New partnership pledges clear and consistent evidence-based guidance on medicines for pregnant and breastfeeding women

A major new initiative to ensure pregnant and breastfeeding women can make informed decisions about their healthcare was announced today by health minister, Nadine Dorries.

The Safer Medicines in Pregnancy and Breastfeeding Consortium brings together 16 leading organisations under a common pledge to meet the information needs of pregnant and breastfeeding women and healthcare professionals, through accessible, clear and consistent advice.

The partnership spans the NHS, regulators, and leading third sector and charitable organisations. Together, this group will develop a long-term programme of work to improve information provision on medicines for women who are thinking about becoming pregnant, are pregnant, or are breastfeeding.

In the UK, hundreds of thousands of babies are born each year, and more than 50% of expectant mums will need to take a medicine of some description when pregnant. However, more needs to be known about the effects of taking medicines in pregnancy.

Work on this is already underway. A report published by the Commission on Human Medicines (CHM) Expert Working Group on Optimising Data on Medicines used During Pregnancy has today provided recommendations on ways in which data on medicines used in pregnancy and breastfeeding can be better collected and made available for analysis. This will enable more robust evidence to be generated through research and will be important in helping to develop clear and consistent advice about medicines used during pregnancy and breastfeeding — the main aim of the Consortium.

Recommendations of the report include the better capture and linking of existing data, exploring new ways to collect relevant information on exposure to medicines during pregnancy and breastfeeding, and improving access to and quality of data to further enable research. The Consortium welcomes the recommendations of the report.

To support the aims of the Consortium, the MHRA has developed <u>a webpage</u> to assist users in finding information and projects related to medicines use in pregnancy and breastfeeding. This webpage includes links to Consortium members' websites, which also contain important information.

Healthcare professionals are asked to report important inconsistencies in UK advice on use on individual or classes of medicines in pregnancy or breastfeeding to the Consortium.

Anyone can report suspected side effects with medicines or adverse events with medical devices, including those experienced by the mother or baby during pregnancy or breast feeding, to the <u>Yellow Card scheme</u>.

Nadine Dorries, Minister of State for Patient Safety, Suicide Prevention and Mental Health, said:

"It is vitally important women are empowered to make informed decisions about their healthcare during pregnancy and this means accessing timely information and answers about any medicines they consider taking while pregnant or breastfeeding.

"I am delighted so many of the health system's main information providers are working closely together to address this and I look forward to seeing positive results from this new collaboration."

Dr June Raine, MHRA Chief Executive and Chair of the Consortium, said:

"We know that in many cases the information on taking medicines when pregnant or breastfeeding can be improved. I would encourage healthcare professionals to report any important inconsistencies you find on our webpage.

"There is vital work to be done, as started by the EWG report published today and continued by our new Consortium, which is addressing the issue head on. Today is an important step, and we are proud to have brought this partnership together."

Notes to editors

The Safer Medicines in Pregnancy and Breastfeeding Information Consortium was set up following the <u>Commission for Human Medicines report on Hormone</u>

<u>Pregnancy Tests</u>, published in 2017.

Its launch was announced as part of a statement setting out the government's response to the recommendations in the Independent Medicines and Medical Devices Safety Review.

The Consortium will focus on delivering recommendation 11 of the report: "The MHRA should work with the key information providers to ensure healthcare professionals and patients receive the best available information, and are empowered to make informed decisions and ask questions about any medicines they may be prescribed in pregnancy."

First level advice for women who are thinking about getting pregnant, are pregnant or breastfeeding, on taking medicines prescribed or bought over the counter, can be found on the NHS websites' pregnancy and baby guide.

The Commission on Human Medicines (CHM) Expert Working Group on Optimising Data on Medicines used During Pregnancy was set up to identify ways in which data on medicines used during pregnancy and breastfeeding can be better collected and processed.

A new valproate registry was launched on 11 February 2021, spearheaded by the

MHRA in partnership with NHS Digital, that will help prevent pregnancy in women taking valproate and make it easier for healthcare professionals to monitor the issue.

Members of the Safer Medicines in Pregnancy and Breastfeeding Information Consortium: