## Robust evidence is vital to bolster trust of the Drug Tariff

## Pauline Beldon, Chair, TVNA

Public confidence in both clinicians and the NHS is paramount and the relationship between all three is often delicately balanced. Patients deserve to believe that clinicians have soundly and thoroughly evaluated medical products using proven methods to ensure that they are safe and efficacious for use.

However, perhaps some evaluation processes may not be as robust as one would like to believe. I have recently had cause to investigate the criteria for inclusion of products in Part IX of the Drug Tariff by the Prescription Pricing Division (PPD) which has four product sections, including 'Dressings, bandages and certain other appliances'. There appear to be three main criteria for the inclusion of products:

- ▶ The products are safe and good quality
- ➤ They are appropriate for GP and, if relevant, nurse prescribing
- ▶ They are cost-effective (DOH, 2006).

Manufacturers of new products for which there are no listed comparators are asked to provide 'satisfactory evidence of improved outcomes/ savings/patient benefits commensurate with the requested price' but the degree of clinical evidence required is unspecified and appears to be flexible, depending upon the concerns of the NHS Business Services Authority.

Section 25 of the application states, 'such evidence may need to include clinical data to demonstrate that the product delivers any clinical benefits'. It is sincerely hoped that this does not imply that clinical evidence is not the primary consideration for accepting or rejecting a product for inclusion on the Drug Tariff. Surely clinical evidence must be sufficiently robust to provide the initial evidence, closely followed by the cost-effectiveness of a product.

Clinicians are aware of the levels of evidence upon which they should base their practice and randomised controlled trials are considered the gold standard of evidence-based care. There is justifable concern that products are included in the Drug Tariff part IX without the support of published RCT data.

All clinicians are keenly aware that any wound care product must satisfy criteria for inclusion within a trust's formulary and it is to be hoped that the same standards apply to the Prescription Pricing Division.

Clinicians are aware of the levels of evidence upon which they should base their practice and randomised controlled trials are considered the gold standard of evidence-based care. There is justifiable concern that products are included in the Drug Tariff part IX without the support of published RCT data.

I am dismayed to find out that products may have found their way

onto the Drug Tariff without having robust clinical evidence behind them. When patients learn about new products, they often want to try them. If a clinician is reluctant to use or prescribe a product that is listed on the Drug Tariff on the grounds that there is insubstantial proof of clinical efficacy then this will undermine the integrity of the Drug Tariff itself as well as bringing discord to the clinician/ patient relationship.

Surely its time to demand a more robust process from the PPD to prevent the inclusion of products that do not have sufficient clinical evidence behind them, and which appear to the clinician to have been included on the Drug Tariff based on optimistic calculations of money saving extrapolated from studies that use small sample sizes of subjects.

I am sure that all clinicians would agree that transparency in our dealings with professional associations, industry and the Department of Health is essential. Surely it is not too much to expect that the PPD examines its current criteria for Drug Tariff inclusion more closely and considers greater consultation with clinicians. Wuk

The Department of Health declined to comment in response to this editorial.

Department of Health (2006) An Introduction to Part IX of the Drug Tariff. www.ppa.org. uk/ppa/Drug\_Tariff\_Part\_IX\_Guidance\_ 052006.pdf Last accessed 10th August 2006. Department of Health, London

For more information on policy or the TVNA in general, please visit www.tvna.org.