## SUMMARY OF ASSESSMENT AND ITS FINDINGS

### BACKGROUND
Generic versions of the cytotoxic agent, capecitabine, have been licensed.

### DETAILS OF PRODUCT ASSESSED
Various brand and generic capecitabine 150mg, 300mg and 500mg products.

### CONCLUSION FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL

Whilst there are inherent risks associated with using any oral chemotherapy preparations\(^1\), this review was carried out from the point of view identifying any additional risks associated with new generic versions and, in particular, the risks associated with introducing a new strength (300mg) that is only available from two manufacturers, being introduced into the system.

If capecitabine 300mg tablets were to be introduced into practice (one manufacturer has stock already available in the UK, the other is considering this), where previously solely the 150mg and 500mg versions have been used, then the following need to be considered –

1. **Dosing** – whether done manually or by systems such as Chemocare, there are a number of complex steps involved depending on the treatment and patient’s body surface area. All protocols and computer software used in producing the final dose schedule for the patient would need to be amended to include the option of a 300mg tablet and all users of the software/prescribers would need to be aware of the additional strength option.

2. **Patient education** – ensuring that patients recognise the additional strength available and how this might impact on their personal dosage schedule e.g. where previously they had taken 2 x 150mg tablets, now only needing to take 1 x 300mg.

3. **Supply chain** – there are currently two manufacturers who make a 300mg strength, whereas there are at least nine manufacturers who make the 150mg and 500mg strengths. Reliance on one or two manufacturers for the 300mg strength could cause problems if there were supply issues.

4. **External contractors** – where hospitals contract out out-patient prescription dispensing, it would be important to ensure that they comply with any policy decisions about the use of specific strength tablets.

5. **All** of the manufacturers use different colours on packaging to highlight the strengths and a variety of tablet colours. It is important to ensure patient and professional awareness of these differences.

### POTENTIAL NEXT STEPS AND MITIGATION ACTIONS

Consideration should be given to the impact the introduction of a 300mg strength and, if used in practice, how prescribing and dosing systems are amended to allow its safe use. The risks may be judged be sufficiently high that it is not considered safe to make use of this strength.

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This report was produced in February 2014 using photographic images (not physical products) of licensed capecitabine available at the time of assessment. Images were obtained primarily from the Commercial Medicines’ Unit PharmaQC database (http://cmu.dh.gov.uk/medicines/pharmaqc-database/) and from various sources within the NHS.

This report summarises the product assessment undertaken by South West Medicines Information and Training, London and South East Medicines Information, and Regional Drug and Therapeutics Centre, Newcastle.

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