DENTAL LABORATORY PRESCRIPTIONS

The following information is an overview of what should be on dental laboratory prescription including suggestions on how to meet the requirements.

Information supplied by the manufacturer – labelling and statement requirements

Labelling - The minimum requirements for a dental lab are: the name or trade name and address of the lab; the details strictly necessary for the user to identify the device; the words ‘custom-made device’; any special storage and/or handling conditions and any warnings and/or precautions to take.

Laboratory prescriptions must have the lab’s name and address on it. There should be a field to record the dentist’s name and where applicable, the clinic name and address; a field to record the patient’s name; a field to record the design requirements of the appliance and the words ‘custom-made device’. It is up to the lab to decide if there should be any special storage and/or handling conditions and any warnings and/or precautions to take.

Statement - The laboratory statement must contain the following information for custom-made devices:

- Name & address of the manufacturer
- Description of the device and any specific characteristics as indicated in the prescription
- The name of the prescriber and if applicable the address of the clinic
- A statement that the device is a custom-made dental appliance and intended for exclusive use by a particular patient, together with the name of the patient
- A statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds;
Therefore an example of a suitable statement including all of the above requirements could be “This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations”.

Note how Annex I is spelt; it should not be referred to as Annexe 1.

It is usually a good idea to add an additional statement to cover repairs and additions etc. for example: “This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient’s use.”

If you use computer software to generate your label and conformity statement, e.g. as part of your invoicing system, then the above MDD requirements still apply and you should ensure that the label and conformity statement satisfy these requirements.

**Patient Statement**

It is a requirement that the manufacturer must supply a statement with the finished appliances so it can be made available to the patient by the healthcare professional who writes the prescription.

There are no strict guidelines on how the patient statement should be presented, however, it is compulsory for the following details to be present:

- Name & Address of Laboratory
- Patient name
- Description of device
- Names of prescriber and if applicable address of clinic
- The Statement of Conformity

The laboratory should decide the most appropriate method for the patient statement which can include for example - a separate patient statement or a triplicate of the lab ticket.
A reminder about your Competent Authority registration number, i.e. the number allocated to you when you registered with the then, Medical Devices Agency or the now, Medicines and Healthcare Products Regulatory Agency. There is no specific requirement for this number to be on your lab ticket but it is good practice to do so. Many dentists are now asking labs for their CA registration number – as part of the dentist’s quality system – and it helps if the number is clearly on display. The display of this reference should state for example - UK CA Registration Number or MHRA Registration Number or a suitable abbreviation e.g. CA Reg. No., MHRA Reg. No.

So does your lab ticket adequately address the MDD labelling and conformity statement requirements? If not, get them corrected as soon as possible as they are legal requirements. The DLA will always review lab ticket artwork and will make suggestions for correcting any errors or omissions in the artwork.