Medicines and Medical Devices Bill briefing

Introduction

This briefing is intended to help parliamentarians seeking to contribute to debates on the Medicines and Medical Devices Bill. It sets out:

- EMIG's perspectives on the Bill as drafted
- EMIG's aspirations for how the powers included in the Bill might be used
- Ministerial commitments we are hoping to see made during the passage of the Bill

EMIG is a pharmaceutical trade body for small and medium sized companies. We have 300+ Member companies and organisations, representing c. 50% of UK branded medicines sales. For further information, please get in touch with Leslie Galloway (Chairman, EMIG) at leslie.galloway@emig.org.uk.

About the Bill

The Bill provides for the UK Government to take powers to update and amend regulations on medicines and medical devices which have historically been exercised at the EU level following the UK's departure from the EU.

The powers on medicines must normally be exercised in a manner consistent with three tests, as follows:

1. Patient safety
2. The availability of medicines
3. The attractiveness of the UK to the life sciences sector

The Bill only imposes a requirement on ministers to have regard to these tests, rather than to act in a way which delivers on these objectives.

EMIG's aspirations

The powers in the Bill can be used flexibly. However, we hope to see them used in the following ways to deliver improvements in patients' access to medicines and to maximise the attractiveness of the UK to the life sciences sector following our departure from the EU:

- First, we want to see a flexible and supportive licensing and reimbursement process. This should ensure the MHRA's 'Early Access to Medicines Scheme (EAMS)' is linked to an efficient NHS reimbursement decision-taking process, so that if the UK chooses to implement a system which licences certain types of medicines more quickly than the EMA, then they are also made available to patients on the NHS more quickly too

- Second, we want to see important changes to NICE to deliver a more modern process for companies seeking to launch products here to work with, such as the use of creative payment mechanisms and synthetic comparators in NICE assessments

- Third, we want to see the promised Innovative Drugs Fund deliver meaningful improvements in access, particularly given that the lower than expected Voluntary Scheme rebates suggest that access has been restricted

- Fourth, we want to see steps to facilitate the creation of ultra-high-tech treatment manufacturing hubs in the UK (such as for CAR T and gene therapies)

- Fifth, we want to see efforts to link together the UK's considerable public investment in research with global research priorities, thus encouraging greater inward investment in UK science

Possible ministerial commitments

We hope parliamentarians will press ministers to make the following commitments during the passage of the Bill, which are in line with our aspirations above:

- First, that the Government will commit to aligning EAMS decisions with NHS reimbursement decisions

- Second, that reforms to NICE will be pursued to ensure it is future-proofed to assess the latest breakthrough technologies

- Third, that the Innovative Drugs Fund will be designed to address issues with clinical uncertainty and expedite patient access to the latest medicines

- Fourth, that the Government will explore setting capital investment allowances and tax credits to encourage inward investments in state-of-the-art manufacturing facilities

- Fifth, that the Government will support the creation of a Life Sciences Sector Research Collaborative, bringing together public funders of research with those who guide global R&D investment decisions