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To: General Practitioners
Community Pharmacists
Medical Directors of Acute Trusts
Chief Pharmacists of Acute Trusts

Copy: Pharmaceutical Advisers of PCTs
Immunisation and Flu Co-ordinators
SHA Medical Directors
SHA Pharmacy/Prescribing Leads

4 January 2011

Dear Colleague

2010/11 Seasonal Influenza: Update on supply and availability of antivirals for children under 1 year of age

In my letter of 23 December 2010, I explained that steps were being taken to support the antiviral medicines supply chain through release of antivirals from the national stockpile.

To help ensure that oseltamivir in forms suitable for administration to children under 1 year of age is available to meet potential demand across the country, we are now adopting a multi-layered approach.

The manufacturers (Roche) have ordered additional quantities of Tamiflu 12mg/ml Oral Suspension. I have also asked specific licensed NHS hospital pharmacies to begin manufacturing Oseltamivir 15mg/ml Oral Solution. This is the same product that was used in the swine flu pandemic and is derived from oseltamivir powder, secured as part of the national stockpile. It may also be possible for a pharmacy to prepare a solution suitable for administration to children from Tamiflu capsules.

Details of how to do this are contained in the Summary of Product Characteristics, which can be located at the following website:

<http://www.medicines.org.uk/EMC/medicine/20294/SPC/Tamiflu+30+mg+and+45+mg+Hard+Capsules/>

Information for Prescribers.

Prescribing for those over 1 year of age

Wherever possible, for those over 1 year of age, the appropriate strength of capsules should be prescribed. This will support continuity of supply of the liquid forms of oseltamivir (both Tamiflu 12mg/ml Oral Suspension and Oseltamivir 15mg/ml Oral Solution) for children under 1 year of age.

For those over 1 year of age who cannot swallow capsules, it is preferable at present to prescribe the appropriate Tamiflu capsule strength, which can be opened by the parent or carer at the time of administration and the contents added to a small quantity of a sugary food substance. More details are available in the Patient Information Leaflets (for the 30mg, 45mg and 75mg capsules respectively) which can be viewed at:

<http://www.medicines.org.uk/EMC/medicine/20372/PIL/Tamiflu+30mg+Hard+Capsules/>

<http://www.medicines.org.uk/EMC/history/22858/PIL/Tamiflu+45mg+Hard+Capsules>

<http://www.medicines.org.uk/EMC/history/10467/PIL/Tamiflu+75mg+hard+capsule>

Prescribing for children under 1 year of age

Tamiflu is not licensed for use in children under the age of 1 year for seasonal influenza and Oseltamivir 15mg/ml Oral Solution is an unlicensed product. Prescribing of oseltamivir in any form for this age group should be based upon the judgement of the clinician, after considering the potential benefit of treatment and any potential risk to the child. Prescribers will wish to note that the Royal College of Paediatrics and Child Health has supported the use of oseltamivir in children.

Dosage for oseltamivir should be calculated on the basis of age group then bodyweight. **Please note that Oseltamivir Oral Solution contains a different strength (15 mg/ml) of oseltamivir, as compared to Tamiflu Oral Suspension (12 mg/ml).**

Tables showing treatment and prophylaxis doses for particular age groups for both Tamiflu 12mg/ml Oral Suspension and Oseltamivir 15mg/ml Oral Solution are shown below. An oral dose syringe should be used to measure and administer the liquid.

Recommended **treatment** doses of oseltamivir for children less than 12 months

Age	Recommended dosage for 5 days
0 to 1 month	2mg/kg twice daily
greater than 1 month to 3 months	2.5mg/kg twice daily
greater than 3 months to 12 months	3mg/kg twice daily

Recommended **prophylaxis** doses of oseltamivir for children less than 12 months

Age	Recommended dosage for 10 days
0 to 1 month	2mg/kg once daily
greater than 1 month to 3 months	2.5mg/kg once daily
greater than 3months to 12 months	3mg/kg once daily

Prescribing antivirals – prescription endorsement

Prescribers are reminded as in accordance with the Chief Medical Officer's communication of 21st December 2010 on the prescribing of antivirals, to endorse all prescriptions for influenza treatment with the reference "SLS". Community pharmacies can only dispense antivirals at NHS expense if this endorsement is made by the prescriber. The letter can be found at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_123096

Writing prescriptions in primary care

When it is available, it is preferable to use the licensed Tamiflu 12mg/ml Oral Suspension rather than either unlicensed Oseltamivir 15mg/ml Oral Solution or solution prepared from Tamiflu capsules by a pharmacy. However, prescribers may not know what is available locally.

If a prescriber writes "Tamiflu 12mg/ml Oral Suspension" or 'Oseltamivir 12mg/ml Oral Suspension' on an FP10, and the pharmacy is unable to obtain Tamiflu 12mg/ml Oral Suspension, but is able to obtain Oseltamivir 15mg/ml Oral Solution or provide a prepared solution from the Tamiflu capsules, the pharmacist will need to contact the prescriber to ask for the prescription to be changed to the other formulation.

In order to give pharmacists flexibility to dispense what they have available to them, prescribers could write "oseltamivir liquid" on an FP10 prescription with the relevant dosage and duration. This will allow a pharmacist to dispense either Tamiflu 12mg/ml Oral Suspension, Oseltamivir 15mg/ml Oral Solution or provide a prepared solution from the Tamiflu capsules. However, prescribers will wish to be reminded that this may mean that the patient receives an unlicensed product (in the case of the patient receiving Oseltamivir 15mg/ml Oral Solution) or a product that is being used outside of its licence or 'off licence' (in the case of the patient under 1 year of age receiving Tamiflu 12mg/ml Oral Suspension for seasonal influenza or a pharmacy prepared solution from the Tamiflu capsules).

Ordering Oseltamivir 15mg/ml Oral Solution

Oseltamivir 15mg/ml Oral Solution will be available from the three full line wholesalers, AAH, Alliance, and Phoenix, who are expected to be able to distribute the product, UK wide, in the early part of the week beginning 10th January 2011. Community pharmacists should telephone their wholesaler on their usual service contact number, placing an order in the normal way, using the description "Oseltamivir Oral Solution, 15mg/ml, 20ml", without the need for extra requirements. I would again urge pharmacists not to over order to help ensure availability across the country. Wholesalers may place restrictions on quantities that can be ordered.

PCTs may want to identify specific, selected community pharmacies to hold supplies of Oseltamivir 15mg/ml Oral Solution. As demand returns to normal and the rate of seasonal influenza sufficiently diminishes, PCTs should quickly review policies of this type and return to normal practice. PCTs should also consider liaising with their Local Pharmaceutical Committee on these matters.

If required, hospital pharmacies should order Oseltamivir 15mg/ml Oral Solution from one of the three wholesalers mentioned above.

The manufacturers (Roche) of Tamiflu 12mg/ml Oral Suspension are expecting further supplies to be available in the country during January. However, it is difficult to predict the level of demand for antivirals over the next few weeks. Therefore, Oseltamivir 15mg/ml Oral Solution may continue to be needed. My Department of Health colleagues are in very regular communication with all the relevant parties to assess whether the manufacture of more Oseltamivir 15mg/ml Oral Solution is required.

Supplies of the capsule formulation of Tamiflu (30mg, 45mg, 75mg) are readily available from wholesalers.

Dispensing prescriptions in primary care

Community pharmacists should send the relevant prescriptions to the NHS Business Services Authority (BSA) for payment in the normal way. Prescriptions will need to be endorsed as follows:

Prescription written as	Endorsement needed	What pharmacy will be paid
Tamiflu 12mg/ml Oral Suspension	No endorsement needed	NHS list price of Tamiflu. Application of deduction scale as usual.
Oseltamivir 12mg/ml Oral Suspension	Brand or manufacturer supplied (Tamiflu)	NHS list price of Tamiflu. Application of deduction scale as usual.
Oseltamivir 15mg/ml Oral Solution Sugar Free	Supplier (AAH, Alliance and Phoenix). Where discount not given also endorse 'DNG'. Sort prescription at the front of batch into the red separator	£10 per 20ml pack. Deduction scale will be applied as usual unless discount not given and endorsed 'DNG'. Out of pocket expenses will not be paid.
Oseltamivir 15mg/ml Oral Solution	Sugar free pack dispensed plus supplier (AAH, Alliance and Phoenix). Where discount not given also endorse 'DNG'. Sort prescription at the front of batch into the red separator	£10 per 20ml pack. Deduction scale will be applied as usual unless discount not given and endorsed 'DNG'. Out of pocket expenses will not be paid.
Oseltamivir liquid	Depending on what is supplied i) Brand or manufacturer supplied (Tamiflu) ii) Supplier (AAH, Alliance and Phoenix). Where discount not given also endorse 'DNG'. iii) Extemp formula. All prescriptions should be sorted at the front of batch into the red separator.	 i) NHS list price of Tamiflu. Application of deduction scale as usual. ii) £10 per 20ml pack. Deduction scale will be applied as usual unless discount not given and endorsed 'DNG'. iii) Extemp formula and fees as outlined in the Drug Tariff.

Information for parents about Oseltamivir 15mg/ml Oral Solution

Information for parents/carers of children under 1 year old gives guidance on the Oseltamivir 15mg/ml Oral Solution and how to administer it. It is available at the following web address:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_123213

Printed versions of the leaflet are not being distributed centrally. Where possible, a copy of the leaflet should be downloaded and given with the medicine.

Further information

Should you require further information please email:

Brandedmedicineshortages@dh.gsi.gov.uk

I hope this information is helpful.

Yours sincerely

A handwritten signature in black ink, appearing to read 'K. W. Ridge', with a long horizontal flourish extending to the right.

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