Appendix 1: proposed explanatory note for the dm+d editorial policy to inform users about when the 'Caution – AMP level prescribing may be advised' value would apply to a VMP

Explanatory notes

A. Licensed medicinal products

Under European medicines legislation, a medicinal product can be granted a Marketing Authorisation on the basis of demonstrating equivalence to an existing 'reference medicinal product', these are so called generic medicinal products. A "generic medicinal product" is defined as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product (innovator), and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. This entails establishing though studies on human volunteers, that comparable blood levels of the generic and innovator product are achieved thus demonstrating comparable efficacy and safety (Article 10(1) of Directive 2001/83/EC). Where the "generic medicinal product" is fully interchangeable with the innovator reference product for all indications and patient populations, it can be licensed with a generic name and prescribed under a generic name.

European law also allows for cases where bioequivalence of the medicinal product cannot be demonstrated through comparable blood levels. Therefore additional results of appropriate pre-clinical tests or clinical trials are required. In such cases, MHRA requires that therapeutic equivalence to the innovator product is demonstrated in the intended patient population and for the indications claimed. Licences for these types of products are granted under a specific legal basis (Article 10(3) of Directive 2001/83/EC); they are not considered to be true generics and, in the UK, may be required to have a brand name, unless they are considered to be interchangeable for all indications and patient populations.

An example of the above is inhaled products on the UK market that are not considered wholly interchangeable with the innovator for all the indications and patient populations and which have been licensed with differences in potency, indications, restricted populations, available strengths, or with an administration device which requires different techniques of administration and training. These differences may require the products to have a brand name.

However, The European Medicines legislation also allows for the licensing of a product referring to an innovator product without including all of the indications or patient populations that have been approved for the innovator product, provided that there are no associated safety concerns.

For the reasons above for some virtual medicinal products, prescribers and pharmacists/dispensers need to be able to identify which actual medicinal product is

appropriate for a particular patient for continuity of treatment and these VMPs will be assigned the status ‘Caution – AMP level prescribing may be advised’. This may be established through review of the Summary of Product Characteristics (SmPC) and/or the British National Formulary (BNF).

Where the release characteristics and therapeutic index mean that the clinical effect may differ between brands and so the relevant authorities (Commission on Human Medicines, BNF, National Institute for Health and Care Excellence) recommend brand name prescribing, the VMP prescribing status ‘Caution – AMP level prescribing may be advised’ will also be assigned.

However where only one licensed AMP is/has been available and the VMP has an ‘approved’ generic name, then that product should not be marked with ‘Caution – AMP level prescribing may be advised’.

A biosimilar medicine (Article 10(4) of Directive 2001/83/EC) is a biological product that has been demonstrated as similar in terms of Quality, Safety and Efficacy to a medicine that has already been authorised to be marketed (the biological reference medicine) in the EU. The BNF advises that when prescribing ‘biosimilar medicines’, it is good practice to use the brand name, and therefore the value ‘Caution – AMP level prescribing may be advised’ will be assigned.

B. Medical Devices

This value is used for medical devices that are appliances listed in Part IX of the Drug Tariff where the VMP name is an approved non-proprietary name but there is no official Drug Tariff specification. Medical devices do not have to demonstrate that they meet Drug Tariff specifications unless they are prescribed on an FP10 prescription when Drug Tariff Part 1 Clause 2 requires products listed in Part IX to conform to the specifications shown in Part IX.