

# MHRA and the Bill & Melinda Gates Foundation to look at the safer, effective use of medicines during pregnancy

In advance of World Patient Safety Day (17 September), MHRA specialists, as part of a broader programme of work, have begun developing ground-breaking research to support the safer use of medicine during pregnancy.

A \$360,000 grant over two years from the Bill & Melinda Gates Foundation (approximately £292,000), will support the MHRA's research, to help predict the need for adjusting a medicine's dose during different trimesters of pregnancy. This will ensure effective use, which is vitally important for the health of mother and baby.

Worldwide, data in this area remain limited, and new insights could potentially impact the health of pregnant women around the world. This would also give obstetricians further clarity on the optimal dose of a medicine, when treating pregnant patients, for whom use of a medicine is necessary.

When pregnant or breastfeeding, it is generally recommended to avoid the use of medicines, although more than half of all pregnant women consume at least one medicinal product during their pregnancy.

Medicine use can be essential to safeguard the health of mother and baby. This includes treating existing conditions such as diabetes, epilepsy or cardiovascular conditions. However, for many medicines, unless indicated for use during pregnancy, the best regimen and dosage levels during different stages of pregnancy are largely unknown.

It is also difficult to predict whether doses of medicines, which are effective during early pregnancy, will produce their desired effect at a later stage. In this research, MHRA specialists will use prediction models to develop recommended medicine dosages for pregnant women in the UK. This includes evaluating existing models— known as physiologically based pharmacokinetic (PBPK) models and simulations to develop a full picture for all stages of pregnancy.

The Agency will also provide training for healthcare professionals on how to use the models, and there will be a dedicated web portal.

The portal will host MHRA research on the effects of physiological changes which occur during pregnancy, and their impact on medicine exposure. The results of model predictions will also be available on the portal, allowing the opportunity for different research groups to upload and share their modelling, turbo-charging developments in this area.

**Dr June Raine, Director of Vigilance and Risk Management of Medicines, MHRA said:**

“Patient safety is our highest priority and we are determined to support innovation in this important area, which helps improve the quality of health for pregnant women in the UK and internationally.

“This work provides a valuable launch pad for new developments into, and improved understanding of how pregnancy affects medicine levels. That’s why we are encouraging healthcare professionals, research groups and those looking to supply medicines during pregnancy, to make full use of the prediction models, data and resources we will provide.”

**Trevor Mundel, President of Global Health, Bill & Melinda Gates Foundation said:**

“We’re excited to play a part in the work that MHRA is doing around maternal health. We hope the innovative use of computer-aided modelling will help make medicine use safer and more effective for pregnant women around the world. We are dedicated to improving the quality of people’s lives and look forward to the outcome of new developments in this area.”

**Notes to Editors**

1. PBPK modelling is a technique for predicting the absorption, distribution, metabolism and excretion (ADME) of synthetic or natural chemical substances in humans and other animal species.
2. PBPK modelling is undertaken using a software used in computer-aided modelling, which the MHRA research will involve.
3. As pregnancy advances, there are considerable physiological changes in the woman over the three trimesters, leading to clinically important changes in absorption, distribution, metabolism and elimination of medicines.
4. Nausea and vomiting and alterations in gastric pH and GIT motility during pregnancy may alter medicine absorption; increased cardiac output and intestinal blood flow may increase absorption.
5. It is essential for clinicians to be aware of the pregnancy-related changes in PK and/or PD and to critically examine the potential clinical implications of these changes for a pregnant patient and the dosage of a medicine she may need.
6. The [Medicines and Healthcare products Regulatory Agency](<https://www.gov.uk/government/organisations/medicines-and-health-care-products-regulatory-agency>) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
7. The MHRA also includes the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). MHRA is an executive agency of the Department of Health and Social Care.

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## Human Rights Council 42: Interactive Dialogue on Myanmar



The Human Rights Council takes place at the Palais des Nations in Geneva.

The United Kingdom thanks the Special Rapporteur for her update. We regret that her ability to discharge her duties continues to be challenged. We call on the Government of Myanmar to cooperate fully with her mandate and grant her full access.

We remain deeply concerned by the escalation of violence in Rakhine, Shan and Kachin states. We call on all parties to the conflicts to de-escalate hostilities, engage in meaningful dialogue, and protect civilians.

We welcome Bangladesh's commitment to ensure that repatriations are voluntary and are conducted in coordination with UN agencies. We agree with the UN High Commissioner for Refugees (UNHCR) that conditions in Myanmar are not conducive to 'safe, voluntary and dignified' returns. We call on Myanmar to grant UN agencies full access to Rakhine.

Accountability for human rights violations in Myanmar is a key step towards reconciliation which is essential for long term stability. A domestic process remains the best hope for accountability in the near future but if that process is not credible nor independent then international processes remain on the table. We regret that the Independent Commission of Enquiry (ICOE) is yet to deliver its report. We strongly welcome the operationalisation of the Independent Investigative Mechanism for Myanmar (IIMM) and we encourage the ICOE to engage with it. Ms Lee, in your view, what are the main barriers to the ICOE releasing its report?

How can we ensure that the IIMM has the flexibility to deliver effectively on its mandate?

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## More victims able to challenge ‘unduly lenient’ prison sentences

- 14 new offences added to Unduly Lenient Sentence scheme
- prison terms for a range of sexual offences to come into scope
- part of wider action to ensure punishment properly reflects severity of crimes

Criminals convicted of stalking, harassment, child sexual abuse and other sex offences could see their sentences increased if victims or the public think their punishment is too lenient.

Under plans confirmed by ministers today (17 September 2019), the Unduly Lenient Sentence (ULS) scheme will be extended to 14 new offences – giving victims the power to query the sentences of a wider range of crimes.

The scheme gives anyone the power to ask the Attorney General to consider referring a sentence to the Court of Appeal for reconsideration – where it could then be potentially increased if deemed unduly lenient. In July, such an intervention increased the sentence of a mother who allowed her partner to rape her daughter from three to five years behind bars.

Crimes such as murder, robbery, and a range of terror offences are already covered, however the government has pledged to extend the scheme to further protect the public and make sure victims see justice done.

The move will bring offences including controlling and coercive behaviour within scope as well as further child sexual abuse offences, such as those involving the taking, distributing and publishing of indecent images of children and abusing a position of trust with a child.

Secretary of State for Justice, Rt Hon Robert Buckland QC MP, said:

We are determined that those found guilty of heinous crimes such as child sex offences receive the sentences their actions warrant.

Sentences are decided by our independent judiciary based on the facts before them, but it is absolutely right that victims have a voice in the system when punishments don't appear to fit the crime.

We are today sending a clear message that this government will use every tool at its disposal to make sure justice is done and the public is kept safe.

Whilst in the vast majority of cases sentences are deemed appropriate, since

its introduction 30 years ago the scheme has helped hundreds of victims and their families – with 99 criminals seeing their sentences increased following review by the courts in 2018 alone.

Today's announcement delivers on a key commitment in the cross-government Victims' Strategy, published last year. It comes as an urgent review, ordered by the Prime Minister, is ongoing to ensure violent and sexual offenders serve sentences that truly reflect the severity of their crimes.

The Solicitor General, Michael Ellis QC MP, said:

The Unduly Lenient Sentence Scheme can bring comfort to victims and their families across the country. The latest extension means that the Attorney General and I can look at even more sentences which look like they don't fit the crime.

Anyone can apply to the scheme and although there is a high bar to any appeal we will do everything we can to challenge a sentence that we regard to be clearly wrong.

## Notes to editors

- The ULS scheme allows prosecutors, victims of crime, their family and the public to ask the Attorney General a review of certain sentences they believe to be too low.
- The Attorney General may then refer a case he believes to be unduly lenient to the Court of Appeal who is able to increase the sentence.
- The government published the cross-government Victims' Strategy in September 2018. It was the first time we have looked in such detail and in such a joined-up way at how we treat victims in the wake of crime. Commitments in the strategy included:
  - keeping the scope of the Unduly Lenient Sentence Scheme under review; and
  - considering a further extension of the Unduly Lenient Sentence Scheme, particularly for some additional harassment, sexual, and indecent images offences.
- An extension of the scheme so that it applies to further terrorism offences came into effect in August 2017 and nine more terror-related offences were added in January 2018.
- Through the cross-government Victims' Strategy we have committed to working with the Ministry of Justice, Attorney General's office and Crown Prosecution Service to address concerns around the lack of awareness of the ULS scheme.
- Government has agreed to extend the scheme to the following offences....
  - Abuse of position of trust: sexual activity with a child (s.16, Sexual Offences Act 2003),
  - Abuse of position of trust: causing or inciting a child to engage in sexual activity (s.17, Sexual Offences Act 2003)
  - Abuse of position of trust: sexual activity in the presence of a child (s.18, Sexual Offences Act 2003)

- Abuse of position of trust: causing a child to watch a sexual act (s.19, Sexual Offences Act 2003)
- Inciting a child family member to engage in sexual activity (s.26, Sexual Offences Act 2003)
- Sexual activity with a person with a mental disorder impeding choice (s.30, Sexual Offences Act 2003)
- Causing or inciting a person, with a mental disorder impeding choice, to engage in sexual activity (s.31, Sexual Offences Act 2003)
- Engaging in sexual activity in the presence of a person with a mental disorder impeding choice (s.32, Sexual Offences Act 2003)
- Causing a person, with a mental disorder impeding choice, to watch a sexual act (s.33, Sexual Offences Act 2003)
- Possession of indecent photograph of a child (Criminal Justice Act 1988, s.160)
- Taking, possessing, distributing, publishing Indecent Photographs of Children (s.1 Protection of Children Act 1978)
- Harassment: putting people in fear of violence (s.4, Protection from Harassment Act 1997)
- Stalking involving fear of violence or serious alarm or distress (Protection from Harassment Act 1997, s.4A, Protection from Harassment Act 1997)
- Controlling or Coercive Behaviour in an Intimate or Family Relationship (s.76, Serious Crime Act 201,).
- Applications to refer a case under the ULS Scheme should be directed to the [Attorney General's Office](#).
- Only one application is needed to review a sentence and the Attorney Generals' Office has 28 days after sentencing to make a decision.
- The government plans to make the necessary secondary legislation in the Autumn, and the change will come into effect shortly after that.
- In August the Prime Minister ordered an urgent [review into sentencing](#) – focussing on whether violent and sexual offenders are serving sentences that truly reflect the severity of their crimes.

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## Multi-million pound funding to protect child abuse victims and track down offenders

A £30 million funding boost will equip law enforcement with pioneering new tech and capabilities to track down more paedophiles operating online and safeguard children who have been abused, the government has announced today.

The additional investment to tackle child sexual exploitation and abuse (CSEA) will help target the most dangerous and sophisticated offenders who

operate on the dark web.

Statistics from the National Crime Agency (NCA) show that last year 2.88 million accounts were registered globally across the most harmful child sexual abuse dark web sites, with at least 5% believed to be registered in the UK.

To tackle this threat, further investment will be made in the UK's world-leading Child Abuse Image Database (CAID), a resource that provides law enforcement agencies with effective tools to search seized devices for indecent images of children, reducing the time taken to identify illegal images of children and increasing the ability to identify victims. The new funds being made available will explore adding enhanced Artificial Intelligence (AI) tools to the system, including voice analytics and age estimation.

The government has also announced it will be co-hosting a major child sexual abuse summit in December in Africa to drive the international response.

Prime Minister Boris Johnson said:

The internet has revolutionised the world by opening up society, facilitating the exchange of ideas, increasing the flow of goods and empowering people in a way many never thought possible. Yet while the internet can be an immeasurable force for good, it can also be used to provide a safe space for criminals.

That is why we are taking further steps to combat those who use the internet to prey upon children. Just as we're giving the police more resources and recruiting 20,000 more officers to keep our streets safe, we are also putting more money and the very best of our world-leading technical abilities into catching offenders operating in the dark web.

Home Secretary Priti Patel said:

Vile predators who prowl the internet abusing children are cowards who need to be caught and punished. That's why it's essential we give our law enforcement agencies the support, resources and powers they need to bring them to justice.

This extra £30 million will help do this – ensuring online paedophiles are no longer able to hide in the shadows preying on our society's most vulnerable.

Fred Langford Deputy CEO and CTO at the IWF said:

We are delighted the government has committed more funding to fight

the spread of child sexual abuse online.

Last year our analysts removed over 105,000 webpages from the clear web. Each page can contain thousands of individual indecent images of children. The IWF is the only non-governmental body with access to the Child Abuse Image Database. This collaboration is vital to ensuring that these images are prevented from being spread online and I am pleased to see that some of the funding has been allocated for further developments of that system.

Since 2016, the IWF has seen a rising trend in “commercial” hidden services, websites hosted within proxy networks (dark web), dedicated child sexual abuse websites offering child sexual abuse imagery for sale. In 2018, we identified 85 new hidden services, 47% of which were assessed as being commercial. We have also seen greater levels of encryption has made these services much harder to locate and it is clear that we have to keep pace with new offending behaviours.

The funding, announced as part of the Spending Round, will build on previous resource to tackle the complex issue of offending on the dark web. Previous funding has helped expand the NCA and GCHQ Joint Operations Team, while the NCA has also established its Dark Web Intelligence Unit- a team tasked with gathering intelligence and patterns on dark web offending.

Law enforcement have already had a number of successes with prosecuting criminals operating on the dark web. Kyle Fox, from Surrey, was jailed for 22 years in March after sexually assaulting a three-year-old on the dark web. The NCA launched an investigation and traced the suspect to his home in the UK. The suspect’s face was not visible in the abuse videos, but investigators were able to use specialist capabilities to piece together clues, including clothing, to identify him and both victims. Last year Dr Matthew Falder pleaded guilty to 137 offences linked to the dark web.

CAID was first introduced to police forces from December 2014 and hosts 14 million images. It is a vital tool to speed up police investigations into CSEA and help safeguard the children who have been abused. State of the art new techniques being explored by the Home Office would see voice analytics added to CAID to help detect offenders and safeguard victims, as well new age estimation tools.

This builds on new £1.76 million capabilities announced by the Home Office this summer to CAID, which included rolling out a new a fast-forensic tool, image categorisation algorithms and scene matching technology. AI tools like these can be used to identify and class images, speed up investigations and take the burden of viewing images off police officers.

The UK is looking to build on its status as a global leader in tackling child sexual abuse by hosting the WePROTECT Global Alliance summit with the African Union. The summit, to be held in Ethiopia, will bring senior leaders from 130 countries together alongside tech firms and civil society organisations to



determine what efforts should be taken to tackle this global issue.

This builds on previous commitments to keep children safe online, including:

- the publication of the Online Harms White Paper, which includes proposals to compel tech firms to keep children safe online
- the Home Office will publish interim codes of practice, which will set out our expectations of tech companies in tackling online CSEA
- the Home Secretary hosted the 5 country ministerial in July, which set out joint actions to combat CSEA
- a commitment to publish a new national strategy to tackle all forms of child sexual abuse

Today, the Ministry of Justice has announced an expansion of the Unduly Lenient Sentence Scheme, which will include adding in a number of sentencing changes for child abuse offenders.

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## **Inclusive Labour Markets – North East Region (0C25S19P1510)**

Call to run a project to remove barriers to employment and increase prospects for unemployed and economically inactive people in the North East Region LEP area.