

Responding to the Independent Medicines and Medical Devices Safety (IMMDS) Review

We welcome the UK Government's response to the IMMDS review, recently published by the Department of Health and Social Care. We support its proposals for improving transparency and for taking forward recommendation eight on conflicts of interest.

While the review was specific to England, as a four-country regulator, we are pleased that patients and patient groups from Northern Ireland, Scotland and Wales were given the opportunity to have their voices heard.

We also welcome the devolved administrations' response to recommendation eight. We look forward to working with the four governments and others, to explore how we can most effectively support implementation of this recommendation and the wider findings of the Review.

Improving transparency over conflicts of interest

We agree that current arrangements to register conflicts of interest (COI) fall short of delivering adequate transparency and assurance for patients. To successfully address this, any solution needs to be:

- accurate, up to date, accessible and presented in a way that is useful for patients, so that they can have confidence in it
- enforceable, so that patients can trust the information is credible
- multi-professional in scope.

We believe that these principles are best addressed through a system of local registers published by a doctor's employer, contractor or organisation where they are providing their services. This is because conflicts of interest are contextual, and employers are better placed to understand the scope of an individual's role, and what may or may not be in conflict. In turn, this would help to ensure that the information remains accurate, up to date and credible. And it would enable patients and the public to access information locally where they can ask questions if they have concerns.

We therefore agree with the Government's proposal for information to be published locally at employer level. We also agree that stronger reporting arrangements should be put in

place for the pharmaceutical and medical device industry for payments made to individual clinicians. We support the Government's intention to explore this further, including the option of making reporting in this area mandatory through legislation. We believe that this information could also help to check and validate interests that are declared locally.

To support the implementation of this approach, there also needs to be:

- clarity about what type of interests should be declared
- assurance that employers and organisations that contract a doctor's services are publishing and maintaining local registers of interest.

Within their response, the Government proposes that it should be a regulatory requirement for all healthcare professionals to declare relevant conflicts of interest to their employer, contractor or organisation where they provide their services. We agree with this proposal.

Our core ethical guidance [Good medical practice](#), and our explanatory guidance [Financial and commercial arrangements and conflicts of interest](#) already require doctors to declare any competing or potentially competing interests to patients. Our explanatory guidance also says that registrants should declare interests in line with the policies of their employer or the organisation contracting their services. We recognise that some registrants may need further advice and guidance to understand when an interest is potentially brought into conflict and should therefore be declared. As part of our review of [Good medical practice](#), we will consider whether it would be helpful to develop additional guidance and illustrative examples to reinforce our expectations in this area. We will also consider this further when we review our [joint statement on conflicts of interest](#) with the other healthcare regulators. But employers and contractors of doctors' services must also play their part in ensuring that appropriate declarations are made.

To provide assurance that local arrangements for managing COI are in place, we agree that these processes should be embedded within existing systems of clinical governance and monitored accordingly (including by the Care Quality Commission in England).

We welcome the proposal to update the NHS England and Improvement guidance on conflicts of interest. We would suggest this revision also consider whether:

- local templates and forms used to collect and declare information on COI are fit for purpose and consistently used - with the potential to explore this as part of the Higher Level Responsible Officer quality assurance visits.
- there are opportunities to more prominently link the declaration of interests' process to the Responsible Officer regulations and local clinical governance systems, including the annual appraisal process. This would build on the current probity declaration to ensure that COI are managed and declared appropriately.

We believe that the Responsible Officer regulations, and supporting statutory guidance, should be amended to facilitate this change. Amending the regulations in this way would also serve to introduce new information sharing requirements (including information on COI) and could be used to ensure that recruitment processes focus more prominently on COI.

We will be actively engaging with the Department of Health and Social Care's work on these points to help ensure an improved and effective system.

Improving transparency over decision making and consent

We also agree that more can be done to promote a transparent approach to decision making and consent.

Last year, we published updated guidance [Decision making and consent](#). Reflecting on the findings of the IMMDS review, we ensured our new guidance clearly states that serious harm can result from patients not being listened to, not being given the information they need to make a decision, and not being given the time and support they need to understand that information. The guidance encourages doctors to be open with their patients about uncertainties, to answer questions honestly and to share all relevant information with patients about potential benefits and harms of the available treatment options, including the option to take no action. This will help patients to make informed decisions about their care. It also states that doctors should accommodate a patient's wishes if they would like to record a consultation; and that recordings made by doctors as part of a patient's care must form part of the patient's medical record.

As referenced in the Government's response, we are now taking forward work to embed the new guidance into everyday practice, including:

- Collaborating with the Professional Records Standards Body to develop an information record standard for consent and shared decision making to meet the needs of all four UK countries.
- Joining with patient organisations to help improve awareness and understanding about shared decision making and what patients can expect of their doctors. We have recently published additional [resources](#) on our website to facilitate this.
- Leading the development of a joint [a case study](#) with the Nursing and Midwifery Council, the General Pharmaceutical Council and several patient groups and individuals, to highlight the risks of taking sodium valproate during pregnancy.

Promoting transparency in the delivery of healthcare, through changing the way in which conflicts of interest are managed and published, and through the way in which informed consent is sought and provided, will deliver significant improvements to patient safety. We remain committed to working with the Government and others to support the effective implementation of their proposals.