Inquiry into Teenage Pregnancy

HRA Pharma

- Teenage pregnancy remains a critical problem in Scotland affecting young women, their opportunities and imposing a substantial cost to health and social services. Action currently underway under the national framework, and at health board level has been, and remains, vitally important in reducing the number of unintended teenage pregnancies.

- Enabling access to more clinically and cost effective forms of contraception represent an important, and currently under-utilised, part of the solution needed to redress this problem.

- Reviewing and updating the national pharmacy scheme by which emergency hormonal contraception (EHC) is made accessible to women in Scotland through pharmacies is a viable, readily-executable, cost-effective and widely endorsed mechanism by which to target reductions in teenage pregnancy levels in Scotland.

- Updating this scheme (the Community Pharmacy Public Health Service for Emergency Hormonal Contraception) to include more effective methods of EHC introduced since its establishment, carries the potential to reduce the number of unintended pregnancies in Scotland by 615 every year.

- It is estimated that this could save the health and social service budgets some £1.5 m yearly not to mention protecting many Scottish women from the emotional, physical and financial impact of unintended pregnancy.

- To paraphrase the Inquiry’s own words, these proposals will directly support those at risk of pregnancy at a young age being given better access to appropriate support and services.

- HRA Pharma seeks to work constructively with partners in Scotland to help realise this vitally important goal in the interests of teenage women and presents this submission to inform the Committee’s inquiry discussions and its eventual recommendations.

Key Recommendations

1. Update the current national patient group direction for emergency contraception, also referred to as the Community Pharmacy Public Health Service for Emergency Hormonal Contraception, to include more-effective, recommended forms of emergency contraception and allow access in the pharmacy setting for the benefit of teenage women in Scotland;

   Improve access in the pharmacy setting to all forms of emergency contraception as is recommended by the national Framework, clinical guidance, the SMC and is endorsed by leading clinicians working in Scottish sexual health.
PLEASE NOTE: HRA Pharma would like to be clear that it has a strong and current product interest in this area. ellaOne (ulipristal acetate) is more effective than existing methods of emergency hormonal contraception (EHC) and has been accepted for use within NHS Scotland by the Scottish Medicines Consortium (SMC). Unintended pregnancy is a multi-faceted problem, and while we appreciate EHC is not the whole answer, optimising the most effective use of EHC presents an opportunity to help reduce the number of unintended pregnancies in Scotland.

Response to Inquiry Question g).

HRA has a recommendation of singular priority to make to the Committee in response to question g) of the inquiry. HRA feels qualified to make the following points to the Committee’s consideration based on its knowledge, experience and credibility in the field of emergency contraception.

**Are there specific approaches to reducing teenage pregnancy that are not currently getting sufficient attention in order to affect positive change for children and young people?**

In the strongest possible terms, HRA would urge the Committee to consider recommending that the Scottish Government (i) review and update the existing arrangements for national provision of emergency hormonal contraception (EHC); and (ii) specifically consider updating the national EHC service to include more effective therapies than the current standard that could help reduce the number of unintended pregnancies in Scotland.

Published evidence is clear that in the first 24 hours following unprotected intercourse, newer forms of EHC are around three times more effective than the existing method in preventing an unintended pregnancy,\(^1\) and from 0-72 hours or 0-120 hours post intercourse are nearly twice as effective.\(^2\) Most women present at pharmacy within the first 24 hours, but currently they are unable to access their best chance to avoid pregnancy and are thus perversely disadvantaged by their prompt and responsible action.

Inclusion of more effective forms of EHC in the Community Pharmacy Public Health Service for Emergency Hormonal Contraception (PHS EHC) would rectify this unsatisfactory situation and provide a more effective service than is currently available, potentially reducing levels of unintended pregnancy.

Scotland led the UK in 2008 by implementing the National Community Pharmacy Public Health Service for EHC and HRA Pharma urges the Committee to recommend that this next logical leading step is taken in the interests of Scottish women of all ages.

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2. Glasier AF et al, Lancet 2010; 375: 555-562
What would updating the Community Pharmacy PHS EHC achieve for teenagers in Scotland?

1). Reduce inequitable variation in access across Scotland

The experience and review of the Community Pharmacy PHS for EHC has confirmed that the pharmacy setting is the most appropriate and convenient for women needing to access EHC. It is critical that women take EHC as soon as possible after unprotected intercourse and the majority of women present at a pharmacy within the first 24 hours.

Presently, only women living in the Highland area are able to go to their GP or contraception clinic, and readily access more effective EHC as “first choice.” In the rest of Scotland access and understanding of more effective EHC therapies remains restricted and blocks access for young women. Stark inequity like this could be resolved by updating the emergency hormonal contraception in the national Community Pharmacy PHS for EHC.

2). More effective EHC could reduce unintended pregnancies

According to latest Government statistics, there were some 2,703 women aged 19 and younger with unintended pregnancies resulting in abortion in Scotland in 2011.4

The Government’s Review of the Community Pharmacy PHS for EHC found that 81,000 items of EHC (in the form of levonorgestrel) were dispensed in 2010/11. Using this figure, if 95%5 of the items dispensed were instead more effective EHC, applying the different pregnancy rates for different methods of EHC as published in the Lancet, over 12 months this may result in 615 fewer unintended pregnancies overall.6

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5 This figure is the percentage of women who are typically medically eligible for ellaOne.
This means that for every month the service remains unchanged 50 unintended, unwanted and/or teenage pregnancies may occur or 12 unintended pregnancies every week! From the beginning of January 2013 to the 7 February, the closing date for submission of evidence to the Health and Sport Committee Inquiry. 59 preventable unintended pregnancies may have occurred and the clock will continue to tick if this urgent and necessary change is delayed.

**What would improving the Community Pharmacy PHS for EHC achieve for Scottish Health and Social Services?**

1). *Improved outcomes that are affordable and cost effective*

The cost of an unintended pregnancy is conservatively estimated at £948, meaning that access to more effective EHC could achieve yearly saving resulting from 615 avoided pregnancies of around £583,020.

However, unintended pregnancy may have different outcomes. The table below shows a cost for each outcome calculated according to the probability of it occurring:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Medical Costs</th>
<th>Probability</th>
<th>Total Number</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induced Abortion</td>
<td>£672</td>
<td>0.66</td>
<td>406</td>
<td>£272,832</td>
</tr>
<tr>
<td>Miscarriage</td>
<td>£474</td>
<td>0.16</td>
<td>98</td>
<td>£46,452</td>
</tr>
<tr>
<td>Delivery</td>
<td>£2380</td>
<td>0.18</td>
<td>111</td>
<td>£264,180</td>
</tr>
</tbody>
</table>

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Given that 111 unintended pregnancies may go to a full term delivery, the social costs will be incurred for some years after birth and, in many cases, will require national support using public funds. A recent report from LV Insurance estimates that to support the first 10 years of a child’s life costs £115,000. As a conservative estimate, even if only 10% of the 111 births above were supported by the welfare system, that represents a budget impact of £1.5 million to deliver and raise those children to 10 years old.

The incremental cost of implementing the national Community Pharmacy PHS for EHC system outlined above with around 95% of items dispensed being more effective methods of EHC would be £900,000. Updating the current service presents an opportunity to reduce the rates of teenage pregnancy whilst achieving a very real cost saving.

These numbers are borne out when you consider that the annual UK cost of teenage pregnancies is £63 million to the NHS alone. It is therefore vital that the need to update the Community Pharmacy PHS for EHC with more effective methods of EHC is recognised in the Committee’s report and recommended to the Government.

2). Cost effectiveness which is supported by several leading authorities

There are several different approaches to showing the cost effectiveness of improving contraception services.

Evidence from a report by FPA looking at the economics of sexual health shows that the NHS could save a further £30 million a year by improving contraception services, in particular ensuring access to the full range of available methods.

The average cost of contraceptive failure is at least £1800 to the NHS including costs of maternity (live births and miscarriages), antenatal services and abortion. This figure also fails to account for the numerous consequential costs such as welfare costs, loss in tax revenue caused by unemployment among some mothers, caused in part by the high cost of childcare in the UK amongst other things.

The Teenage Pregnancy Independent Advisory Group (TPIAG) at the Royal College of General Practitioners, the Terence Higgins Trust, NHS

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Manchester\textsuperscript{15} and the APPGSRH have all suggested that contraception services could save the NHS over £2.5 billion a year\textsuperscript{16} since for every £1,000 spent on contraception services £11,000 is saved\textsuperscript{17}.

Furthermore, and perhaps most importantly, the SMC accepted a more effective form of EHC for use in NHS Scotland in February 2010 saying that ulipristal acetate (ellaOne) \textit{‘...is accepted for use within NHS Scotland for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure\textsuperscript{18} on the basis that it is ‘...statistically superior’ and ‘offered reasonable value for money.’\textsuperscript{19}}

The clear conclusion is that restrictions to contraceptive services contribute to high abortion rates and the costs of abortions far exceed the cost of providing more accessible contraceptive services. Greater use of \textit{all} emergency contraceptive methods represents a real opportunity to reduce the number of unintended pregnancies amongst teenage women in Scotland without imposing greater costs to the health service.

**Review of the Community Pharmacy Public Health Service for Emergency Hormonal Contraception?**

The introduction of the Community Pharmacy Public Health Service for Emergency Hormonal Contraception in 2008 (PHS EHC) was a significant step forward in improving access to a critical intervention in the prevention of unintended pregnancies

The PHS EHC is a national service specification whereby emergency contraception is provided for free via community pharmacies under the Community Pharmacy Contract\textsuperscript{20}. It is available to any woman aged 13 years or over and must be provided by the pharmacist in person after appropriate


\textsuperscript{16} Department of Health, Better prevention, better services, better sexual health: The national strategy for sexual health and HIV (London: DH, 2001)

\textsuperscript{17} McGuire A and Hughes D, The Economics of Family Planning Services (London: FPA, 1995)

\textsuperscript{18} ulipristal acetate, 30mg tablet (ellaOne), SMC No. (599/10), February 2010, available at: http://www.scottishmedicines.org.uk/files/ulipristal__EllaOne__FINAL_January_2010__for_website.pdf

\textsuperscript{19} SMC Briefing Note: ulipristal (EllaOne), available at: http://www.scottishmedicines.org.uk/SMC_Advice/Advice/599_10_ulipristal__EllaOne_/Brief_Note_ulipristal__EllaOne_.pdf

\textsuperscript{20} http://www.communitypharmacyscotland.org.uk/nhs_care_services/public_health_service/phs_ssexual_health_specifications.asp
consultation and presentation of all necessary information as to available options.\textsuperscript{21}

**What has the national PHS EHC enabled? What have been its successes?**

Since its introduction, the PHS EHC service has enabled increased access to EHC complementing the service provided at local specialist sexual health services and GPs. It has proved vital in allowing teenagers access to emergency contraception in situations where this presents the only option to avoid an unintended pregnancy and for the majority the potential trauma of a medical termination.

Since its introduction in 2008, the PHS EHC service has increased in size and in 2009-10 it dispensed just over 82,000 items and 81,000 in 2010-11.\textsuperscript{22} This accounted for 66\% of the emergency hormonal contraception items dispensed in Scotland using a prescription.\textsuperscript{23} According to Community Pharmacy Scotland: ‘The emergency hormonal contraception service now supports 80\% of all interventions in primary care for this service need.’\textsuperscript{24}

There are approximately 1,200 community pharmacies across Scotland providing the PHS service at any one time. The service has provided numerous benefits to young women particularly those living in remote locations or areas of social deprivation where a community pharmacy offers the only easily accessible service available.\textsuperscript{25} Here the service has been described by a review of the service as ‘fulfil[ing] a crucial role.’\textsuperscript{26}

**How can the PHS EHC be developed to further reduce the number of unintended pregnancies in Scotland?**

The PHS EHC needs to be developed as improvements in the service could have a direct impact on reducing teenage pregnancy. The review of Community Pharmacy PHS for EHC conducted in 2011 by Scottish Government Social Research recommended that:

The PHS EHC service be enhanced through the provision of ‘other contraception and support’ and highlighted suggested improvements


\textsuperscript{24} Extract from Community Pharmacy Scotland’s Submission to Health and Sport Committee, December 2012


to the scheme including the inclusion of new therapies that can be prescribed up to 5 days.\textsuperscript{27}

HRA would be keen to learn how the Scottish Government intends to move the suggested improvements to the service from this review forward.

**Government Policy**

According to the Sexual Health Framework, the Scottish Government will support the delivery of the Sexual Health and Blood Borne Virus Framework through certain national activity including ‘…the role of community pharmacy in the provision of sexual health and blood borne virus services including the continuation of Emergency Hormonal Contraception in the national Community Pharmacy Contract.’\textsuperscript{28} The groundwork has been already laid for updating the current service.

**Clinical Guidance**

A further reason for development is that since the establishment of the PHS EHC, the applicable Clinical Guidance for Emergency Contraception has itself changed and developed given the availability of new products and new evidence. The latest Emergency Contraception Guidance from the Glasgow-based Clinical Effectiveness Unit of the Faculty of Sexual & Reproductive Healthcare (FSRH) provides that women should be informed of all contraceptive options available to them particularly where these might present a more effective option.\textsuperscript{29} An expanded national PHS EHC would help move towards achieving this.

**Community Pharmacy Scotland (CPS)**

Community Pharmacy Scotland, in its position paper to the Committee submitted in advance of this inquiry recommended three priority areas of service development, one of which was the updating of existing community pharmacy arrangements for the provision of emergency contraception to include more effective methods.\textsuperscript{30}


\textsuperscript{29} Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit - Clinical Guidance (August 2011 – Updated January 2012); available at: http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf

\textsuperscript{30} Extract from Community Pharmacy Scotland’s Submission to Health and Sport Committee, December 2012
Community Pharmacy Scotland has expressed a desire to enhance the current service provision and move the emergency contraception service from being a reactive service to a more comprehensive offering for women.31

Scottish Lead Clinicians for Sexual Health Group

The need to widen the methods of emergency contraception available via a national scheme has been recognised recently by the Lead Clinicians in Sexual Health Group, comprising leading clinical figures in sexual health from all the Scottish Health Boards. This position acknowledges the increased efficacy of new methods and their potential to produce real health benefits for women in Scotland. HRA believes the Group is in the process of exploring ways in which this priority might be implemented and urges the Committee to openly support this initiative of an expert clinical group.

Response to Other Inquiry Questions

a). Do you have any views on the current policy direction being taken at the national level in Scotland to reduce rates of teenage pregnancy?

Whilst the teenage pregnancy rate in Scotland has seen a small but consistent decline over the last four years, the rates of unintended pregnancy and terminations amongst teenagers in Scotland remain high in comparison to other Western European countries.32 There clearly remains more to be done to reduce unwanted pregnancies and improve sexual health services for young Scottish women. New, more effective, approaches are therefore required and merit exploration.

b). Do you have any views on the action being taken at the local level by health boards, local authorities and other relevant organisations to reduce teenage pregnancy, particularly in the under 16 age group?

Each NHS board is expected to provide the full spectrum of sexual health services to meet the identified needs of its local population and to prevent

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31 Extract from Community Pharmacy Scotland’s Submission to Health and Sport Committee, December 2012
inequity among NHS board areas.\textsuperscript{33} NHS boards are responsible for ensuring that sexual health services provide high quality delivery of care consistent with current evidence-based practice.\textsuperscript{34}

HRA’s experience within Scotland reveals that whilst some Boards have begun to expand the range of contraceptive options made available to teenage women,\textsuperscript{35} many still fall short of recommended practices and fail to offer the full range of contraceptive options, including emergency contraception, as recommended by national clinical guidance, the SMC and leading sexual health clinicians.

c). What are your views on the relationship between high levels of teenage pregnancy and socio-economic inequality?

Teenage conceptions carry a particularly heavy cost since they impact on women early on in the life course and, in turn, negatively affect wider determinants of health such as child poverty, social contentedness, and participation in education, employment and training.

There is a strong association between deprivation and rates of teenage pregnancy. Under-16s living in Scotland’s most deprived areas have approximately five times the rate of teenage pregnancy (14 per 1,000 compared with 3 per 1,000).\textsuperscript{36} Moreover, young women living in socially disadvantaged areas are less likely to opt for an abortion if they get pregnant.\textsuperscript{37}

This is a stark health inequality that requires urgent and direct action. HRA is looking to work with partners in Scotland to explore ways of improving access to more effective emergency contraception to women living in all communities, particularly by opening up access within the pharmacy setting which provides early and convenient access to therapy.

d). What are the barriers and challenges to making progress in achieving positive change in communities that might lead to reductions in the levels of teenage pregnancy?

There is a particular need to ensure that young people have full access to contraception, as they may face specific barriers including opening times and locations of providers, perceived negative attitudes of staff and fears about confidentiality. These need to be addressed comprehensively to ensure that

\textsuperscript{34} Respect and Responsibility (2005), NHS Quality Improvement Scotland, available at: http://www.scotland.gov.uk/Publications/2005/01/20603/51182  
\textsuperscript{35} See NHS Grampian’s inclusion of ellaOne for 72-120 hours: http://www.communitypharmacy.scot.nhs.uk/documents/nhs_boards/grampian/EHC.pdf  
\textsuperscript{36} Health Inequalities Scotland, Audit Scotland (Dec 2012), at p. 11, available at: http://www.audit-scotland.gov.uk/docs/health/2012/nr_121213_health_inequalities.pdf  
young women feel confident about how and where to access contraception which is suitable for them and their lifestyle.

Access to the full, recommended range of contraceptive options is varied across Scotland as is the level of information provided to teenagers as to the best options to suit their needs. HRA strongly agrees with Community Pharmacy Scotland’s position that the access offered through its network of pharmacies throughout Scotland offers opportunities to improve teenage sexual health.  

**e). What are your views on the current support services available to young parents/ young mothers, e.g. range of services, focus of services and whether services are being delivered in the most appropriate settings?**

HRA note the publication of the *Evaluation Of The Family Nurse Partnership Programme In NHS Lothian, Scotland: 3rd Report – Infancy.* The programme of support provided by Family Nurse Practitioners to teenage mothers seems to be having a beneficial effect and HRA are keen to observe its evolution and mainstreaming as a core service over the coming years.

**f). Are there specific initiatives that you would wish to highlight to the Health and Sport Committee that you consider indicate good practice with regard to reducing teenage pregnancy rates in Scotland, either in the public sector, voluntary sector or in partnership?**

It is Community Pharmacy Scotland’s and many clinical expert and third party organisation’s belief that pharmacy offers the most appropriate and accessible setting for the provision of more effective emergency contraceptive methods. HRA strongly supports this position as has been expanded on in its response above.

**h). Do you have any comments on any other aspect of teenage pregnancy policy or examples of good practice that you wish to raise with the Committee?**

Outside of a national PHS EHC including more effective methods of emergency hormonal contraception, we would strongly recommend that the most appropriate procedure for the provision of emergency contraception for teenagers in Scotland is to perform a risk-based assessment of the presenting patient and then offer the patient the full choice of recommended contraceptive methods provided with accompanying information to inform the patient’s decision.

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38 Extract from Community Pharmacy Scotland’s Submission to Health and Sport Committee, December 2012
This approach ensures that:

- Choice is given to the patient having been informed of the risks of becoming pregnant and the different contraceptive options available to her.
- The most appropriate methods of contraception are made available.
- Faculty and professional clinical guidance on the issue is followed.
- Fair and equitable access is provided to women across the country who have the necessary information to decide on their preferred contraceptive option given the probability of falling pregnant.

‘All women must have access to a full choice of contraceptives and contraceptive services, including comprehensive information and advice that enables them to choose the method which is best for them. Any restrictions on access on the basis of age, residence or method should be removed as a matter of urgency.’

Conclusions

HRA believes that respect for choice is essential to the proper functioning of sexual and reproductive health services in Scotland. Unfortunately, as this paper has shown, the majority of women in Scotland are denied access to more effective and recommended emergency hormonal contraceptive options.

Access to contraception and choice as to method is fundamentally important for young women. It impacts on their ability to control their lives and, moreover, teenage women who have a choice of contraception and are confident with their chosen method are more likely to use it effectively, protecting themselves against an unintended pregnancy and its emotional, physical and financial impact.

Scottish clinical opinion and FSRH Guidance and the SMC have all recognised that more effective emergency contraceptive options provide choice, and evidence demonstrates clear cost effectiveness, which is currently unrecognised by the commissioning arrangements of many NHS boards.

The most effective and readily executable way of resolving this inequitable situation for the benefit of teenage women is to update the remit of the existing, and highly successful national PHS EHC service providing emergency hormonal contraception through community pharmacies in Scotland.

Offering more effective emergency hormonal contraceptive methods can produce better results for teenage women, improve public health outcomes as well as achieve important cost savings in the process. HRA Pharma acknowledges the role to be played by all contraceptive methods, it simply

40 All-Party Parliamentary Group on Sexual and Reproductive Health, Healthy women, healthy live? The cost of curbing access to contraception service, at p. 7.
seeks to highlight the importance of emergency contraception and, in particular, ellaOne, as part of the suite of important treatments available to teenage women.

About HRA Pharma

HRA Pharma is a pharmaceutical company that discovers and develops innovative drugs, devices and services in the fields of reproductive health and endocrinology where therapeutic gaps perpetuate.

HRA Pharma is an expert in emergency hormonal contraception (EHC) and in countries outside the UK markets both ulipristal acetate (‘ellaOne’) and levonorgestrel under the brand name ‘NorLevo’. It is therefore well positioned to comment on the role emergency oral contraception has to play as part of the whole suite of contraceptive methods as well as on the overall landscape of contraceptive services in Scotland.

In parallel with its open and transparent commercial and health mission, there is a clear socially conscious approach running through the company and over the last two years HRA Pharma has sought to work constructively with clinical services in Scotland with a view to helping enhance local services for those women that attend sexual and reproductive health clinics.

HRA Pharma strives, both with commercial and social marketing activities, to ensure that its products are accessible everywhere, empowering women to choose the contraception options most appropriate for them. So we find it very concerning that in the Scotland, where so much has been achieved over the years in improving access to emergency hormonal contraception (EHC), there remains grave inequity and lack of choice across the country.

About ellaOne®

ellaOne® (ulipristal acetate) is an oral emergency contraceptive which according to its licence is almost twice as effective from 0-72 hours as levonorgestrel, the most widely used emergency contraception currently. Moreover, published evidence is clear that in the first 24 hours following unprotected intercourse, ellaOne is almost three times more effective than levonorgestrel in preventing an unintended pregnancy. This improved efficacy may be due to the fact that ellaOne has been shown to be effective right up to the point of ovulation, even after luteinising hormone (LH) levels have started to rise – a time when levonorgestrel has been shown to be no better than placebo.

41 Glasier AF et al, Lancet 2010 ; 375 : 555-562
42 I Prabakar, A Webb, BMJ March 2012; 344: 61-64
43 Glasier AF et al, Lancet 2010 ; 375 : 555-562
44 Brache V et al, Human Reproduction 2010; 25:2256-2263
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