National Institute for Health and Clinical Excellence

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Additional Submission Information

[NICE324/EP094]

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the original manufacturer submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the manufacturer
b) need to check "real world" assumptions with NICE's Expert Advisers, or
c) need to ask the manufacturer for additional information or data not included in the original submission

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Summary, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request to Manufacturer or Expert Adviser *Please indicate whether Manufacturer or Expert Adviser was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Request to Maria Silabon Business Development Manager, H&R Healthcare Ltd (UK distributor): 1. Requested copies of the publications submitted as clinical evidence in the manufacturer's submission of MIST therapy as we were unable to obtain all the relevant published references and much of the data was held on file by Celleration. 2. Requested clarifications on some of the references cited and copies of the publications in the Cost Analysis (section 6) of the manufacturer's submission. 3. Requested access to posters presented at Wounds UK conference	The requested publications were sent as attachments in a series of emails from 21/10/2010.	No further action required

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	outlining the UK experience of using the MIST Therapy system.		
1.4	**Request to Maria Silabon** Business Development Manager, H&R Healthcare Ltd (UK distributor of MIST Therapy System) Requested clarification on the validity of the EC certificate and it's expiry in 2012.	**See Appendix 1** *Manufacturer's response in italics*	No further action required.
	Request to Ray Norris Tissue Viability Nurse South West Essex Community Services Information was sought regarding the use of the technology in the UK.	This expert was amongst the first group of users of the MIST Therapy system and was able to provide valuable insight into its use, effectiveness and training requirements**.**	No further action required.
	Request to Dr. A Ibrahim Amin Consultant General Surgeon, Queen	This expert, a surgeon, gave valuable insight into wound care	No further action required

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	Margaret Hospital, Dunfermline Sought advice on the standard care provided to patients in the UK with "hard to heal" wounds as the majority of the studies where noncontact ultrasound therapy was used were conducted in the USA and this may have had an impact on the outcomes measured.	management and the patient's experience of pain and living with the conditions, which may exceed a year in some instances. Clarification was provided by this expert regarding how the standard of care compares with that offered in the UK to that in the USA, with the main difference being how care is accessed rather than the treatment itself.	

Appendix 1

16. Telephone conversation with Maria Silabon, Business Development Manager H&R Healthcare Ltd requesting clarification on the validity of the EC certificate and it's apparent expiry on April 24, 2012. *Response from Jack Slovick, USA - The actual CE mark on a label, for example, would not have an expiration date applied to a box label or an "instructions for use"; however, the actual certificate ALWAYS contains an expiration date. There is no notified body I know of (BSI, Intertek, TuV Product Service, etc.) that does not put an expiration date on their certificates.*