



The Royal College of Pathologists  
Pathology: the science behind the cure

## **Purpose & function of NICE and MHRA**

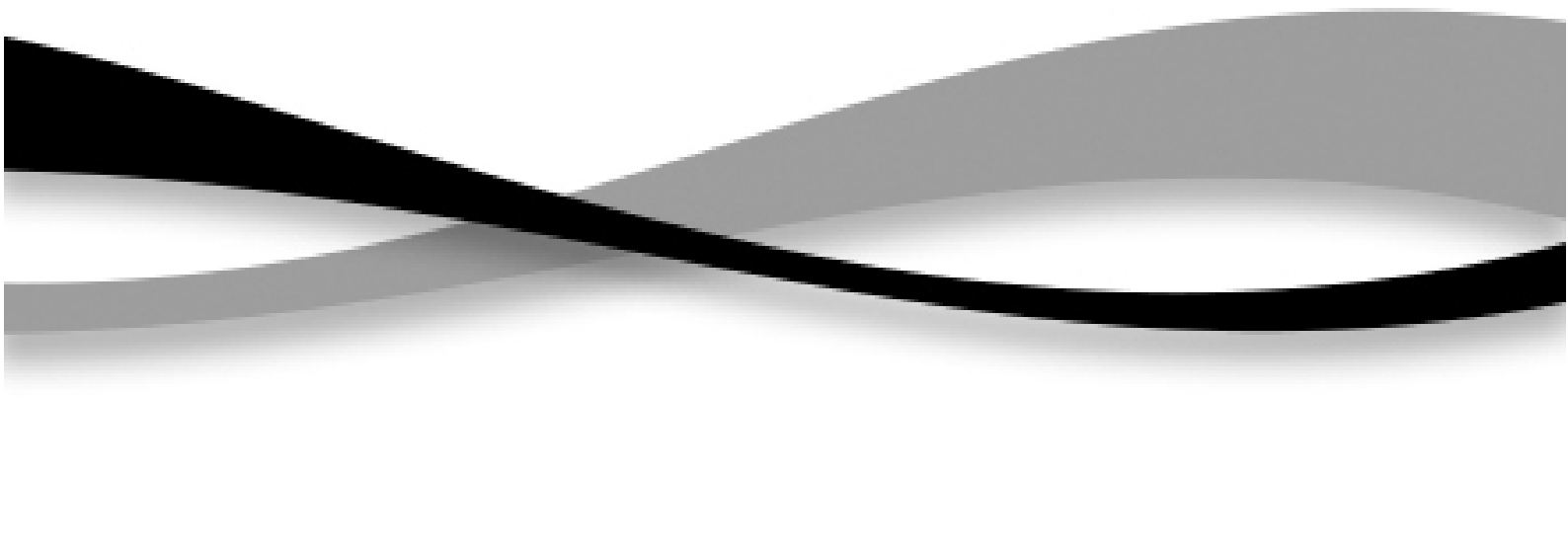
### **The Royal College of Pathologists' written submission**

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## **Summary of The Royal College of Pathologists' written submission**

### **National Institute for Health and Care Excellence (NICE)**

The Royal College of Pathologists considers that NICE provides useful guidance for clinicians and many healthcare systems are envious of NICE and the system that exerts some control over drug costs.

However, the Royal College of Pathologists notes that NICE appraisals of new drugs are performed long after the drugs have been licensed and extensively used, firstly in clinical studies and then on expanded access. The reason for this delay is the NICE requirement for evidence from publications with longer-term outcomes. While this position is understandable, the Royal College of Pathologists believes that this approach by NICE does not fit with modern clinical practice. Specifically, specialists in any field get their information from presentations at peer reviewed academic meetings but the related peer-reviewed papers are often published 12 to 18 months later. NICE will not accept the evidence provided by abstracts from the academic meetings and so NICE is always out of date.

In their appraisals NICE also use comparators which are no longer used in clinical practice. The choice of comparators appears to Fellows of the RCPATH to be because they are cheap rather than effective.

The technology appraisals are conducted by university groups who are very knowledgeable and experienced in some respects but may have little knowledge of the disease. Therefore these groups need a lot of guidance. The provision of this guidance is time-consuming and frustrating for our Fellows as the appraisal outcome can often be easily predicted.

The Royal College of Pathologists considers that the drug companies are aware of a 'magic figure' to get their drug approved. Essentially there is a feeling among our Fellowship that so long as the drug cost is less than 30K per year it will be approved by NICE.

### **Medicines and Healthcare Products Regulatory Agency (MHRA)**

The Royal College of Pathologists maintains that MHRA has a key role in drug and medical devices regulation, as well as transfusion

The Royal College of Pathologists considers the significant overlap with MHRA requirements and ISO 15189, JACIE and HTA requirements to be a major problem. Strategic thinking to reduce overlap and streamline these mandatory requirements would reduce the administrative burden and costs for participating clinical services. Indeed there is a belief that the accreditation bodies are now vying with each other to be 'the toughest' and have lost sight of the place of clinical laboratories and the needs of patients.

College Fellows comment that a whole industry is being created to meet the ambitions of the accreditation bodies. The costs of these multiple layers of accreditation are borne by the health service at the expense of other areas of provision of patient care.

As part of the 2013 Sherwood Forest investigation report for the Care Quality Commission the Royal College of Pathologists made specific comments which concern the MHRA. It is not clear to the RCPATH what, if any, action the MHRA has taken to prevent a recurrence of such problems with reagents and equipment in widespread use in clinical laboratories.

## **1 About The Royal College of Pathologists**

**1.1** The Royal College of Pathologists (RCPATH) is a professional membership organisation with charitable status. It is committed to setting and maintaining professional standards and to promoting excellence in the teaching and practice of pathology. Pathology is the science at the heart of modern medicine and is involved in 70 per cent of all diagnoses made within the National Health Service. The College aims to advance the science and practice of pathology, to provide public education, to promote research in pathology and to disseminate the results. We have over 10,000 members across 19 specialties working in hospital laboratories, universities and industry worldwide to diagnose, treat and prevent illness.

**1.2** The Royal College of Pathologists makes specific comments on the Department of Health Triennial Review of the Medicines and Healthcare Products Regulatory Agency and the National Institute for Health and Care Excellence. These comments were compiled by Dr Rachael Liebmann, RCPATH Registrar following a consultation with all of the Fellows which ran from the 15th December 2014 until 31<sup>st</sup> December 2014.

## **2 Feedback on the Purpose & function of National Institute for Health and Care Excellence (NICE)**

**2.1** The Royal College of Pathologists considers that NICE provides useful guidance for clinicians. Many healthcare systems are envious of NICE and the system that exerts some control over drug costs.

**2.2** It was noted that there is now significant overlap with NICE and the medicines consortia in the devolved administrations.

**2.3** The Royal College of Pathologists notes that NICE appraisals of new drugs are performed long after the drugs have been licensed and extensively used, firstly in clinical studies and then on expanded access. The reason for this delay is the NICE requirement for evidence from publications with longer-term outcomes. While this position is understandable, the Royal College of Pathologists believes that this approach by NICE does not fit with modern clinical practice. Specifically, specialists in any field get their information from presentations at peer reviewed academic meetings but the related peer-reviewed papers are often published 12 to 18 months later. NICE will not accept the evidence provided by abstracts from the academic meetings and so NICE is always out of date.

**2.4** In their appraisals NICE also use comparators which are no longer used in clinical practice. The choice of comparators appears to Fellows of the RCPATH to be because they are cheap rather than effective.

**2.5** The technology appraisals are conducted by university groups who are very knowledgeable and experienced in some respects but may have little knowledge of the disease. Therefore these groups need a lot of guidance. The provision of this guidance is time-consuming and frustrating for our Fellows as the appraisal outcome can often be easily predicted.

**2.6** The Royal College of Pathologists considers that the drug companies are aware of a 'magic figure' to get their drug approved. Essentially there is a feeling among our

Fellowship that so long as the drug cost is less than 30K per year it will be approved by NICE.

### **3 Feedback on the Purpose & function of Medicines and Healthcare Products Regulatory Agency (MHRA)**

**3.1** The Royal College of Pathologists maintains that MHRA has a key role in drug and medical devices regulation, as well as transfusion. Interactions with the MHRA are described as very positive and cordial and the MHRA is described as well run, accessible, timely and thoughtful by our Fellows.

**3.2** The Royal College of Pathologists considers the significant overlap with MHRA requirements and ISO 15189, JACIE and HTA requirements to be a major problem. Strategic thinking to reduce overlap and streamline these mandatory requirements would reduce the administrative burden and costs for participating clinical services. Indeed there is a belief that the accreditation bodies are now vying with each other to be 'the toughest' and have lost sight of the place of clinical laboratories and the needs of patients.

**3.3** College Fellows comment that a whole industry is being created to meet the ambitions of the accreditation bodies. The costs of these multiple layers of accreditation are borne by the health service at the expense of other areas of provision of patient care.

**3.4** It was also noted that the MHRA needs to consult with the laboratory community more and to consider the consequences of its decisions on effective laboratory practice.

**3.5** The RCPATH comments that MHRA should not simply quote the manufacturer of a product when responding to complaints. MHRA should be prepared to use their position to adjudicate on issues which involve risk to patients.

**3.6** In its 2013 report on the investigation into problems with breast cancer diagnostic quality at Sherwood Forest NHS Foundation Trust undertaken by the Royal College of Pathologists on behalf of the Care Quality Commission, the Royal College of Pathologists made specific comments which concern the MHRA. These are itemised below.

**3.6.1** Paragraph 3.8.9 of the report<sup>1</sup> states:

*'EQA scheme organisers are in a privileged position, collecting information about the performance of technology and reagents. At an early stage they may identify technologies or reagents that are not fit for purpose. EQA scheme organisers and the MHRA need to liaise on a regular basis to ensure a timely, proportionate response'*.

**3.6.2** Paragraph 3.9.5 of the report states:

*'The remit of the MHRA in the licensing of laboratory equipment such as histopathology tissue processors should be strengthened in the light of patient-care issues. Use of the Alert system must also become a top priority where appropriate'*.

**3.7** It is not clear to the RCPATH what, if any, action the MHRA has taken to prevent a recurrence of such problems with reagents and equipment in widespread use.

<sup>1</sup> <http://www.rcpath.org/Resources/PDF/Kings%20Mill%20RCPATH%20CQC%20report%205%20April.pdf>

<sup>2</sup> <http://www.sfh-tr.nhs.uk/index.php/latest-news/956-in-house-immunohistochemistry-restarts-at-the-trust>

<sup>3</sup> <http://www.rcpath.org/Resources/PDF/Sherwood%20Forest%20hospitals%20press%20release%20Dec%20%202014%20Final.pdf>