Department of Health & Social Care

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Dear Professor Healy,

Thank you for your correspondence of 25 November to Matt Hancock about clinical guidelines. I have been asked to reply.

I appreciate your concerns.

As you know, the National Institute for Health and Care Excellence (NICE) is the independent body responsible for developing authoritative, evidence-based guidance for the NHS on best practice. NICE is responsible for the processes it uses in the development of its recommendations, and it follows very robust processes to develop its guidance.

NICE's processes for developing guidelines have been periodically reviewed, in consultation with stakeholders, and updated and published on NICE's website. These processes also provide opportunities for public consultation on draft recommendations. Consultation comments and the developer's responses, the list of stakeholder organisations that registered to participate in the development of NICE's guidance, and the membership of each guideline committee is published on the website. NICE processes are designed to ensure objective, systematic, transparent and consistent consideration of the evidence and feedback received from stakeholders with an interest in the topic.

With regard to clinical guidelines, the search strategies, review questions and evidence identified as a result of these strategies are also published on the NICE

website. The review of the evidence, and the link between the evidence and NICE's recommendations, are also published.

NICE guidelines are based on a thorough assessment of the best available evidence, and are developed through extensive engagement with stakeholders. They represent best practice, and healthcare professionals are expected to take them fully into account. However, NICE guidelines do not override clinical judgement. When exercising their clinical judgement, healthcare professionals should consider the circumstances and wishes of each individual patient and make appropriate decisions on a case-by-case basis, in consultation with them and their families, carers or guardians..

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are supported by clear and detailed product information that contains the relevant information to use the approved medicines as safely as possible.

At the time of first authorisation, medicines regulators have access to information on all clinical trials carried out in support of the application for that medicinal product. Companies are legally required to provide all information, both favourable and unfavourable, for the regulator to reach a conclusion on the overall balance of benefit and risk in the claimed indications. As part of that application, a risk management plan is required to address identified and potential risks, and the product information sets out those risks and provides details on adverse events known at the time.

As you are aware, all medicines have the potential to cause side effects in some patients. The product information is available to patients and doctors to inform them of the risks and benefits associated with treatment. The product information is kept up to date during the lifecycle of the product through post-marketing obligations. The product information can be found on the MHRA website and the patient information leaflet is supplied with each package of medicine.

As you will know, sertraline is a selective serotonin reuptake inhibitor (SSRI) and is an effective medicine for the treatment of depression and related conditions. The product information for sertraline contains a clear warning that its use has been rarely associated with the development of akathisia. This is most likely to occur within the first few weeks of treatment.

Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide, and this risk persists until significant remission occurs. As a patient's

depression may not improve during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery. Accordingly, the product information for sertraline clearly states that patients and carers should be alerted, especially in early treatment, about the need to monitor for any clinical worsening, suicidal behaviour or thoughts, and unusual changes in behaviour and to seek medical advice immediately if these symptoms present. The data does not exist to show how many patients, through successful treatment of depression and related conditions, may have been prevented from taking their own lives.

The balance of benefits and risks for SSRIs remains under close monitoring, and any new data that may affect the benefit/risk balance are assessed as data emerges.

Now that Parliament has been dissolved before the General Election, the Department cannot comment further on this matter. What happens on this issue in the future will be a matter for the incoming Government.

Yours sincerely,

Leigh Smale
Ministerial Correspondence and Public Enquiries