ROYAL ACADEMY OF ENGINEERING

Triennial review

A response to the National Institute for Health and Care Excellence (NICE) and Medicines and Healthcare products Regulatory Agency (MHRA)

January 2015

1. This evidence is submitted by the Royal Academy of Engineering. As the UK's national academy for engineering, we bring together the most successful and talented engineers from across the engineering sectors for a shared purpose: to advance and promote excellence in engineering.

2. Due to the short timeframe within which to respond to this inquiry, this response restricts itself to summarising the key points from recent work. Additional views described in this response were assembled through consultation with our Medical Technologies Community of Practice. This group comprises of Academy Fellows who have expertise in IT systems, biomedical engineering and medical technologies.

3. The response attached provides a joint response to both the NICE and MHRA triennial reviews.

Key messages

4. Innovation and engineering of new medical technologies and digital healthcare can offer a great deal to alleviate the growing pressures on healthcare. It is particularly relevant when looking at the boundaries of public-private care; the pursuit of integrated social care and healthcare; prevention as well as cure; wellness as well as illness. It is in relation to this innovation agenda that the Royal Academy of Engineering would like to contribute towards the Triennial review for both MHRA and NICE.

5. It is clear that NICE and MHRA provide a vital and respected role in guiding treatment and evidencing the safety and efficacy of drugs and medical devices, with a high degree of independence and impartiality. It is this level of impartial, expert scrutiny we would like to see extended to medical technologies and software in the name of better patient care, and clinician and industry clarity.

6. We are concerned that innovation, particularly in digital healthcare, is inhibited by the lack of a clear regulatory framework, interoperability and common quality criteria.

7. There is a continuing need for the functions undertaken by NICE and MHRA. The Academy would like to see coherent guidance and a clarification of the respective roles of NICE, MHRA, NHS England and the Department of Health. This would greatly benefit industry and entrepreneurs navigating the regulatory and procurement system.

8. We propose that the functions of NICE and MHRA be reviewed to consider whether both could become part of the broader UK innovation landscape that works with other bodies or agencies as well as introducing closer links with each other, while retaining their expertise and neutrality. Recent work undertaken by the Academy concludes that better alignment between NICE and MHRA is needed to maintain confidence in new patient care pathways that will include more devices and software dependencies (see Paragraph 16).

9. The Academy is concerned that the pace and scale of innovation in digital healthcare and mobile health pose challenges beyond current resources and skills within NICE

and MHRA. We recommend that a new approach now needs to be considered. Any changes would need to drive the European, and hence UK, regulatory system towards providing optimal levels of regulation (ie not over-regulation) and clear guidance on the safety requirements, quality criteria, certification pathways and liability rules for current and emerging digital healthcare and medical devices.

10. Any proposed changes to the regulatory system will need to carefully consider NICE and MHRA remits, staff resources and budgets to ensure that they remain fully responsive to changes in the wider health and care system.

11. Determining the optimum regulatory system would include a more thorough look at:
    - pathways for integrated healthcare and digital systems;
    - patient centred initiatives focused on prevention, wellness, patient information and patient records – this would include better use of wearables and activity monitors, but would also be using technology such as point of care testers and applications;
    - a stronger focus on telecare;
    - devices and apps that are for clinical use in primary or secondary care;
    - an open approach to using internet-based solutions for community and condition monitoring and
    - international benchmarking of best practice in digital healthcare.

12. A review of NICE and MHRA must consider future medical technology innovations. The regulatory system should be set up so that such future innovations can pass through quickly into the healthcare system while ensuring quality, efficacy and cost-effectiveness. Personalisation and customisation of medical products is a growing trend. While the current system is not yet set up to best handle such products any new structure would need to consider how to approve and regulate unique and 'one of a kind' products.

13. The Academy is concerned that the current European regulatory system does not complement the international characteristic of innovation and legislation. Interpretation of EU and UN directives, as well as national and international standards, is onerous. This has led to 'regulation tourists' with innovators taking the route of least resistance between the US and Europe. The US Food and Drug Administration (FDA) has already begun to move towards harmonising rules which could be an approach also considered by NICE and MHRA.

14. In addition, the FDA has reacted to trends in digital health. With industry, it is developing guidance to define general wellness devices, apps and accessory devices. The FDA has also begun to clarify to industry when these would fall under the agency's purview and would be regulated as a medical device. Lessons can be learnt from the FDA approach to ensure the UK does not stand still in this ever evolving area.

15. Engineering can contribute beyond technologies. As mentioned in paragraph eight, NICE and MHRA should move towards considering themselves in the content of the external regulatory landscape (both UK and internationally) as well focusing on their internal processes. Taking a systems approach would enable these organisations to

think about their roles in the wider landscape and how to prepare for future change. Systems engineers and the Academy are well placed to provide such perspectives.

16. The Academy, with the Academy of Medical Sciences, recently held a meeting on *Health apps: regulation and quality control* which brought together software developers, distributors, accreditors, academics, clinicians and policy representatives with regulators to foster cross-disciplinary solutions. This included developers of the first two healthcare apps to be approved by the MHRA and FDA. A report of this meeting is being prepared that identifies some of the key challenges relating to the current UK regulatory system and proposes potential solutions to create a clearer and better connected process to regulate health apps.

17. It is recognised that what is being proposed could represent a major undertaking for NICE, MHRA and other regulatory bodies. As already mentioned in paragraph 10, this will need to be fully resourced with an appropriate budget and staff with the requisite skills.

18. In support of ongoing debates on how to speed up patient access to new cost-effective medical devices and digital healthcare, the Academy intends to respond to the Innovative Medicines and MedTech Review. Our response will build upon and delve into the key messages outlined in this response.

19. We would welcome a meeting with NICE and MHRA to discuss any of the issues raised in this response.