Praise where it’s due

The GDC’s new initiative is set to help stamp out the problem of unregulated, imported dental appliances. Richard Daniels explains

Public bodies, especially those involved in the administration of healthcare, are more often targets for criticism than congratulations, and the General Dental Council is no exception. Here at the Dental Laboratories Association (DLA), we have certainly had our own disagreements with that August institution, but on this occasion we happily applaud, and welcome, its new initiative.

The problem of unregulated, imported dental appliances has been with us for some time, and in the US, a number of patients have suffered unfortunate consequences from their use, which have attracted the attention of the mainstream media. Following intensive lobbying by the DLA and pressure from other professional dental bodies, the GDC has at last responded by opening a consultation process to consider standards on commissioning and manufacturing of dental appliances.

The consultation seeks to identify the responsibilities of all registered practitioners, or their agents, who commission, source or receive custom-made dental appliances, whether manufactured within Europe or in other regions beyond the jurisdiction of the EU’s Medical Devices Directive.

Investigating quality

Historically, the UK agencies responsible for the regulation of imported, customised or bespoke dental appliances have relied on the individual importers exercising their own judgement and standards of quality control over the suitability of the appliances. In effect, the end-user, the dentist, has been responsible for enforcing the EU Directive and little attention has been paid by the authorities as to whether the individuals concerned actually carried out the relevant checks, had the knowledge or experience to do so, or were even aware of this responsibility. In any event, even those who conscientiously fulfilled their obligations could not be expected to investigate the quality of the actual materials, which comprised the appliance.

For example, how many dentists have actually registered with the MHRA as on-site manufacturers of their own custom-made appliances, or as the recipients of custom-made appliances directly imported from overseas dental laboratories? While this information is currently unavailable, it’s a fair bet the list is far from inclusive.

Action is required

However, action by the GDC to spread awareness across the dental profession of this responsibility is not the complete answer. To ensure the patients benefit from a uniform and improving standard of care, complementary action is required from the Medicines Healthcare and Regulatory Authority and the Department of Health. A simple inspection programme, which should include dental laboratories both within and outside the UK as well as dispensing practices, will not in itself ascertain the source or quality of either the materials or the manufacturing processes involved in producing the appliances. To achieve transparency a verifiable audit trail needs to be established.

The dental profession’s responsibility, as well as that of the industry’s governing authorities, to the individual patient is absolute, and this dictum is as relevant to the lab technician as it is to the clinical practitioner. The universal application of the Medical Devices Directive, ensuring that all manufacturers conform to the regulations, will not only establish a fully transparent system, it will relieve the pressure on the hard pressed individual practitioners registered with the GDC.

For further information, please visit the DLA website at www.dla.org.uk, or call 0115 925 4888.