

**DH Consultation: Pandemic Influenza**

**Possible amendments to medicines and associated legislation during an influenza pandemic.**

Response date 22<sup>nd</sup>

**Consultation response from:**

**The Pharmaceutical Society of Northern Ireland**

**A1)**

- The protocol is reasonable, but should only be implemented at the appropriate phase of the pandemic.
- It is advisable that training for personnel using the protocol is given, and that personnel are able to determine the circumstances if / when supplies are denied.
- There is a risk of inappropriate supply of the drugs leading to shortages of drugs for patients in real need.

**A2)**

- Provided that the NHS and target stocks are not depleted.
- That NHS workers are not affected by stock supplies.
- With respect to supplies to family members, only in specific circumstances if persons are included in the 'at risk groups'

**A3)** Yes. Seems reasonable and should remain in force until the situation reverts to alert Level 1

**A4)** Yes. Seems reasonable and appropriate in a pandemic situation.

**B1)**

- The extension for 28 days seems reasonable providing current guidelines are followed as far as possible.
- Query possible restrictions on drugs subject to abuse e.g. benzodiazepines
- Current stock holdings should be borne in mind

**B2)** Yes, support this proposal.

**B3)**

- Access to manufacturer guidelines would be helpful as expiry dates may vary for individual drugs.
- Perhaps a list of drugs that should be excluded could be drawn up.
- Consideration should be given to the possible risk to a patient of supplying a date expired drug.
- Potential risk to the pharmacist when they supply a date expired drug and patient experiences a reaction.

**B4)**

- Professional judgement of pharmacist making decisions to use unwanted medicines and potential adverse reactions.
- It is advised that certain drugs be excluded for example fridge lines.
- Measures should be taken to avoid potential “dumping” of unwanted drugs by patients.
- There is a risk of patients sharing their medicines with others where clinically inappropriate.
- Advisable to ensure that the products used in this way are still in sealed packs.

**B5)**

- Yes, this should be permitted to meet the unusual circumstances.
- Detailed records of each supply must be maintained for future reference.

**C1)** Reasonable in overall approach.

- Site should have been registered previously for manufacture and there should be no recorded infringements.
- This needs further discussion between UK and EU bodies

Consideration should be given to the Northern Ireland situation where we have cross border links with another EU country and product licences may vary.

**D1)**

- Safeguards must be in place to avoid poor quality products.
- A sound evidence base is required to permit this strategy.
- Forward planning should be considered at this stage for drugs currently in the development stage to facilitate more rapid progress.

**E1)**

- It is important that consideration is given to the specific areas from which medicines would be outsourced.
- There should be similar standards for these products to those already in force in the UK.
- The associated risks/ benefit to patients must be addressed.

**F1.1)**

- The proposals are accepted in principle, but the potential risks must be considered.

## **F1.2)**

- The proposals are accepted in principle.
- The risks of over consumption and potential abuse must be considered.
- By enabling pharmacists to use their discretion in relation to instalment prescribing provides protection for the pharmacist.

## **F2.1)**

- The risk/benefit of the prevailing situation during a pandemic may warrant the supply of S2 and S3 CDs in an emergency.
- Security issues and protection for the Pharmacist must be considered in the event of potential abuse of the system.
- Guidelines in relation to such supplies should be issued by the Department in conjunction with the Professional Body.
- Indemnity cover may need to be amended to cover such supplies by the pharmacist.
- May consider supplying such medicines at NHS expense during the period of the pandemic as mentioned previously for other drugs.

## **F2.2)**

- Yes, due to prevailing circumstances would be appropriate.
- Need to consider risk to addict if supplies are not received and effect on behaviour/health. The addict may pose a greater risk to the public if suffering withdrawal symptoms.
- The equivalent legislation in Northern Ireland would need to be amended.

**F2.3)** Yes, the Society supports this proposal.

## **F2.4)**

- Relaxation of the safe custody regulations would require careful consideration to prevent security risk. Guidance should be given to pharmacists as to the type of alternative security that would be acceptable.
- Specific guidance should be given in Northern Ireland as time delay safes are used in all pharmacies.

## **G1)**

- Yes, the supply of such medicines could be accommodated within the normal guidelines for minor aliment scheme.
- This could be facilitated by extension of the current list of products and associated protocols.

## H1)

- The legislation controls for minimum staffing levels does not apply in Northern Ireland.
- Relaxation of the legislation would be a reasonable step to meet conditions prevailing under a pandemic.

## H2)

- Variation in opening hours would be helpful to meet patient need in the circumstances and to assist pharmacists.
- Consideration must be given to staff to avoid undue pressure if they are forced to work for longer hours.

## H3)

- Temporary additional contracts could be administered for locations such as church halls, and leisure centres to allow access for patients to medicines.
- Consider other circumstances where an additional contract may be required.

**Page 32** – *“If amendments to legislation are agreed, when should they take effect and when should they end?”*

The Society is supportive of the introduction of legislation at UK alert level 2 and this should cease when the situation in the UK returns to alert Level 1. However provision should be included to enable the institution of the legislation again for a temporary period of time if resurgence in cases of influenza occurs.

### **Broad issues that must be considered in relation to points discussed above are:**

- Appropriate record keeping by pharmacists
- Reimbursement of pharmacists for medicines supplied
- Stock problems that may be more acute in some areas such as Northern Ireland, outer islands of Scotland etc where supplies may be seriously disrupted.