

11 March 2009

## Guidance on Commissioning and Manufacturing Dental Appliances

The GDC has issued new guidance for all GDC registrants involved in prescribing, manufacturing and fitting dental appliances. This follows a 12 week consultation on the issue which closed in August 2008.

All registrants have a role to play in protecting patients from harm and in providing a safe and effective standard of care. The purpose of this guidance is to ensure that dentists, dental technicians and clinical dental technicians (CDTs) understand and are responsible for the decisions they make when commissioning or manufacturing dental appliances.

The guidance, which complements the GDC's Principles of Dental Team Working, is in three parts:

- GDC expectations with regards to the European Commission's Medical Devices Directive,
- guidance for those who arrange for dental appliances to be made in the UK, and
- a third section for registrants who subcontract or prescribe dental appliances to be made outside the UK – or use a dental laboratory or agent which sources dental appliances outside the UK.

The full guidance can be read on our website [www.gdc-uk.org](http://www.gdc-uk.org)

### Ends

For media enquiries, please contact Elizabeth Curtis on 0207 009 2728 or [ecurtis@gdc-uk.org](mailto:ecurtis@gdc-uk.org)

### Notes to editors:

1: The full guidance is as follows:

### STANDARDS ON COMMISSIONING AND MANUFACTURING DENTAL APPLIANCES

*Issued by the General Dental Council under Sections 26B and 36M of the Dentists Act 1984.*

All GDC registrants involved in prescribing, manufacturing and fitting dental appliances have a role to play in protecting patients from harm and in providing a safe and effective standard of care. All GDC registrants must comply with the GDC Standards guidance. With regards to the commissioning and manufacturing of dental appliances, Principles 4.7 to 4.9 of the Principles of Dental Team Working have particular relevance. These overriding principles are complemented by the standards of practice below.

#### ***Registrants who make dental appliances***

If you make a dental appliance, you must understand and comply with your legal responsibilities as "manufacturer" under the Medical Devices Directive. These are legal requirements rather than GDC rules and the GDC expects you to fulfil these responsibilities and will hold you accountable for doing so.

#### ***Registrants who arrange for dental appliances to be made***

---

If you arrange for dental appliances to be made in the UK, you are professionally responsible for issuing the prescription to and receiving the appliance from a UK-registered dental technician. If you prescribe a dental appliance to be made by a person in the UK who is not a registered dental technician you are liable to face a GDC fitness to practise inquiry. Equally, you are liable to face a GDC fitness to practise inquiry if you receive a dental appliance made in the UK by a person who is not a registered dental technician.

***Registrants who sub-contract or prescribe dental appliances to be made outside the UK***

When making the decision to either sub-contract the manufacture of a dental appliance, or use a dental laboratory or agent which sources dental appliances, outside the UK, your choice not to use a UK-registered dental technician puts a particular responsibility on you.

You will be held professionally accountable for the safety and quality of the appliance. This is because you have chosen not to sub-contract or issue the prescription to a registered dental technician who would otherwise be accountable him or herself. You take on the dental technician's responsibilities for the appliance and the GDC will hold you accountable for your decision.

Further we expect you to have taken appropriate steps to discharge the extra responsibilities you choose to accept when you make this decision.

<Ends>