MANUFACTURERS & TECHNICAL GROUP

THURSDAY 29th JUNE 2017 AT 2.00 TO 4.00 PM

Tylney Hall, Rotherwick, Hook, Hampshire, RG27 9AZ

MINUTES

Chairman:	Ian Pope	Dürr Dental UK Ltd
Present:	Patrick Allen	Henry Schein
	Mark Beckwith	NSK
	Gary Bond	Dental Directory
	Alex Breitenbach	NSK
	Jayne Cahill	SDI
	Mike Cann	Septodont
	Daniel Davis	J&S Davis
	Peter Dyer	British Dental Association
	Joe Earl	Dental Sky
	Michael Farrow	SDI
	Andy Golub	Dental Life Sciences
	Vikki Goodall	Henry Schein
	Peter Gowers	Panadent Ltd
	Dean Hallows	A-dec Dental Ltd
	Jonathan Hampton	Planmeca UK
	Sachie Kajimoto	Advanced Healthcare Ltd
	Greg Kalbarczyk	Dental Life Sciences
	Amin Khan	OsteoCare Dental Implants
	Chris Knight	SPS/Nesor
	Gavin Knight	W&H
	Mimi Lau	Dental Directory
	Rene Madsen	Stoddard Mfg
	David Mason	J&S Davis
	Alistair Mayoh	Kemdent
	Richard Muller	Prima Dental Group
	Simon Nicholson	NSK
	Karl O'Higgins	Planmeca UK
	Kym Penfold	Dental Sky
	Ravi Prabaharan	Advanced Healthcare Ltd
	Andy Prior	Dental Sky
	Mark Pryer	Advanced Healthcare Ltd
	Avtar Photay	PSP Dental Co
	Andrew Rose	Stoddard Mfg
	Brian Schottlander	Schottlander
	Kate Scheer	W&H

	Michael Stoddard	Stoddard Mfg
	Robert Teague	CALCIVIS
	Sonia Tracey	W&H
	Simon Tucker	Dental Sky
	Carl Walker	W&H
	Adam Welbourn	Dental Sky
In attendance:	Edmund Proffitt	BDIA
	Adam Stanley	BDIA
	Terry Prodger	BDIA Technical Consultant
	Martin Penver	Lloyd's Register Quality Assurance Ltd
	Phil Brown	ABHI

1291. **APOLOGIES**
No apologies were received.

1292. **MINUTES (Com 525/16)**
The minutes 1193 - 1290 of the meeting held on 16 June 2016 were approved.

1195. **MATTERS ARISING**
There were no matters arising not covered elsewhere on the agenda.

1196. **NOTIFIED BODY UPDATE AND Q & A SESSION**
Martin Penver of Lloyd's Register Quality Assurance Ltd (LRQA) delivered an update on Notified Body (NB) activity and changes related to the new Medical Device Regulations (MDR) and the status Virtual Manufacture (VM) from an NB perspective.

Mr Penver's presentation highlighted that a number of areas within the MDR would be subject to interpretation, and discussed a particular example of reusable surgical instruments and NB requirements. There was also an unanswered question, he explained, relating to situations where an OEM loses its CE marking and how this would differ, from an NB perspective, to a critical supplier.

On VM, he also noted that it was not made clear how the MDR's requirement for NBs to sample and test devices would apply during audits. Addressing the sharing and redaction of technical documentation, he suggested that, where an OEM was not willing share a specific formulation with even the NB, VMs should complete their own chemical and biocompatibility testing with an independent test house.

He reiterated that, for some VM companies, becoming a distributor may offer significant advantages and represent less of a regulatory burden, with no NB costs and no unannounced audits.

1197. **MEDICAL DEVICES REGULATIONS (MDR)**
Phil Brown (ABHI) reported that the MDR had been published in the Official Journal of the European Union in May, which marked the start of the three year transition period. However, he noted that after the time required for NB redesignation this would leave roughly a one year period. He further noted that, even when placing products on the market under the old regulation during this time, certain elements of the MDR would still apply. On the impact of Brexit, he reported that the MHRA, whilst yet to

publish an official statement, had made it clear that there was no appetite to apply anything other than MDR-based regulation in the UK. He raised the question of what would happen after 2019, when the MDR is frozen into UK law, in the event of any amendments being made by the EU, which would not automatically apply to the UK legislation, which could lead to divergent sets of regulation.

The Technical Consultant reported that the status of nanomaterials under the MDR was still not fully known, but could involve the upclassification of some devices previously under Class I, such as impression materials. On implant cards, he noted that the final text of the MDR omitted the previously specified exemption for dental implants.

1198. **MHRA GUIDELINES ON VIRTUAL MANUFACTURING**

It was noted that this agenda item had been addressed by Martin Penver's presentation. The Chief Executive reminded members that a joint ABHI/BDIA seminar on Virtual Manufacturing, with participation from industry, the MHRA and Notified Bodies, would be taking place in London on 19th July 2017 and would address the subject in greater detail.

1199. **BDIA CSIDI ACTIVITY**

The Chief Executive reported on the Association's CSIDI activity. He explained that the BDIA had partnered with the MHRA for the campaign, and believed it to be the only such partnership between the regulator and a trade association. Dental products had been identified by the MHRA as one of its top areas of priority for tackling counterfeits, he noted. The BDIA would continue its strategy of press advertising supported by editorial coverage in the dental press.

1200. **MHRA**

The Chief Executive reported that the Association had been in discussion with the MHRA regarding its plans for raising £9.1 million from industry. Whilst the BDIA maintained that full central Government funding of the MHRA was preferable, it had been stressing the need for a proportionate funding model should this not be the case. The MHRA was exploring a system of bands or tiers based on turnover in order to determine charges, and the Association had received a positive response through its participation in the Medical Devices Industry Liaison Group (MDILG) in calling for a funding model that would not place a disproportionate financial burden on members. These discussions were ongoing and members would be advised of any developments.

Martin Penver reported that concerns had been raised with the MHRA regarding the requirement for GMDN codes to be used in registrations of Class I devices. He explained that there was a cost associated with registering with GMDN as well as a subsequent charge for each individual product code. From an NB perspective, he added, there was no way of checking whether a particular code was valid. Phil Brown explained that the issue had been raised at both UK and EU levels, and that the European Commission was investigating further with GMDN.

1201. **NHS ePROCUREMENT STRATEGY & GS1 BARCODING**

The Policy and Public Affairs Manager reported that the NHS eProcurement programme had been progressing under the "Scan4Safety" title and that the previously circulated implementation timetable was still in effect. The Association's most recent update from the Department of Health had advised that, contrary to their previous statements, the Department would not be aligning their implementation timetable with that of UDI under

the MDR now that the legislation had been published. Members were advised to continue to progress with the implementation of GS1 barcoding/PEPPOL as per the existing timelines that had already been circulated.

1202. **DENTAL AMALGAM**

The Technical Consultant reported that the Minamata Convention on Mercury had been ratified by the European Union, with a new regulation on Mercury adopted on 25 April. The new regulation included requirements relating specifically to dental amalgam, principally that all dental practices must have an amalgam separator installed and that only encapsulated amalgam may be used. He explained that dental amalgam was prohibited for use on children and pregnant or breastfeeding women, with some provision for exceptions arising from clinical necessity.

The Chairman added that, although it is already a requirement for amalgam separators to be in place in dental practices in the UK, they were often not installed or did not meet requirements, however.

1203. **STANDARDS (BS/ISO/EN)**

The Technical Consultant reported that progression of EU harmonised standards had encountered an obstacle due to a question mark over the legal status of standards. He explained that standards were not documents produced by governments, but were published and sold to users. However, information required to comply with the law needed to be available free of charge.

The Technical Consultant reiterated previous requests for additional involvement from members on standards development, noting that UK representation continued to be lacking in this area.

1204. **OTHER DIRECTIVES/REGULATIONS**

The Technical Consultant reported that the EU had passed a new regulation in May 2017 to stop conflict minerals and metals being exported to the EU. He noted that this could potentially have an impact on materials used in the dental industry, such as tungsten and gold.

On REACH, it was reported that new substances continued to be added to the register and that this had started to cause some issues for disinfectants, leading to products being withdrawn. These were products sometimes involved in the validation and cleaning processes for medical devices, he explained.

1205. **OTHER ORGANISATIONS**

The Chief Executive reported that the BDIA had recently joined MDILG, which gathered together senior figures from the MHRA and key industry stakeholders, and attended a meeting on 12 June. The group allowed the BDIA to work with the MHRA on a range of key issues such as regulation, Brexit and the funding of the regulator at a high level.

Continuing, he reported that the BDIA was working closely with ADDE and FIDE, and that there had been useful cooperation and information sharing on the MDR. In particular, he noted a recent ADDE meeting with a number of the authors of the MDR in Brussels.

Turning to the constitutional arrangements of ADDE he noted that, following its Annual General Meeting, representatives sitting on the ADDE board would all be required to be representatives of national associations in future.

1206. **EXPORT GROUP**

The Policy and Public Affairs Manager reported that the Association's UK Pavilions at overseas trade shows continued to perform well, with strong growth at IDS Cologne and AEEDC Dubai in particular. He explained that there had been considerable uncertainty surrounding the future provision of Tradeshow Access Programme (TAP) funding for exporters, but that the Association had been successful in securing the funding for events over the past year and into 2018. The Association continued to work closely with the Department for International Trade and was feeding into an ongoing review of the TAP system, he added.

1207. **ANY OTHER BUSINESS**

The Technical Consultant raised an item regarding cobalt-chrome and dental devices under REACH. He explained that a requirement to add cobalt-chrome to its list of carcinogens would necessitate this being reflected on the labels of dental devices containing more than 0.1% of such substances. This would include stainless steel instruments, for example.

1208. **DATE OF NEXT MEETING**

To be confirmed.

Circulation: All BDIA Members