National Measurement System

‘The drugs don’t work’... detecting counterfeit drugs and packaging

LGC, in collaboration with GlaxoSmithKline, is applying high accuracy mass spectrometry to measure small variations in isotope ratios to detect counterfeit pharmaceutical drugs and packaging and distinguish between counterfeit sources.

LGC *Setting standards in analytical science*

The Requirement

The World Health Organisation (WHO) has defined counterfeit pharmaceutical drugs as those which are “deliberately mislabelled with respect to identity and/or source”. These drugs may contain incorrect amounts of the active pharmaceutical ingredients (API), none of the API or even completely the wrong ingredients. Counterfeit drugs can also be identified by fake packaging. Counterfeits are always illegal and affect both manufacturers and consumers. The WHO estimates that counterfeit drugs, which now account for 10% of the global market, cost the pharmaceutical industry US$46 billion annually. For the consumer though, it is less the impact of the direct financial cost associated with purchasing counterfeit medicines that is the major concern; rather, it is the missed health benefits associated with any uncertainty over the likely effectiveness of counterfeit medicines or, indeed, the potential health risk associated with any unexpected clinical effects that may arise from the unknowing use of counterfeit medicines.

Traditional detection and discrimination of counterfeit drugs relies on visual examination as well as the physical and chemical analysis of goods and packaging. Historically these techniques have been fit for purpose, however, as counterfeiting techniques are becoming increasingly sophisticated more sensitive detection methods are needed. Many counterfeit pharmaceuticals now contain the same compounds as genuine tablets; their elemental composition is often very similar, if not identical to that of the real drug. Additionally, drug packaging materials are ubiquitous and a given manufacturer or counterfeiter can be served by different suppliers. It is therefore difficult to identify counterfeit items seized from different locations.

The Solution

New approaches based on the measurement of small, naturally occurring isotopic variations in compounds present in both the genuine and the counterfeit products are of great interest to researchers. All naturally occurring elements consist of one or more stable isotopes. The isotopic profile of elements can show subtle variations depending on the source of origin. Advances in mass spectrometry have made possible the detection of these very small variations in isotopic composition.

LGC scientists are using a high accuracy mass spectrometry technique to measure small differences in isotope ratios in order to determine authenticity and origin of drugs and packaging. This technique, which consists of a laser ablation system coupled to a multicollector inductively coupled plasma mass spectrometer (LA-MC-ICP-MS), is being used to measure the isotope ratios of calcium and lead present in the ink used on pharmaceutical packaging. Isotope ratio variations can be used to discriminate between genuine and counterfeit packaging. LGC also use the same technique to provide high accuracy sulfur isotope ratio measurements to identify counterfeit pharmaceutical drugs.

Impact

Dr Rebeca Santamaria-Fernandez, Science Leader in Inorganic and Isotope Ratio Mass Spectrometry at LGC commented “Collaboration with GlaxoSmithKline was vital to the success of this work as it enabled LGC to gain first hand a real insight to the problems facing pharmaceutical companies in tackling counterfeiting. Through this successful collaboration, LGC was able to demonstrate the applicability of the technique as a potential tool for identifying counterfeit drugs and packaging for the pharmaceutical industry.”

Dr Jean-Claude Wolff from GlaxoSmithKline, who carried out visual analysis of the packaging and supplied the test samples, added “GlaxoSmithKline recognises that the pharmaceutical industry has a major role to play in helping to minimise the counterfeiting of our products. We are pleased to be involved in a collaboration that has the potential to detect both counterfeit drugs and packaging, reducing the threat to patients.”

The work described in this case study was funded by the UK National Measurement System.

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2490/TK/0610