DH Department of Health

Regulations under the Health Act 2009: market entry by means of pharmaceutical needs assessments and quality and performance

Equality Analysis

July 2012

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Equality Analysis

Prepared by: Medicines, Pharmacy and Industry – Pharmacy Team in conjunction with the Advisory Group on the NHS (Pharmaceutical Services) Regulations

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Equality analysis

Title: Regulations under the Health Act 2009: market entry by means of pharmaceutical needs assessments and quality and performance

Relevant line in DH Corporate Plan 2012-2013**: Better Value – providing better quality care by improving productivity and ensuring value for money for the taxpayer**

What are the intended outcomes of this work? *Include outline of objectives and function aims*

The policy objective is to manage the supply of pharmaceutical services (medicines and appliances) in order to align provision with local needs – and in particular ensure adequate service provision in areas of lower demand. Achievement of this objective would reduce the impact of the imperfections in the current regulatory system, improve the economic efficiency of pharmaceutical provision, and increase patient and consumer benefits by aligning services more closely with the requirements and needs of local populations. These provisions reflect the principles set out in *Equity and excellence*: *liberating the NHS*, particularly in respect of improved patient choice, greater commissioning autonomy and more responsive, better quality services.

Who will be affected? *e.g. staff, patients, service users etc*

Primary Care Trust (PCT) staff who are responsible for implementing the Regulations locally, existing and potential pharmacy contractors, dispensing appliance contractors, dispensing doctors and their staff who provide NHS pharmaceutical services, patients and the public requiring pharmaceutical services and staff in the Family Health Services Appeal Unit of the NHS Litigation Authority.

Evidence *The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the assessment. For more information, see the current DH Transparency Plan.*

What evidence have you considered? *List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.*

Sources of evidence:

Consumer research carried out alongside the previous Government's White Paper, *Pharmacy in England – Building in strengths – delivering the future – Understanding the pharmacy market in England* produced in 2009 –
http:///www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_101093.pdf
General Pharmaceutical Council's Equality Scheme published in 2010 –
http://www.pharmacyregulation.org/pdfs/other/gphcequalityanddiversityscheme.pdf
Primary Care Trust websites
General Pharmaceutical Services in England 2001-02 to 2010-11 – http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/pharmacies/general-pharmaceutical-services-in-england-2001-02-to-2010-11
Health Survey for England, 2004 –
http://www.dh.gov.uk/en/PublicationsAndStatistics/PublishedSurvey/HealthSurveyForEngland/Healthsurveyresults/index.htm
2001 Census – http://www.statistics.gov.uk/census2001/get_facts.asp
Pharmacy in England: building on strengths – delivering the future – regulations under the Health Act 2009: pharmaceutical needs assessments – regulations under the Health Act 2009: pharmaceutical needs assessments – information for PCTs –
http://www.dh.gov.uk/en/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/DH_114953
Pharmacy in England: building on strengths – delivering the future – draft regulations under the Health Act 2009: pharmaceutical needs assessments – response to consultation –
http://www.collections.europarchive.org/tna/20100509080731/http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH-114809
The General Pharmaceutical Council's *guidance on the provision of pharmacy services affected by religious and moral beliefs* -
http://www.pharmacyregulation.org/pdfs/other/religiousmoralbeliefguidancev13.pdf

Consideration of evidence - general

Access to NHS pharmaceutical services, advice and supply of medicines and health consumables is an integral part of primary care in the NHS and, as such, should be available on an equitable basis to all people in England. The general principles underpinning the requirement for PCTs to devise and to publish pharmaceutical needs assessments (PNAs) and to use these as a basis for market entry are to promote equality of access to fair, personalised, safe and effective NHS services for all groups in society and to reduce health inequalities. As such, it is intended to benefit all the population, with particular emphasis on supporting disadvantaged groups (for example those in poverty or not registered with a GP), those groups currently adversely affected by either specific conditions or the way services are delivered and those groups with long-term conditions.

PCTs are required as a public body to act in accordance with the public sector equality duty and all have equality and diversity policies (sample of PCT websites reviewed). The NHS (Pharmaceutical Services) Regulations 2005 as amended and accompanying guidance detail the information to be included in PNAs as part of the assessment and the guidance encourages PCTs, for example, to gain a complete picture of populations within the area and how their needs differ as well as identifying specific communities with particularly poor health.

The previous Government asked in its consultation on the draft Regulations requiring PCTs to devise PNAs from consultees, particularly from those representing affected communities, whether key equality issues have been raised and addressed within the draft Equality Impact Assessment published alongside the consultation document. The majority of those who responded to this question in the PNA consultation felt that there were no further matters to be included in the Equality Impact Assessment. However, some patient/public respondents felt there needed to be caution in the element of collection as collecting the data might become more important rather than the quality of patient experience and that some groups will be prevented by geographical location from accessing services unless special provision is made. The homeless, travellers and prisoners also warrant special consideration. Following the consultation, these findings were reflected in the final version of the regulations and the guidance, *Pharmacy in England: building on strengths – delivering the future – regulations under the Health Act 2009: pharmaceutical needs assessments – regulations under the Health Act 2009: pharmaceutical needs assessments – information for PCTs.*

Disability *Consider and detail (including the source of any evidence) on attitudinal, physical and social barriers.*

Patients/public

Consumer research carried out alongside the previous Government's *Pharmacy in England – Building in strengths – delivering the future* indicated that among the most frequent users of pharmacies include those with a long-term health condition or disability. Gender, age, speaking English as a main language and having a long-term condition or disability are all key drivers of pharmacy usage, in that order. It is expected that the introduction of entry based on local pharmaceutical needs should help further support the development of services got those with long-term conditions or mobility problems.

The profession

All contractors providing NHS pharmaceutical services have an existing and ongoing responsibility under the Equality Act 2010 to make reasonable adjustments to their services and provide auxiliary aids where appropriate for people with disabilities.

Sex *Consider and detail (including the source of any evidence) on men and women (potential to link to carers below).*

Patients/public

Consumer research carried out alongside the previous Government's *Pharmacy in England – Building in strengths – delivering the future* indicated that women are among the most frequent users of pharmacies. It also indicated that if gender and age are considered together, the highest frequency pharmacy users are females aged 35-74 and males aged over 55. Males aged 16-24 use pharmacies the least. Gender, age, speaking English as a main language and having a long-term condition or disability are all key drivers of pharmacy usage, in that order. NHS pharmaceutical services geared to the needs of women (for example, emergency hormonal contraception) and men (for example, men's health advice) are being commissioned by PCTs as locally funded services. It is expected that the introduction of entry based on local pharmaceutical needs should help further support the development of gender specific services.

The profession

The General Pharmaceutical Council (GPhC) in its *Equality Scheme* report on the number of pharmacists and pharmacy technicians on the GPhC 2010 register that 50% of registrants are female and 49% male. However, amongst registered pharmacists, 57% are female and 42% male.

Race *Consider and detail (including the source of any evidence) on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.*

Patients/public

There is no evidence that the proportion of people from ethnic minorities who make use of pharmaceutical services differs significantly compared to the population as a whole. However, it is likely that where ethnic minorities have a higher incidence of a particular health problem than the population as a whole they are more likely to have increased requirements for regular access to such services to help meet their health needs. The research referred to below identifies that there is very low use of other health related services offered by some pharmacies such as regular monitoring of current health conditions and health screening for conditions which may be of particular benefit to people from ethnic minorities where such incidence is higher.

While the health complications of increasing obesity affect all ethnic groups in society, two have particular impact on specific groups. These are Type 2 diabetes for people of Indian, Pakistani, Bangladeshi or Black Caribbean origin, where NHS figures show prevalence is 2 - 4 times higher than in the general population and Black Caribbean men who have the highest prevalence of hypertension.

Similarly, men in Pakistani, Bangladeshi and Irish groups are more likely to report smoking than men in the general population. Both Black Caribbean women and Irish women showed a slightly higher prevalence of smoking than among women in the general population (Health Survey for England, 2004 - these findings are the latest available on smoking and ethnicity). Local, easily accessible, culturally appropriate and targeted services in local high street community pharmacies will help reduce inequality and promote equality.

Data on ethnicity are not recorded for teenage pregnancy, but the 2001 census showed higher rates of motherhood in young Mixed, Other Black and Black Caribbean groups than in the general population. In 2004, NHS data showed that Black Caribbean and African women presented for 9% of terminations, while accounting for 3% of the population.

492 pharmacies were in contract with their PCT in England as at 31 March 2011 to provide language services to people whose first language is not English. Special language services at pharmacies are likely to encourage attendance and improve access to services for people who might encounter language barriers. The proportion of people from ethnic minorities is higher in urban areas, where such pharmacies tend to be located, than rural areas.

It is expected that the introduction of entry based on local pharmaceutical needs should help further support the development of services got those with long-term conditions or mobility problems.

The profession

The GPhC in its *Equality Scheme* report on the number of pharmacists and pharmacy technicians on the GPhC's 2010 register that 23% of pharmacists are from black and ethnic minority backgrounds compared with 8% for the general population as a whole (drawing on 2001 Population and Census data) – this breaks down as 63% White, 17% Asian, 3% Black, just under 3% Chinese origin and 10% of registrants were recorded as "ethnic origin unknown".

Age *Consider and detail (including the source of any evidence) across age ranges on old and younger people. This can include safeguarding, consent and child welfare.*

Patients/public

The consumer research carried out alongside the previous Government's *Pharmacy in England – Building in strengths – delivering the future* indicated that if gender and age are considered together, the highest frequency pharmacy users are females aged 35-74 and males aged over 55. Males aged 16-24 use pharmacies the least. Gender, age, speaking English as a main language and having a long-term condition or disability are all key drivers of pharmacy usage, in that order. It is expected that the introduction of entry based on local pharmaceutical needs will further strengthen the availability and use of services specific to age differences.

The profession

The GPhC in its *Equality Scheme* report on the number of pharmacists and pharmacy technicians on the GPhC's 2010 register that almost half of the pharmacists on the Register are aged under 40 years. Female pharmacists are younger than males – 55.2% are aged less than 40 years, compared with 40.47% of males.

Gender reassignment (including transgender) *Consider and detail (including the source of any evidence) on transgender and transsexual people. This can include issues such as privacy of data and harassment.*

Patients/public

No specific evidence has been found concerning the availability and use of pharmaceutical services in relation to transgender or transsexual people.

The profession

The GPhC in its *Equality Scheme* states the 'general duty to promote equality between women and men and to eliminate unlawful discrimination and harassment on the grounds of gender, gender reassignment or sexual orientation when carrying out functions'.

Sexual orientation *Consider and detail (including the source of any evidence) on heterosexual people as well as lesbian, gay and bi-sexual people.*

Patients/public

No specific evidence has been found concerning the availability and use of pharmaceutical services in relation to a person's sexual orientation.

The profession

The GPhC in its *Equality Scheme* states the 'general duty to promote equality between women and men and to eliminate unlawful discrimination and harassment on the grounds of gender, gender reassignment or sexual orientation when carrying out functions'.

Religion or belief *Consider and detail (including the source of any evidence) on people with different religions, beliefs or no belief.*

No specific evidence has been found concerning the availability of pharmaceutical services in relation to a person's religion or belief. However, we do know of some individual pharmacists who have ethical objections to supplying emergency hormonal contraception. The GPhC has published guidance to those pharmacists and their employers about how to deal with such ethical dilemmas whilst ensuring patients receive appropriate pharmaceutical services in their *Guidance on the provision of pharmacy services affected by religious and moral beliefs*.

Pregnancy and maternity *Consider and detail (including the source of any evidence) on working arrangements, part-time working, infant caring responsibilities.*

PCTs have a duty to ensure pharmaceutical services are accessible to all parts of the population at times required including out of hours. Many PNAs stated that where there is a provision of pharmacies opening at least 100 hours per week, these are required to continue to provide services across those hours. This is of benefit to all those who are unable to access pharmaceutical services during normal working hours or in an emergency such as those caring for sick children. The evidence from previous public surveys indicate that women generally are high frequency users of pharmacy.

Carers *Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.*

PCTs have a duty to ensure pharmaceutical services are accessible to all parts of the population at times required including out of hours services. Many PNAs stated that where there is a provision of pharmacies opening at least 100 hours per week, these are required to continue to provide services across those hours. This is of benefit to all those who may be unable to access pharmaceutical services during normal working hours or in an emergency such as carers.

Other identified groups *Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.*

The provision of services for drug misusers provides a strong indication that pharmaceutical services are developed for and accessible to other groups who may experience disadvantages or barriers to access. It is expected that the introduction of entry based on local pharmaceutical needs should help further support the development of services to those who misuse drugs.

Engagement and involvement

Was this work subject to the requirements of the cross-government Code of Practice on Consultation? (**Yes**)

How have you engaged stakeholders in gathering evidence or testing the evidence available/ How have you engaged stakeholders in testing the policy or programme proposals?

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

In July 2009, an independent regulatory Advisory Group drawn from interested parties including representatives from pharmacy, the NHS and patients/public was set up to help devise the regulations on requiring PNAs and these draft regulations on market entry and market exit. The previous Government asked (in its consultation on the draft Regulations requiring PCTs to devise PNAs) consultees, particularly those representing affected communities, whether key equality issues had been raised and addressed within the draft Equality Impact Assessment published alongside that consultation document. The majority of those who responded to this question in the PNA consultation felt that there were no further matters to be included in the Equality Impact Assessment.

However, some patient/public respondents felt there needed to be caution in the element of collection as collecting the data might become more important rather than the quality of patient experience and that some groups will be prevented by geographical location from accessing services unless special provision is made. The homeless, travellers and prisoners also warrant special consideration. Following the consultation, these findings were reflected in the final version of the regulations and the guidance, *Pharmacy in England: building on strengths – delivering the future – regulations under the Health Act 2009: pharmaceutical needs assessments – regulations under the Health Act 2009: pharmaceutical needs assessments – information for PCTs.*

Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.

Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

We believe these proposals will support the elimination of discrimination, harassment and victimisation.

Advance equality of opportunity *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

We believe these proposals will support the advancement of equality of opportunity.

Promote good relations between groups *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

We believe these proposals will support the promotion of good relations between groups.

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?*

Access to NHS pharmaceutical services, advice and supply of medicines and health consumables is an integral part of primary care in the NHS and, as such, should be available to all people in England. The general principles underpinning the requirement for PCTs to devise and to publish pharmaceutical needs assessments (PNAs) and to use these as a basis for market entry are to promote equality of access to fair, personalised, safe and effective NHS services for all groups in society and to reduce health inequalities. As such, it is intended to benefit all the population, with particular emphasis on supporting disadvantaged groups (for example those in poverty or not registered with a GP), those groups currently adversely affected by either specific conditions or the way services are delivered and those groups with long-term conditions. We have therefore not identified any adverse impacts which would affect the above. Providing NHS pharmaceutical services to greater quality and dealing with underperforming pharmacy contractors so that high quality services are the norm in all areas will have a positive impact for all groups. If an established sole contractor were to be removed on grounds of inadequate quality, it is likely that other contractors would wish to step in to fill in the market and PCTs would actively seek providers who can provide services to a high quality which meet specific needs.

Addressing the impact on equalities *Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.*

No negative impacts have been identified. We believe the policy proposals should have a positive impact on equalities.

Action planning for improvement

Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.

A consultation was held on the draft 2012 Regulations – the majority of those who responded had no comments to make on the equality analysis. However, three comments were received on the analysis:

- *Excessive numbers of 100 hours per week applications across the country in anticipation of the possible change to the Regulations* – we did not consider this relevant to this Equality Analysis.
- *The lack of equality for individual newly-qualified pharmacists to set up their own businesses within both the current (2005) control of entry system and the 2012 Regulations* - as at 31 March 2011, 39% of pharmacies were owned by “independent” contractors (five NHS premises or fewer) and 61% were owned by larger businesses with six or more NHS premises including multi-nationals and supermarkets. This is covered on page 25 of the Impact Assessment. Overall, whilst there may be some impact on small businesses from the new proposals for market entry, it is not clear that such an impact would be

disproportionate. However, this impact can be assessed and any mitigating measures considered as part of a comprehensive evaluation of the proposals once introduced. Also any changes to legislation would apply to all NHS contractors, the Department does not consider it would be appropriate to exempt (either fully or partially) smaller firms from these provisions. Under the 2012 Regulations,

- *The Analysis focuses almost entirely on pharmacy and does not address the specific needs of patient groups relying on the specialist provision of incontinence and ostomy products* - this Equality Analysis covers NHS pharmaceutical services provided by pharmacists and appliance contractors and covers the needs of all patient groups in relation to appliance provision. We do not feel that we need to mention specific specialist provision within the Analysis. In their PNAs, PCTs are required to assess the needs of all patient groups including those who rely on the specialist provision of incontinence and ostomy products.

In light of the above, we do not feel that the draft Equality Impact Analysis needs to be amended substantially – and will be published unchanged and will be alongside the final regulations concerning the new market entry and performance sanctions procedures.

PCTs are required to keep their PNAs under review on a regular basis and to use as a basis for ensuring access to NHS pharmaceutical services.

DH will assess any impact the introduction of the new market entry and quality and performance regulations have on the equality issues outlined above in a comprehensive evaluation to be carried out in 2016.

For the record

Name of person who carried out this assessment:

Catriona Patterson

Date assessment completed:

July 2012

Name of responsible Director/Director General:

Giles Denham

Date assessment was signed:

July 2012

Action plan template

This part of the template is to help you develop your action plan. You might want to change the categories in the first column to reflect the actions needed for your policy.

Category	Actions	Target date	Person responsible and their Directorate
Data collection and evidencing	Continue to monitor impact of proposals using existing data collections and other relevant evidence.	ongoing	Catriona Patterson
Analysis of evidence and assessment	Analyse any gaps which become apparent during monitoring.	ongoing	Catriona Patterson
Monitoring, evaluating and reviewing	Conduct a comprehensive evaluation in 2016.	2016	Catriona Patterson
Transparency (including publication)	Publish equality analysis	Spring 2012	Catriona Patterson