhC.

The consultation scheduled for summer 2008 will need to provide the detail that has been lacking in this White Paper. Until there is clarification and assurance around these issues, the confidence of the pharmacy sector that it will be treated fairly under the reforms set out in *Pharmacy in England* will be at risk. Without

this confidence, pharmacists are unlikely to engage and participate in the process of reform, and the government's worthy objectives will be undermined.