ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

Department of Health

SUPPLY OF NON-COMPLIANT NUTRITIONAL PRODUCTS

The function of the Advisory Committee on Borderline Substances (ACBS) is to assure the suitability and quality of products for prescribing in primary care in the NHS. Where there is appropriate evidence, the ACBS will give approval for the product to be used in an identified patient group, as indicated in Part XV (Borderline Substances) of the Drug Tariff. The ACBS have stated that, while recognising the need to work within current legislation, there is also a need to minimise the risk of clinical errors due in particular to inappropriate labelling. To ensure this, the ACBS after consultation with stakeholders, has issued guidance - 'Information Notes / Application for a Nutritional Product to be considered by the ACBS (Paragraph 9.2)' - http://cmu.dh.gov.uk/acbs/

With regard to labelling, when medical foods are imported and put on the market in England, the importer is obliged to notify the Nutrition Science and Delivery, Health and Wellbeing at the Department of Heath, (formerly part of the Food Standards Agency) who examine the product, including the labelling, to see if it complies with nutritional legislation. If not, the Agency will write to the importer, copying in the Trading Standards Officer in the relevant local authority, advising of the changes that need to be made.

There is increasing evidence that a number of products are being dispensed to patients in primary care in response to prescriptions for products recommended by the ACBS, that do not comply with the product descriptions approved by ACBS and / or Food Labelling requirements. While products supplied in or by hospitals will not necessarily need to comply with ACBS product descriptions, they will need to comply with Food labelling requirements.

Non-compliant products may differ from the ACBS recommended products in a number of ways including different formulations, different labels (often an "over-wrap") which may be in another language, different presentations, different product names and incorrect information provision (more detailed information about these practices is presented in the attached table). For these reasons, supply of non-compliant products potentially poses a significant clinical risk to individual patients.

Non-compliant products should therefore not be supplied against a prescription for an ACBS approved product. The Committee request that any examples of non compliant products encountered locally should be appropriately reported. In the first instance this should be to the UK manufacturer concerned.

Advisory Committee on Borderline Substances
c/o Commercial Medicines Unit, Castle View House, East Lane, Runcorn, Cheshire, WA7 2AA

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SOME POTENTIAL CLINICAL RISKS INCURRED BY NON-COMPLIANT NUTRITIONAL PRODUCTS
Note: This is not an exhaustive list

Breach of Approval	Source of Guidance	Potential Risk	Clinical Implication
Different formulation	ACBS will only approve specific formulations after careful scrutiny of the clinical evidence	- Amounts of individual ingredients/nutrients may be different - Product may not be suitable as a sole source of nutrition	- Patient may not be dispensed with what the GP/HCP intends to prescribe - Patient may suffer unintended consequences e.g. GI intolerance, potential allergens
Different labels	ACBS approves specific labels EC/UK Food Labelling requirements are mandatory	- the label is unlikely to include specific UK requirements e.g. mmol - mandatory information is missing e.g. potential allergens, ingredient listing	- GP / HCP may be confused and inadvertently prescribe an unsuitable product - patient may be exposed to avoidable complications e.g. allergic reactions
"Overwraps / over-labelling"	EC/UK Food Labelling requirements state that labels must be indelible and, therefore, unable to be removed The ACBS will only approve specific formulations for inclusion on the Drug Tariff	- the label can wear away / come off e.g. if product is stored in the fridge - additional labelling by the wholesaler / retail pharmacist can further obscure key information - the label could obscure the foil tab on a tetrapak - the product may be completely different from that which it purports to be	- the patient / HCP would not have access to key information e.g. expiry date, warnings etc because information on the original pack would be in a foreign language and use unfamiliar terminology, and measurements - the product would be difficult to use especially if the patient has limited manual dexterity - the patient would receive an illegal product and is unlikely to receive the nutrition that has been prescribed

Different product names	ACBS will only approve specific products after careful scrutiny of the clinical evidence	- the patient receives a product which is not ACBS approved and is not on the Drug Tariff - the product name may be slightly different due to different marketing within Europe	- the patient could be exposed to avoidable complications caused by an inappropriate product e.g. excessive intake of a particular nutrient - The GP/HCP/carer could be confused about what to give the patient
Different presentations	ACBS only approves specific presentations	- the patient could receive a different volume from that which was prescribed - it may not be possible to administer the product as prescribed due to the need for additional equipment e.g. bottle vs. tetrapak for bolus feeding	- there could be significant alterations to the nutritional and/or fluid intake with consequent clinical sequelae - there would be an increased likelihood of microbiological contamination. Patients would be confused and may not use the product at all.

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