

Press release: MHRA awarded £1.3m for collaboration with the Bill and Melinda Gates Foundation and the World Health Organization

New medicines and vaccines, for diseases such as malaria and HIV, may be introduced for the first time in LMIC's where there are weak or no regulatory systems in place for effective safety monitoring. These new treatments have been developed with urgent public health needs in mind and therefore the need to gather and analyse information quickly on their safety and effectiveness is important.

The healthcare and regulatory systems in these settings may often lack the tools, training and capacity to operate a robust safety monitoring system. Whilst great progress has been made with many of LMIC's now involved as members of the World Health Organization Program for International Drug Monitoring, the experience in collecting, assessing and acting on adverse reaction data, and risk management planning is limited.

Without an effective system, public health programs are at risk and patients may be affected, should they suffer from adverse drug reactions (ADRs) which are not promptly identified and treated. This can consequently undermine the program and result in a loss of trust in the product or a vaccine. Ultimately, this may lead to lower uptake and therefore, the disease not being effectively treated.

WHO and the Gates Foundation have launched 'Project Smart Safety Surveillance' (also known as Project 3-S) to help LMIC's identify, assess, and adequately manage the risks associated with new products. MHRA will be joining this initiative to bring regulatory expertise to the project. This will be for a three-year period where it is intended to run three pilot exercises in different LMIC settings.

Dr Ian Hudson, Chief Executive Officer at MHRA said:

We are delighted to be involved in such an important global initiative. New drugs and vaccines are being brought to the market for the first time in public health programmes in settings where the safety monitoring and regulatory systems need strengthening. The expertise we can bring to the project will help national safety monitoring centres identify risks and benefits early and take appropriate regulatory action to support global health.

Dr Dan Hartman of the Bill and Melinda Gates Foundation said:

The Triple S project is vitally important to the success of public health programmes to combat some of the world's major diseases. When a new medicine or vaccine is being used it is critical that potential risks are identified early and well understood. The involvement of MHRA in this project will ensure scientific and regulatory expertise are developed within the national centres.