Safeguarding public health

Press Release

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Medicines regulator implements innovative software to analyse risk data and target inspection activity

As part of its risk-based inspections regime which ensures compliance with statutory obligations relating to medicines the Medicines and Healthcare products Regulatory Agency (MHRA) is implementing new IT software.

MHRA inspections across all the disciplines will be better prioritised as a result, helping to target its activity to the areas of greatest risk and ultimately help protect public health.

This risk-based approach helps reduce the overall administrative and economic burden on companies and organisations operating in the public health arena who are regulated by MHRA and who demonstrate a high level of compliance.

Gerald Heddell, the MHRA's Director of Inspections, Enforcement and Standards, said:

"It's vital we move with the times and this new software will help collate all the information we need in one location to make informed risk-based decisions on those we inspect and improve our capability to ensure the quality of medicines used in the UK.

"Our inspectorate teams will focus their time on inspections in order of priority from the risk signals flagged.

"We have a defined resource and an increasing number of inspections we require to consider. This information available will ensure that our resource is utilised effectively and that less inspection time is spent on companies with a good compliance record, and therefore a lower risk."

Mark Hammond, Accenture managing director of Life Sciences' Research & Development practice for UK/Ireland, said: "The enhanced use of data to inform decision-making is critical to enabling the MHRA to fulfil its responsibility to industry and the general public. We are pleased to build on our long-standing relationship with the MHRA and play a role in the development of this leading-edge proposition, supporting the Agency's continued innovation around regulation and compliance."

"MHRA, through its inspection processes and programs, plays an essential role in safeguarding public health. The ability to apply resources to the areas of greatest potential risk is vital to optimizing the agency's resources and impact," said Neil de Crescenzo, senior vice president and

general manager, Oracle Health Sciences. "We are delighted to work with MHRA on this innovative initiative."

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Notes to Editor

1. Oracle and Java are registered trademarks of Oracle Corporation and/or its affiliates. Other names may be trademarks of their respective owners.

2. Oracle developed Oracle Health Sciences Empirica Inspections, Accenture developed the custom regulatory systems ("Sentinel") and Risk Based Inspections data aggregation components, Oracle Health Sciences Consulting together with Accenture led the implementation and integration effort. The IT software is the product of three years' work between the MHRA, Accenture and Oracle Health Sciences.

3. The IT software contains a Risk Information Case Folder (RICF) that stores all information from previous inspections in one single location and, using a statistical algorithm, compares data against previous and/or current company issues to help inform the inspection planning and process.

4. The full potential of this software following implementation will not be seen until 12-18 months until a sufficient repository of data has been built up**.** This system, being new, will not work in isolation and will be closely monitored over the coming year with a view to the development of enhancements to facilitate continuous improvement.

5. Inspections are carried out to monitor and ensure compliance with statutory obligations relating to medicines across all inspection disciplines. These are Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Distribution Practice (GDP), Good Pharmacovigilance Practice (GPvP) and the Blood Safety & Quality Regulations (BSQR).

6. Further information on risk based information programmes can be found at: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/Risk-basedInspectionProgrammeforgoodpracticeinspections/index.htm

7. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone – the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action. www.mhra.gov.uk

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