

Response to the informal consultation: Changes to the HMR2012 in relation to supply and the UK's exit from the EU

Response

National Voices would like to thank DHSC for including us in this informal consultation, as this topic is of very significant interest to patients and the organisations working with them.

The circumstances and period of the consultation have been too short for us properly to consult our members, or to hold discussions with professional bodies.

We have been able to work with a small number of member charities to understand the scenarios that could affect patients in relation to emerging shortages of supply. We include some of these below. These examples cover large numbers of patients; and we consider that there may well be comparable scenarios for many other patient groups.

The examples show that if pharmacists make any of the four types of changes suggested in the proposals, without reference back to the prescribing clinician, the risks to patient safety could be serious.

Regulatory protocols therefore must include a requirement for pharmacists and clinicians to communicate together on prescription changes – and should make reference to the need for shared decision making with the patient, which is a professional and legal duty of all doctors.

Based on the seriousness of these members' concerns, and of the potential risks to patients that could arise, National Voices must answer 'No' to consultation questions 1 and 2.

We would urge DHSC to find a better process to take this forwards, enabling more discussion within and between stakeholders., to ensure patient interests are properly protected.

Prescribing scenarios from National Voices members

Four of our member organisations were able to respond to the news about the DHSC proposals and to provide us with examples of what might be the risks to patients. (Note they were responding to news reports about the proposals in The Times and Pharmaceutical Journal, rather than the full proposal document.)

The emphases in bold have been added by National Voices to draw attention to the strength of concerns.

a. Kidney patients

In regard to transplant patients, Kidney Care UK has told us:

“Immunosuppressant drugs, also referred to as anti-rejection drugs, are prescribed to people with transplants to prevent rejection of the organ by reducing the body’s normal response to foreign cells. They must be taken regularly without fail and will have been painstakingly titrated to work for the individual.

“Many people with transplants take a combination of several drugs and once stable are reviewed quarterly using a blood test to ensure they are working correctly. Immediately after a transplant there will be lots of swapping of drugs and the full range is needed so the transplant physician can ensure the best combination with the least side effects and most chance of retaining the transplanted organ. They are prescribed by specialist professionals and there are mixed models of delivery, either directly from one of the 24 transplant units or via them through the GP and local pharmacy.

“**On no account can the amounts or frequency of these drugs be safely varied without specialist medical oversight.** It is unlikely that high street pharmacists or GPs would be confident or safe in adjusting such medications without close guidance from specialists.”

In regard to dialysis patients, Kidney Care UK have told us:

“The fluids used for peritoneal dialysis are also prescribed medications. They are used to remove toxins from the body by osmosis, as they are entered into the peritoneum via a catheter, where the fluid rests for a period, is drained out and the process repeated either four times a

day or continuously overnight. We know that this supply line is vulnerable as there was [an incident](#) a few years ago. While the company has learnt from this experience and made great improvements to its supply line it is an example of vulnerability.

"We have had further concerns from patients re their dialysis consumables and supply chains, with one doing an analysis showing that virtually none of the materials are manufactured in the UK. **We would contend that only evaluating medicine supplies without considering that of consumables is an oversight and encourage the government to look at both**, especially as these items are used so frequently – daily or thrice weekly for those on haemodialysis."

b. Diabetes patients

In regard to [insulin supplies](#), Diabetes UK has told us:

"Supply of insulin needs to continue uninterrupted, as people with diabetes, especially those with Type 1, become seriously ill if they do not have access to insulin for even a few hours.

"Similar insulins may affect the person differently: for example, some will take effect more quickly than others. Switching with no warning or support would be dangerous.

"We must ensure that there is no possibility that ministers have to order pharmacists to dispense a "reduced quantity" of the medicine, an "alternative dosage form", a "therapeutic equivalent" or a "generic equivalent"."

"People with diabetes cannot just switch to a different type or brand of insulin without harmful consequences for their health."

c. People with epilepsy

In regard to epilepsy patients, Epilepsy Action has told us:

"There are well established and very good reasons why treatment decisions are made by clinicians in discussion with patients. We have the upmost respect for pharmacists and value the crucial role they play in the health system. Despite this, what we have seen of the government's draft proposals are wholly unsatisfactory for people with epilepsy.

"The draft 'serious shortage protocol' could present a number of specific concerns for people with epilepsy. Epilepsy medicines must be available and taken consistently to ensure that optimum seizure control is properly maintained. **They cannot safely be dispensed in 'reduced quantity'.**

"Over twenty epilepsy medicines are prescribed in the UK with many people having to take more than one drug to achieve optimum seizure control. Finding the right drug or combination of drugs can be a long and difficult process and is rightly overseen by experienced clinicians. **These drugs, or combinations of drugs, cannot be safely replaced by a 'therapeutic equivalent'.**

"Some epilepsy medicines can have different effects on a patient's seizure control depending on the manufacturer. This has been recognised by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines (CHM). Subsequent MHRA guidelines have categorised epilepsy medicines according to the evidence of differences between various manufacturers' versions of these drugs and the potential effect of switching on seizure control and side-effects. **"Epilepsy medicines in category 1 and 2 of the MHRA guidelines cannot be safely replaced by a 'therapeutic equivalent' or 'generic equivalent'.**

"It is not easy for people with epilepsy to achieve optimum or even adequate seizure control. The process for achieving optimum seizure control and mitigating potential side-effects is a complex process that can only be safely navigated by patients with the advice of expert clinicians. Any change to this process such as those proposed in the 'serious shortage protocol' presents an unacceptable risk to people with epilepsy."

d. People with heart conditions

In regard to people with heart conditions, a charity with expertise on the subject within our membership has told us:

"For those with high blood pressure, as well as abnormal heart rhythms, it takes time for medications to be titrated to the right dose. A change in dose that lasts for any significant length of time affects medical treatment, increasing the risk of symptoms and may even result in hospitalisation.

These scenarios illustrate that there can be no assumptions made, either by government centrally in issuing protocols, or by pharmacists or doctors locally in considering changes to medication, that any particular switch to an alternative version, therapeutic equivalent or reduced dosage can be considered 'safe' or 'effective': prescribing decisions must be personalised and taken in full consultation with the patient.

National Voices considers that – in light of that principle – these examples are likely to be representative of many other scenarios affecting many other patient groups and prescribing decisions.

Given the strength of these concerns, and of the potential risks to patients that might result from the DHSC proposals as they stand, we have no choice other than to disagree with consultation questions 1 and 2, and to request that the government finds a better process than this abrupt and shortened 'informal consultation' to help cope with the potential problems of 'no deal' shortages.

Shared decision making

In addition to these scenarios, all three organisations have commented on the need for professionals and patients to work in partnership to explore how to achieve the right version, or right combination, of drugs for the individual.

We would therefore expect any further iteration of the DHSC proposals to make more explicit reference to the requirements for shared decision making with patients. It would be unacceptable for pharmacists or doctors to make any changes to people's medication regimes without full discussion and agreement with the patient.