National Institute for Health and Care Excellence

NICE and MHRA Partnership Working to Develop an Innovative Licensing and Access Pathway

This report gives details of partnership working between the Medicines and Healthcare products Regulatory Agency (MHRA) and NICE, with a focus on work to deliver an Innovative Licensing and Access Pathway for medicines. The new pathway will be in operation from 1st January 2021, as part of the regulatory arrangements following the UK-EU Transition Period.

The Board is asked to note the progress relating to the development of the Innovative Licensing and Access Pathway.

Meindert Boysen

Deputy Chief Executive and Director, Centre for Health Technology Evaluation

Felix Greaves

Director, Science, Evidence and Analytics

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Background

The MHRA and NICE have developed a strong collaborative relationship in line with the Partnership Agreement between the two agencies. Interactions are far reaching including collaboration on patient safety issues, medicines, medical devices, diagnostics, and digital health.

Proposals to further strengthen collaboration through establishing the MHRA and NICE Core Strategic Group were approved by the MHRA and NICE Boards in April and May 2020 respectively. The proposals recognised that MHRA has a UK-wide remit whereas NICE is an England-only body and there may therefore be scope to engage the devolved administrations. Since then, the Scottish Medicines Consortium (SMC) has become a member of the Core Strategic Group.

The initial focus of the Core Strategic Group is developing aligned regulatory and health technology assessment pathways for medicines for application from January 2021, when the UK-EU Transition Period ends and the MHRA becomes the standalone UK regulator for medicines and medical devices.

In parallel with the work of the Core Strategic Group, the Office for Life Sciences (OLS) and MHRA launched a major initiative on the Future of Regulation. The work of the Core Strategic Group has become a key delivery vehicle for the Future of Regulation project and is integrated within the project delivery infrastructure.

The objective of the new pathway is, through joint working between the MHRA, NICE, SMC, NHS England and NHS Improvement and other partner organisations in the UK, to develop a frictionless pathway to the timely availability of effective and safe medicines. The pathway also has the potential to maintain and further develop the UK as a major life sciences destination.

The key features of the approach will include a new medicine designation (the Innovation Passport), that links to the development of a roadmap (the Target Development Profile) to patient access in the UK healthcare system. The Target Development Profile will provide a clear pathway for product development, offering a toolkit of support options and providing a platform for sustained multi-stakeholder interactions. There are currently 12 tools in the toolkit and NICE are co-developing 4 with the MHRA and SMC (see progress summary below).

The toolkit is intended to drive efficiencies in the development programme by supporting data generation and advising on evidence requirements. An integrated pathway will pull together expertise from across the MHRA, NICE, SMC and other partners in the wider healthcare system with multiple entry points available to developers.

Development of the Innovative Licensing and Access pathway is managed through several work packages. Progress in key areas is outlined in the following paragraphs.

Progress Update

Work is on-going to identify the resources needed and funding models for operating the pathway. The pilots with industry (see below) will be used to monitor the resources required for full participation in producing Target Development Profiles for products. This will inform further work on funding models and fee structures for companies participating in the pathway.

Criteria for granting the new designation, the Innovation Passport, have been developed (subject to final approval) and the company application process and template developed. The criteria have been designed such that innovative products with the potential to benefit patients could receive the designation and access the new pathway and toolkit of support options.

The process and templates for producing product Target Development Profiles have been developed. Four companies were invited to take part in the pilot and all four accepted. The pilots are scheduled for completion in November. NICE input to the pilots is led from the Office for Market Access and builds on the considerable access pathway work delivered over recent years.

NICE is participating in the co-development of 4 of the tools as follows:

* 1. Work on a tool on Innovative Licensing Routes is in progress. A first full draft of the tool was completed in mid-October and includes conditional marketing authorisation, marketing authorisation with conditions, marketing authorisation under exceptional circumstances and options for a rolling review, as well as a new route for oncology products through the US Food and Drug Administration ‘Orbis’ initiative. A future iteration of the Earlier Access to Medicines Scheme as a vehicle leading to marketing authorisation will be considered once the pathway is up and running. For NICE, the most urgent work here relates to the Orbis route which could potentially be used from early 2021 leading to UK marketing authorisations several months ahead of the EU.
	2. The Patient Engagement tool is developing well with input from NICE’s Public Involvement Programme. The tool was the subject of a special meeting of the MHRA’s Patient Group Consultative Forum held on 12th of October to discuss the pathway and to seek views from the attendees (including patient groups from NICE). This informed the content of the tool, which is available as an advanced draft.
	3. The tool on Novel Methodology and Clinical Trial Design is under development with NICE’s input being led from NICE Scientific Advice. Key components of the tool have been mapped out and a draft of the tool completed. The application of this tool through joint MHRA and NICE Scientific Advice is expected to be an important part of the support package offered to companies engaging at an early stage of product development.
	4. Finally, the co-development of a tool on Continuous Benefit Risk Assessment and Real-World Evidence is in progress. NICE’s input is being led by NICE Scientific Advice with key input from the data and analytics community across NICE. The core principles and attributes of the tool have been agreed. A representative of NHS England and NHS Improvement has also joined this working group to provide views on data collection.

Procedures for integrated partnership and governance across the organisations engaged in the new pathway are also under development. A high level map of the interactions has been developed which provides the basis for more detailed process development. Arrangements for information sharing between the partners participating in the pathway will also be developed.

Activities on horizon scanning are also included in the work programme. The intention is to build on the approach used in the RAPID-C19 collaboration where expertise and resources from NICE, NIHR and MHRA were successfully aligned. To date, a schematic and notes have been produced, highlighting the capabilities of each of the partners for horizon scanning, and how the different activities may add value to the pathway.

Progress is also being made in the Engagement and Communications work package which to date has involved input from NICE and MHRA Comms teams as well as from the Core Strategic Group members. Given that the new pathway relates in part to arrangements following the UK-EU Transition Period, external communications are subject to DHSC/Government approval processes.

In addition to work on the Innovative Licensing and Access Pathway, the Partnership Agreement between NICE and the MHRA is due for review. A team to lead on the review has been identified, the scope of the review mapped out and work initiated. Revisions to the Partnership Agreement will reflect the establishment of the Core Strategic Group and on-going collaboration in the establishment and operation of the Innovative Licensing and Access Pathway.

Next Steps

Building on the strong progress outlined above, key next steps are:

* 1. Contributing to the production of Target Development Profiles for the products in the company pilots (through to mid-November).
	2. Continued work on the Core Strategic Group work packages.
	3. Applying the learning from the pilots to the pathway launch versions of key documents and templates.
	4. Formal launch of the pathway in mid-December.
	5. On-going participation in and the further development of the pathway leading to an efficient and sustainable national access pathway for medicines. We will continue to monitor resource requirements to take this work forwards.

Conclusion

Strong progress is being made in establishing an Innovative Licensing and Access Pathway for operation from January 2021 following the UK-EU Transition Period.

Issues for decision

The Board is asked to note the progress relating to the development of the Innovative Licensing and Access Pathway.

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