Sundhedsstyrelsen
Danish Health and Medicines Authority

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MARKET SURVEILLANCE PROJECT 2014

Inspection of dental laboratories and analyses of fixed dental prosthetics

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INTRODUCTION

During the past five years, the Danish Health and Medicines Authority (DHMA) has increased its focus on the dental sector, and the inspection of dental laboratories is a priority area.

Being a regulatory authority, DHMA performs regular inspections of Danish manufacturers, importers and distributors of medical devices to verify how and whether they comply with the legal requirements. The purpose of the proactive market surveillance is to identify areas of non-compliance with the legal requirements.

The results of the inspections are important to identify the needs for additional legal guidance and information on how to comply with the legal requirements in practice. Against this background, we can launch individual follow-up and major initiatives, such as targeted information campaigns and dialogues with relevant players.

As a basis for the market surveillance project 2014, we selected a number of dental laboratories for inspection.

In connection with the inspections, we took samples of fixed dental prosthetics to analyse the metallic material as part of the market surveillance project. The purpose of the analyses was to examine whether the metallic composition of the products was in accordance with the reported composition.

The inspections and analyses were carried out from August 2014 to February 2015.

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BACKGROUND FOR THE MARKET SURVEILLANCE PROJECT

The purpose of the market surveillance project 2014 was to examine whether dental laboratories comply with the legal requirements and whether there is consistency between the metallic material and the reported composition of fixed dental prosthetics (custom-made medical devices) randomly selected at the manufacturers.

In addition, the market surveillance project 2014 is also a follow-up on the inspection of dental laboratories in 2011, which can serve as a basis for comparison to review the status of the area.

Generally, the market surveillance project was carried out as part of our general market surveillance of medical devices and the member states' obligations to organise and carry out market surveillance, see article 16 of Regulation (EC) no. 765/2008[1]. The project forms part of DHMA's market surveillance programme.

The inspections of the dental laboratories were carried out in accordance with section 15(1) and (2) of the Danish executive order no. 1263 of 15 December 2008 on medical devices, which gives DHMA the legal authority to control that a manufacturer of medical devices or his representative complies with the rules of the executive order on medical devices, including that the devices meet the essential requirements of the executive order, see section 3(1) and annex I of the executive order, and which gives DHMA's representatives access to all relevant production, business and storage premises used by the manufacturer or his representative.

[1] Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

In connection with such inspections, we can also require the manufacturers to provide samples of the devices and all documents and information necessary for the control activities, see section 15(2) of the executive order.

We notified the selected dental laboratories of the inspections and the sampling for control.

We conducted a total of 16 inspections of dental laboratories. As part of the market surveillance project, fixed dental prosthetics were sampled for non-destructive analysis in connection with the inspections.

2.1 DENTAL LABORATORIES – MANUFACTURERS OF CUSTOM-MADE MEDICAL DEVICES

Dental laboratories and analyses of fixed dental prosthetics were the focus areas of our market surveillance project 2014.

Dental laboratories mainly comprise manufacturers of custom-made medical devices. They produce custom-made medical devices, including various fixed and removable prostheses. Examples of removable appliances are various prostheses, such as dentures. Fixed dental prosthetics include full ceramic or gold/metal crowns and bridges for both natural teeth and implant-supported prostheses.

Custom-made medical devices, fixed and removable prosthetics, are a special category of medical devices, specifically manufactured for one particular patient. Based on the individual patient's preparation, impression and bite registration performed by a dentist, the dentist makes a written prescription. The dentist sends the prescription to a dental laboratory that produces the specified product. Manufacturers of custom-made medical devices must issue a statement with information about the individual product and the manufacturer's confirmation that the product conforms with the essential legal requirements as to quality, safety and performance, see section 10(1) and annex VIII, section 2.1 of the executive order.

CE marking is not required for custom-made medical devices. Fixed dental prosthetics belong to risk class IIa, see rule 8 in annex IX of the

executive order on medical devices. It appears from section 5(1) of the executive order that classification of medical devices is made in accordance with annex IX.

We inspected 16 dental laboratories, 15 of which were manufacturers of custom-made medical devices. One of the dental laboratories did not manufacture fixed dental prosthetics, but custom-made removable prostheses. Consequently, we did not analyse products from this manufacturer as part of the market surveillance project. Thus, we analysed samples from a total of 14 dental laboratories.

2.2
ANALYTICAL METHOD FOR EXAMINING THE METALLIC MATERIAL OF FIXED DENTAL PROSTHETICS

In connection with the market surveillance project, we took samples of fixed dental prosthetics for examination. We asked FORCE Technology to analyse the fixed prosthetics.

FORCE Technology made non-destructive XRF analyses of the ready-made products to verify the reported composition of the metallic material. FORCE Technology is accredited by DANAK to perform the analyses.

XRF is the abbreviation for X-Ray Fluorescence, an analytical method used to examine the element composition of materials. With this method, the material to be examined is exposed to X-ray radiation, and the resulting fluorescent X-rays can be used to make the measurement. This method makes it possible to examine the metallic material of fixed dental prosthetics.

The measurement accuracy is estimated to be between 0.03% and 0.1%. The analysis is a screening examination.

After the analysis, we returned the products to the dental laboratories together with a copy of the analysis results.

2.3
REPORTED COMPOSITION OF FIXED DENTAL PROSTHETICS

As stated in executive order no. 1263 of 15 December 2008 on medical devices, manufacturers should pay special attention to the choice of

materials and compatibility between the materials used and the biological tissues, which the materials are to be used for, while taking into account the intended purpose of the device, see annex I, section 7.1. This can be documented in the reported composition or standards and the evaluation of the material's properties and safety.

Medical devices must be made from materials that are appropriate for the purpose, and the risk of any adverse reaction and any unwanted effect must be acceptable in relation to the performance of the device, see annex I, section 6. The manufacturer must remove or to the extent possible minimise any risks associated with the device and must inform the users of any remaining risks, see annex I, section 2. The documentation of compliance with the essential requirements as to safety and performance must include a clinical evaluation, see annex I, section 6a of the executive order.

Harmonised standards describe in detail how to comply with the overall legal requirements. By following the standards, the manufacturers comply with the essential requirements of the executive order on medical devices, which implements the EU Directive on medical devices[2] into Danish legislation, in the areas that are covered by the standards. It appears from section 3(1) of the executive order that the essential requirements described in annex I are considered to be complied with if the medical devices are in accordance with the relevant national standards for the completion of the harmonised standards, if references have been published in the Official Journal of the European Union.

A number of harmonised standards for medical devices and specifically within dentistry are available, for example DS/EN 1641:2009 (Dentistry - Medical devices for dentistry - Materials) and DS/EN 1642:2011 (Dentistry - Medical devices for dentistry - Dental implants). DS/EN 1641:2009 refers to e.g. DS/EN ISO 22674:2007 (Dentistry - Metallic materials for fixed and removable restorations and appliances), as a way to meet the requirements for materials. DS/EN ISO 22674:2007 is not on the list of references for harmonised standards for medical devices.

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Directive 2007/47/EC of 5 September 2007.

The harmonised standard for dental materials DS/EN ISO 22674:2007 is relevant, because it lays down specific requirements as to chemical composition and indication of the material content, see the project's analysis of metals. In this connection, we recommend manufacturers to follow the instructions in DS/EN ISO 22674:2007 about how to report the metallic materials of fixed dental prosthetics.

According to DS/EN ISO 22674:2007, chapter 5, manufacturers must declare all elements present in excess of 1.0% to an accuracy of 0.1% of the mass fraction.

For silver-based and noble-metal alloys, the constituents must not deviate by more than 0.5% from the value declared by the manufacturer.

As regards base-metal alloys (without silver and gold), all elements present in excess of 20% of the mass fraction must not deviate by more than 2% from the manufacturer's reported value. Elements present in excess of 1%, but not in excess of 20%, must not deviate by more than 1.0% from the manufacturer's reported value.

In addition, the standard contains requirements as to hazardous elements; alloys must not contain more than 0.02% cadmium and beryllium.

Nickel is also listed under hazardous elements in the standard. If the alloy contains more than 0.1% nickel, the content must be given to an accuracy of 0.1% in the reported specification. Nickel may lead to allergic reactions. As mentioned, manufacturers of medical devices must remove or to the extent possible minimise any risks associated with the device and inform the users of any remaining risks that may be associated with use of the product, see annex I, section 2 of the executive order. The risks could for example be caused by the use of materials that may be allergenic.

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ANALYSES OF FIXED DENTAL PROSTHETICS

During the inspections, we took samples of fixed prosthetics made from both noble metal and base metal from 14 dental laboratories. Not all of the inspected dental laboratories manufactured noble-metal crowns or had any crowns available on the inspection day. Moreover, some of the samples were metal-ceramic crowns containing metal/gold in the inner core with a ceramic cap on the outside. The dental laboratories enclosed the reported compositions for the prosthetic restorations, and we compared them with the analysis results.

Overall, we do not find that the results of the project cause any significant public health concern. The public health risks associated with the findings of this project are assessed to be remote.

Based on the analyses, we estimate that there is potential for improvement of several of the manufacturers' reported values, see the harmonised standard DS/EN ISO 22674:2007. A comparison of the reported values with the results of FORCE Technology's analyses shows examples of percentage deviations in the quantities declared for the metals, which do not fulfil the instructions in the standard.

For example, deviations were found in the reported value of a base-metal dental crown with a CoCr alloy. The cobalt content was declared to be 60.5% (m/m), and the analysis showed that the content amounted to 64.8% (m/m). The chromium content was declared to be 28% (m/m), but the analysis showed 21.3% (m/m). The percentage deviations from the manufacturers' declarations are 23.9% for chromium, the content of which is lower than declared, and 6.63% for cobalt, the content of which is higher in the dental crown alloy than described, see the analysis. In future, the dental laboratory will make random controls and has informed its supplier about the matter.

The analyses also showed that in samples from a specific dental laboratory not all metals were declared, even though they were present in excess of 1% of the total mass fraction of the fixed dental prosthetics. Nickel was found in one of the samples. In the fixed dental prosthetics, the manufacturer had not reported any nickel content, but the analysis showed a content of 0.29% (m/m). We have followed up on this matter and informed the dental laboratory about the issue and have also had a dialogue with the laboratory's supplier, whose production is located outside the EU. The dental laboratory has changed suppliers.

The most significant deviation among the samples of fixed dental prosthetics in the market surveillance project was found in a dental crown reported to contain noble metal. The manufacturer declared a gold content of 40% (m/m), and the analysis showed 0.6% (m/m), which is a percentage deviation of 98.5% for gold. The silver content of this dental crown was analysed to be 2.1% (m/m), but the manufacturer had declared 4.95% (m/m), and the percentage deviation amounted to 57.6% for silver. We have had a dialogue with the dental laboratory and its supplier about the matter. It was due to human error and a mix-up with another known alloy from the product range. Several samples from the same supplier were analysed and they did not meet the requirements in the standard either, due to lack of declaration of metals. For this reason, the dental laboratory has changed suppliers. In addition, this matter has led to increased focus on dental laboratories' control with their suppliers and increased traceability of materials.

Another dental crown sampled at the inspection also showed a lower content of noble metal than declared, but the deviation was much smaller than the above-mentioned deviation. The content in this sample was analysed to be 67.2% (m/m) for gold, but the manufacturer had declared 68.6% (m/m). Moreover, the silver content was analysed to be 11.5% (m/m) against the declared 11.85% (m/m). The dental crown's content of palladium was also higher than the declared value. Based on the analysis results, the fixed dental prosthetics deviated by 2% for gold and 3% for silver in relation to the manufacturer's declared value. We have informed the dental laboratory of the deviations that do not meet the standard in the area. The dental laboratory does not mix the metals, but buys ready-made tablets from a Danish supplier. We have informed the dental laboratory that they are responsible for checking the materials they use.

However, several of the samples showed that the gold and silver contents in the dental crowns were somewhat higher than the contents declared by the manufacturers. We encourage dental laboratories to make efforts to ensure that the declared values are as accurate as possible, see the harmonised standard for dental materials DS/EN ISO 22674:2007.

Overall, the analyses illustrate that there is a need for improving the declaration of the material used and the control of the manufacturing process. The manufacturer is responsible for ensuring that custom-made medical devices meet the requirements in the executive order on medical devices, and the manufacturer must take all the necessary measures to ensure that it can be guaranteed from the manufacturing process that the manufactured product is in accordance with the manufacturer's documentation that the device is in accordance with the requirements of section 10(1) and annex VIII of the executive order.

In this connection, we would like to emphasise that the dental laboratories are responsible for ensuring that the declared materials meet the specifications. Consequently, the dental laboratories should pay attention to the need for self-inspection of suppliers and the materials they use, e.g. by way of controlling the ratio between new and reused metals and random analyses of purchased material.

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INSPECTION OF DENTAL LABORATORIES

DHMA inspected dental laboratories to investigate whether they meet the requirements as to medical devices in executive order no. 1263 of 15 December 2008. The inspections focused on the requirements as to technical documentation, control of raw materials, risk analysis, clinical evaluation, market surveillance and reporting of serious incidents.

The overall results of the inspections of 16 dental laboratories show that in some areas they should pay more attention to the legal requirements. This is in line with the conclusions from the inspections of 10 dental laboratories made in 2011.

Risk analysis was a major deficiency among the inspected dental laboratories and this gave rise to several deviations. The risk analysis must identify and process significant risks that may be associated with the manufacture and use of custom-made dental products, see section 3(1) and annex I, sections 1, 2 and 9 of the executive order. In the risk analysis, dental laboratories must refer to the laboratory's relevant internal procedures, e.g. the procedure for informing dentists, the manufacturing procedure and the procedure for the choice of supplier and material.

Deviations were found in the majority of the inspected dental laboratories due to lack of clinical evaluation documenting that the devices are in accordance with the essential requirements as to safety and performance, see section 3(1), annex I, section 6a and annex X of the executive order.

Moreover, the inspections showed that the majority of the dental laboratories had not established a market surveillance system to process and document the experience gained with devices after the manufacturing process. Manufacturers of custom-made medical devices are obliged to inform DHMA of serious incidents related to their products and initiate any necessary corrective actions, see section 10(1), third sentence and annex VIII, section 5 of the executive order.

The inspected dental laboratories included both manufacturers of custom-made medical devices and dental laboratories buying dental prosthetics outside the EU, e.g. in Asia. We found significant deficiencies in the technical documentation for both types of dental laboratory. There was no documentation demonstrating that the dental products were in accordance with the legal requirements as to custom-made medical devices. We found deviations in the manufacturer's documentation of the manufacturing process and quality control phases, see section 10(1) and annex VIII, section 3 of the executive order.

The area in which we found the lowest number of deviations was declarations of devices for special purposes, see section 10 and annex VIII, 2.1 of the executive order. Declarations for custom-made devices must contain certain information, for example the manufacturer's name and address, the characteristics of the individual product and information making it possible to identify the relevant device.

We follow up on all the deviations found during the inspections, and several dental laboratories have made corrective action plans to make sure that they meet the legal requirements. We monitor the relevant dental laboratories until the matters have been settled and the legal requirements are being met. Moreover, we have prepared an action plan for how to improve the knowledge level in the dental sector and inform the dental laboratories in the best possible way about the legal requirements for manufacturers of custom-made medical devices.

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ACTION PLAN FOR THE DENTAL SECTOR

We have set out an action plan on the basis of the results of the inspections of the dental laboratories and the analyses of fixed prosthetics.

The market surveillance project reveals a great need for additional information about the requirements laid down in the executive order on medical devices for manufacturers of custom-made medical devices and how to implement the requirements in practice in the dental sector.

In the past couple of years, several EU member states have also observed that the dental market lags behind when it comes to complying with the legal requirements as to medical devices. Other countries have issued information aimed at the dental sector, and we also find this initiative relevant.

We will also prepare information material to the dental sector and contact relevant players, including the industry organisation Danske Dental Laboratorier, to enter into dialogue about the need for information and targeted dissemination of knowledge about the legal requirements.

The information material will be made available on the DHMA website and distributed to relevant stakeholders, for example dental laboratories with own production as well as manufacturers buying fixed dental prosthetics from EU countries and non-EU countries. We will involve the users by establishing focus groups with people from the industry and ask them to provide input and feedback on the information material so that we can tailor the material specifically to the needs of the target group.

In addition, we will enter into dialogue with relevant educational institutions, including institutions for dental technicians, dentists etc., to establish or give greater priority to training in the legal requirements as to medical devices.

Moreover, we will maintain our focus on the dental sector and inspect dental laboratories every year for a number of years to investigate the compliance with the legal requirements.

Thus, DHMA's action plan includes several levels and contains different types of dialogue with players in the dental sector, information material and continued inspections of dental laboratories. The action plan will be implemented in the course of 2015.

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CONCLUSION

Based on the results of our market surveillance project 2014, we can conclude that the inspected dental laboratories, in several areas, have difficulties complying with the requirements in the executive order on medical devices.

As manufacturers of custom-made medical devices, dental laboratories must comply with specific requirements as to specially designed devices as well as general requirements in the executive order on medical devices. We found a number of significant deviations in the majority of the inspections of dental laboratories, for example lack of/insufficient technical documentation, risk analysis, clinical evaluation, market surveillance procedures and reporting of serious incidents. Based on the inspections we performed in both 2011 and 2014, we can conclude that dental laboratories seem to face general challenges in complying with the legal requirements.

The analyses of fixed dental prosthetics showed examples of insufficient information about the metals used in the prosthetics, including a specific example of the potentially allergenic material nickel. The project results reveal a need for self-inspection and controls of the materials suppliers deliver. In addition, the analyses showed that there is a need for reconciliation of several material specifications due to percentage deviations in the declared metallic contents that are greater than the threshold values, for both noble metals and base metals, as specified in the harmonised standard for dental materials.

Generally, we do not find that the project results cause any significant public health concern. The public health risks associated with the findings of this project are assessed to be remote. However, the results indicate that in rare cases fixed dental prosthetics may unintentionally contain inappropriate metals or products may be swapped by mistake. Consequently, it is important that dental laboratories ensure that they

make adequate material specifications and perform control activities on a continuous basis. Moreover, it is very important that the legal requirements are complied with, because dental laboratories' risk analyses, market surveillance and reporting of serious incidents contribute to promoting patient safety in Denmark.

The market surveillance project demonstrates that there is a need for greater focus on the legal requirements and the implementation of harmonised standards in the dental sector. Thus, dental laboratories must make efforts to ensure that they comply with the requirements as to manufacturers of custom-made medical devices and improve the documentation, quality and safety in the area in accordance with the executive order on medical devices.

DHMA carries out individual follow-ups on all inspections and has also prepared a strategic action plan for additional follow-up on the findings in the market surveillance project to meet the need for more information about how to comply with the legal requirements in practice. Moreover, DHMA will continue to monitor dental laboratories by way of annual inspections. DHMA will implement the action plan for the dental sector in the course of 2015.

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