

Embargoed until 00.01 (GMT) Friday 12 July 2013**Action needed to deliver potential of personalised medicines**

The development of a stratified and increasingly personalised approach to medicine is being prevented because existing regulation and pricing systems are not set up to enable their effective widespread adoption, according to a new report from the Academy of Medical Sciences.

Stratified medicine is an approach to therapy that forms a key step on the path towards personalised healthcare. It assesses patients' biological makeup to help medical practitioners create a more targeted treatment plan based on the individuals risk of disease or their response to a particular treatment. This tailored approach could help medical staff make difficult decisions when treating patients and maximise the impact of administered therapies.

For example, a genetic test has been developed for patients diagnosed with HIV, to check their compatibility with anti-HIV medication known as Ziagen (abacavir). Ziagen has been found to cause extremely severe reactions in 2 – 9% of patients with a particular genetic makeup, who are now prescribed alternative treatments.

Similarly, Xalkori (crizotinib) is a drug indicated for the treatment of patients with a particular strain of lung cancer, which represents approximately 5% of all lung cancer patients. This patient population has a 10% response to standard chemotherapy, yet 55% respond to the targeted therapeutic, vastly improving their long-term prospects.

However, despite rapid advances in research and technology, existing systems for clinical development, regulation, pricing and reimbursement are preventing the widespread development and adoption of stratified and increasingly personalised medicine.

Professor Sir John Bell FRS HonFREng FMedSci, Chair of the Academy of Medical Sciences group that produced the report, said, *'Fast and efficient progress in the stratification – and ultimately personalisation - of medicine will rely on the collection, storage and analysis of significant amounts of data regarding the molecular and genetic basis of disease. This data driven approach to medicine requires the development of appropriate infrastructure and working practices to provide the high quality data needed to personalise medicines to individuals.'*

The report emphasises a need to harmonise and link databases and biobanks, both nationally and internationally, to maximise the potential of collected data. It recommends an international effort to ensure that the data arising from whole genome sequencing are of consistently high quality for clinical use by developing 'Good Genomic Practice' guidelines.

Another barrier is the current pricing system, in which the cost of a drug remains the same or decreases once entering the market. This removes any incentive to stratify existing products, as the size of the relevant patient population may decrease, lowering the financial return. However, changing the system to allow prices to go both up and down to reflect the changing value of a product would provide an incentive to develop increasingly personalised medicines.

Professor Sir John Bell added: *'Current pricing and reimbursement systems do not provide adequate incentives for the development of personalised medicines. A new system of pricing needs to be developed that enables prices to be adjusted over time to reflect the increases in value.'*

Increasingly personalised approaches to medicine depend upon reliable and accurate diagnostic tests. The report also highlights an urgent need to incentivise the generation of evidence for these diagnostic tests. Whereas for drugs the costs of evidence generation are rewarded through an effective patent system, this is not the case for diagnostics. To ensure that we drive the development of more accurate and reliable tests for patients, we need to minimise the risk presented by the use of unregulated 'generic' in-house tests.

The report concludes that influencing clinical practice and collaboration will be critical for stratified – and increasingly personalised - medicines to become embedded in healthcare. Academia, healthcare systems, industries, research funders, regulators, health technology assessment bodies and patient groups must come together to take forward the recommendations. The report calls for the expansion of the UK Stratified Medicine Innovation Platform to provide an overarching body that brings together all the key stakeholders, unifying existing initiatives and co-ordinating future activities in this area.

Sir John concluded, '*Stratified medicine offers promising advances to patients across the UK and worldwide. Embracing this technology, and empowering researchers in the field, will help the UK remain at the forefront of this pioneering approach.*

'The Academy's report released in 2007 identified some of the key challenges that would be faced on the path to fully integrating personalised medicine into UK healthcare. We still face many of these obstacles, and we must work with all stakeholders to ensure we are not in the same position five years from now.'

- ENDS -

For further information, please contact:
Holly Rogers, Communications Officer, Academy of Medical Sciences
t: 020 3176 2183 m:0770 7745201 e: holly.rogers@acmedsci.ac.uk

Notes for Editors

Copies of the report *Realising the potential of stratified medicine* are available on request.

The independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated into benefits for patients. The Academy's Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service.

Further details may be obtained from The Academy of Medical Sciences, 41 Portland Place, London W1B 1QH. Tel: 020 3176 2183 <http://www.acmedsci.ac.uk>

Oversight group members

Professor Sir John Bell FRS HonFREng FMedSci (Chair) Regius Professor of Medicine, University of Oxford

Dr Richard Barker, Director, Centre for the Advancement of Sustainable Medical Innovation

Dr Graham Bell, Lead Technologist in Stratified Medicine, Technology Strategy Board

Professor Lou Garrison, Associate Director of the Pharmaceutical Outcomes Research and Policy Program, University of Washington

Dr Jeremy Haigh, European Chief Operating Officer, Research & Development, Amgen Ltd

Dr Louise Leong, Head of R&D, The Association of the British Pharmaceutical Industry

Dr Tom Lillie, International Therapeutic Area Head for Oncology, Amgen Ltd

Dr Thomas Lönngren, Strategic Advisor, NDA Advisory Service Ltd

Dr Iain Miller (Member of preparatory group 2) Global Head of Personalized Healthcare Strategy and Partnerships, GE Healthcare

Professor Andrew Morris FRSE FMedSci, Professor and Dean of Medicine, University of Dundee and Chief Scientist for Scotland

Professor Adrian Towse, Director, Office of Health Economics

Dr Desmond Walsh, Head of Infections and Immunity and Lead for Stratified Medicine, Medical Research Council