

Question A1

Do you agree that in the event of a pandemic flu, the use of date-expired medicines should be allowed?

Yes No Not Sure

Please explain your answer:

The Pharmaceutical Society of Northern Ireland views such a measure as potentially life-saving in successfully continuing a supply of medicine to members of the public in need, at a time of severe pressure on resources and stock.

Guidance from the regulator on judgement and practise will be an important accompaniment to ensure patient safety, as will communication of the guidance to the profession.

The Society also recommends that the Government consider developing guidelines with manufacturers for extending the expiry date of certain medicines in the case of a national emergency.

Question A2

Are there any medicines that should be excluded from this provision?

Yes No Not Sure

Please explain your answer:

For the safety of the public a fuller assessment should be compiled of the varying level of risk attached to each licensed drug's date expiry and how the risk changes according to time beyond date expiry e.g. 1 week, 1 month, 6 months etc. This assessment could then assist pharmacists and professional guidance in the case of a pandemic flu and the need to use date expired medicines. Particular attention should be given to the risk attached to using cold-chain medicines beyond date expiry.

The Society appreciate this might be a lengthy exercise but recommend such activity be factored into the Government's present contingency plans. Some drugs will lose potency to a greater degree beyond date-expiry than others, and a form of understanding of these differences is required to maintain standards of patient safety and care.

Question A3

What concerns do you have about allowing the use of date expired medicines in the event of a pandemic flu?

Please explain your answer:

The reasons for date expiry can be fundamentally different depending on the nature of the formulation. There will be heightened risks associated to particular products.

Pharmacists should be advised to strongly caution patients against unilaterally administering medications post expiry without checking with a pharmacist. The pharmacist should make a judgment based on a scientific evaluation and in keeping with professional guidance. This situation should only be permitted in a national emergency and the culture of extending expiry should never become commonplace.

The RPSGB team reviewing the professional standards should give full consideration to the issue of pharmacist liability in the event of a pandemic flu and the necessity to use date-expired medicines.

Above all, it is preferable that the Government make adequate emergency provisions for the supply of pandemic flu related medicines in order to prevent as far as possible the need to use date-expired medicines

Question A4

If *Professional standards and guidance for the sale and supply of medicines* were to be amended in the event of a pandemic flu, what guidance would you want the RPSGB to provide?

Please explain your answer:

The PSNI, as always, wish to harmonise guidance with the RPSGB to ensure common standards are applied across the UK. We would therefore recommend that a working group be constituted to work along with the RPSGB on the development of Professional Standards to be applied in the event of a national emergency like a pandemic flu-.

Guidance should include:

- Use of date expired medicines
- Liability for professionals after due diligence
- Use of Unlicensed medicines

Further comments (Date expired medicines)

Please let us have any further comments about this proposed amendment.

A further question to consider is the extent of information on date-expired medicines that should be made available online during a flu pandemic, for both pharmacists and members of the public.

Any amendment to professional standards and guidance for the sale and supply of medicines in the event of a pandemic flu should include advise to pharmacists on keeping records of dispensing activity that involved date-expired medicines.

The RPSGB team reviewing current professional standards and guidance in this area should also consider patient consent – the need for a pharmacist to inform a patient that the dispensed medicine is date-expired, and also any potential requirement for the patient to give a form of written consent for the pharmacist's records.

Guidance to pharmacists will need to be clear as to when different emergency periods begin and end, and how guidance and standards adapt accordingly (e.g. Level 1, Level 2).

B: Patient returned medicines

Question B1

Do you agree that in the event of a pandemic flu, the use of patient returned medicines should be allowed?

Yes No Not Sure

Please explain your answer:

The Pharmaceutical Society of Northern Ireland views such a measure as potentially life-saving in successfully continuing a supply of medicine to members of the public in need, at a time of severe pressure on resources and stock.

Guidance from the regulator on judgement and practise will be an important accompaniment. Pharmacists should keep records of all dispensary activity involving returned medicines with clear audit trails and rationale recorded

Preferably, returned medicines that are re-dispensed should always be within a sealed pack.

Question B2

Are there any medicines that should be excluded from this provision?

Yes No Not Sure

Please explain your answer:

The PSNI suggest that cold chain drugs be excluded.

As with date-expired medicines, the Government should commission an extensive assessment exercise as the variable risk rates of reusing a medicine. This should then form the basis of decision-making on whether particular medicines should be excluded from the provision.

The RPSGB review team should also consider what level of professional judgement should be given in terms of dispensing patient returned medicines.

Question B3

What concerns do you have about allowing the use of patient returned medicines in the event of a pandemic flu?

Please explain your answer:

Robust systems will be required for professionals in judging the integrity of returned medicines to be reused. The safety of the patient must never be compromised. It may be a professional requirement to inform the patient that their medicine is a patient returned medicine and this has been checked by a pharmacist to assure quality

There are also risks of patients stockpiling and/or sharing medicines with each other without medical advice. Government communication activity should be deployed to prevent this.

As stated elsewhere in this response, the Society recommend the review team consider patient consent (potentially in written form) should be given before dispensing patient-returned medicines.

Question B4

If *Professional standards and guidance for the sale and supply of medicines* were to be amended in the event of a pandemic flu, what guidance would you want the RPSGB to provide?

Please explain your answer:

Guidance should include advice to pharmacists on how to judge the integrity of medicines and how to satisfactorily record details of dispensary activity involving returned medicines.

Please let us have any further comments about this proposed amendment

Comments:

In the event of a pandemic flu, the Government will need to implement communications activity to the public to encourage the sensible return of medicines to the pharmacy potentially for reuse.

Patients need a communication message to discourage stockpiling of medicines and/or unsupervised sharing of medicines with others. Patient expectations should be to receive their medicines on a short duration but regular basis. Such communications from Government should be factored in to current contingency plans.

The review team should consider issues of pharmacist liability in a pandemic flu national emergency, where a dispensed medicine which was patient returned is the cause of an adverse drug reaction.