

16 February 2017

For the attention of all Mental Health Act administrators, Mental Health Pharmacists, Responsible Clinicians, and Second Opinion Appointed Doctors

Dear Colleague,

Shortage of Hyoscine – CQC approach: Information for Providers

We have been advised that there is a national supply problem with Hyoscine Hydrobromide tablets, used to treat hypersalivation resulting from antipsychotic medication. This situation also occurred in 2013, and at that time we gave guidance to our Mental Health Act Reviewers (MHAR) and Inspectors, and we gave information for providers. This is now refreshed in the paragraphs below:

If a supply of hyoscine tablets runs out there will of course be a need to review the continued need for medication in each individual case.

If any proposed alternative is not covered by the current SOAD certificate, what should be done?

Form T2: If the patient is able to consent to this treatment, and does so, the Responsible Clinician (RC) can certify on a Form T2.

Forms T2 & T3: The issuing of concurrently valid Forms T2 & T3 for the same patient is potentially problematic because the person certifying (whether the RC or a SOAD) should be in a position to consider the totality of a plan, and while we would be reluctant to see this generalise, it is less of a problem when confined to medication for side-effects and we are content that a Form T2, by the RC, for an alternative to hyoscine can co-exist with a Form T3.

Form T3: If the patient does not consent, or is not capable of, consenting then the position in law is that an opinion from a SOAD will be needed. Providers may be aware that we make efforts to prioritise requests for SOADs in relation to those patients who are perceived as needing the greatest level of protection. These patients include those for whom ECT is proposed, those whose condition is rapidly evolving, and those whose are at the end of the '3 month rule' period. Requests for SOADs for patients which arise from the current supply difficulty with hyoscine tablets will likely be of lower priority. Providers will not attract criticism arising from our decision to prioritise other clinical situations.

s62: There is, however, an interim approach which may be of interest. Approved Clinicians in charge of the treatment (AC) and RCs should note that Section 62(2) allows for the continuation of any treatment pending a SOAD visit if the AC considers that stopping the treatment would cause serious suffering to the patient. In order to authorise treatment under this provision the AC would write in the notes that henceforth until the situation changes drug xyz is being given under s62(2). No further forms are needed, and in particular it is not necessary for entries to be made on a daily or dose-by-dose basis. Naturally it will be good practice to review the continuing need for s62(2) at any MDT or similar meeting. Our view is that even though the precise route of the drug may have changed, the essence of the treatment is the same and we are content that s62(2) can reasonably apply to the continuation of a treatment for medication-induced side-effects, used in the way described.

Section 62 may also be used for 'new' treatment, the need for which has arisen since the supply shortage became apparent. Providers will know that the criteria for s62 are in effect a decision tree. It is the third limb of this which may apply in the circumstances of giving medication to address side-effects, without which treatment the antipsychotic might not be tolerated: "to alleviate serious suffering by the patient"; providers are invited to consider if, as is likely, the treatment is 'immediately necessary' – if so, it is likely that the criteria for s62 will be met.

As has previously been explained to SOADs, consideration may also be given to the use of hyoscine patches. The 'route' for these is transdermal. This requires certification on the T form in the same way as any other route; reference to both routes in the same authorisation is entirely acceptable, eg "oral/transdermal".

Providers are reminded that, though some seem to view Hyoscine as licensed for use associated with Clozapine therapy, it is not – the reference to Clozapine in the BNF entry for Hyoscine makes it clear that this is so. Certification of hyoscine (on a 'T' form) will therefore need to include reference to its off-licence use, eg "Hyoscine Hydrobromide oral/transdermal for medication-induced hypersalivation" or some similar such wording.

Providers will doubtless know that the purpose of specifying a route is to ensure that the patient is not being given medication by a route excessively intrusive or inappropriate to the justifiable clinical need or one which carries with it a liability to greater side-effects. For example, that IM medication is not being given instead of the less intrusive oral approach.

We have reminded MHARs & Inspectors that the transdermal route is generally even less intrusive than orally administered medication. As a consequence, we consider that in these circumstances we should be slow to criticise a provider who gave a medication by a more patient-sensitive and less intrusive route. Therefore, although a patient's T form may specify hyoscine orally, if transdermal administration is being used as an alternative then enforcement of the need to change the form or to seek a further Second Opinion will not be seen as the highest priority.

Our over-riding aim is to continue to protect the patient, and their rights, while ensuring that patients receive treatment which is necessary to their overall wellbeing, and avoiding an unnecessary administration burden for those involved. We recognise that some patients find a discussion with a SOAD an intrusive intervention, albeit necessary, and we have encouraged SOADs and Reviewers to bear in mind that an additional SOAD visit purely for the purpose of certifying an alternative to hyoscine may be seen by some patients as being of limited value. Providers will wish to know that we are sensitive to the circumstances in which the patients and providers find themselves when medication supply suddenly alters due to factors outside of their control.

A handwritten signature in black ink, appearing to read 'Simon Wood', written in a cursive style.

Simon Wood
Principal SOAD