IDA – EUDAMED

Global Implementation Plan V2.1A

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Introduction

The harmonisation and standardisation of design and manufacturing rules in the various EU countries should prevent Member States from refusing equipment coming onto the market or being put into service due to national design and manufacturing rules. Member States should be given access to basic information relating to the devices placed on the market. A database has been designed containing this basic information and called EUDAMED-database (European Database for Medical Devices) the legal basis for which is laid down in Directives 90/385/EEC, 93/42/EEC, 98/79/EC and 2000/70/EC. In order to better guide the project, the Member States' Medical Devices Expert Group has created a dedicated working group called EUDAMED-WG. (See the list of EUDAMED working group members in annex.) Information collected by the European database for medical devices, EUDAMED, will be accessible only by the competent Member States authorities and Commission Officials (DG ENTR). A more widespread access to the system may be allowed following discussion, at a later stage. Manufacturers & NB do not participate in the present project. Their participation may be envisaged in an other project.

A feasibility study was conducted by DIMDI and demonstrated the weak and strong points of the proposal. Details about the exercise can be found in the final report in annex1.

1. Description of the Project

1.1 Objectives

The aim is to develop a system for exchanging information relating to the application of the European Directives on medical devices. The exchange will be based on a database (EUDAMED-database) and a telecommunication network between the EC-services competent in the relative domain, and the CA (Competent Authority) in a Member States.

In a second phase, once the EUDAMED-database is loaded with high quality operational data, a vigilance-extension will be developed. With this vigilance module, Member States will be informed on incidents and near-incidents relating to certain devices on the market.
1.2 Features

Regulatory data in accordance with medical device Directives shall be stored in a European databank accessible to the CA (Competent Authorities) to enable them to carry out tasks relative to this Directive on a well-informed basis.

The databank shall contain the following:

- Data related to registry of manufacturers and devices in accordance with Article 10.
- Data related to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedure as laid down in Annexes III to VII.
- Data obtained in accordance with the vigilance procedure as defined in Article 11.

Data exchange will be based on an agreed standard format (XML, …) and web-interfaces will be used extensively.

The EUDAMED system will be split into different, interconnected subsystems. The focus will be placed on Medical Devices, or in other words, it must be possible to collect and visualise all relevant information concerning Medical Devices. The relevance of the information to be collected is linked to the use to which the information is to be put. In case of problems with a device, the vigilance module will collect vigilance information relative to a device, so that every Member State can verify the incident history of a device present on the market.

The EUDAMED system will establish connectivity between CAs and the EUDAMED database hosted by European Commission (DG ENTR).

The EUDAMED system will be able to load, extract and modify data, and to make reports and queries on the EUDAMED Database.

The system will use already existing components, and will be modular so that its components can be reused for similar purposes linked to Directives covering other domains.

During the start-up phase data-migration processes must be planned between the Member State CA infrastructure and the EUDAMED-database.
1.3 Participants

The key players in the EUDAMED system are the Members States CAs (whether one or more CAs per Member State have access to the system will have to be decided), the Notified Bodies, the Manufacturers and the EC (European Commission).

1.4 Technical approach

- The EUDAMED database will be hosted on EC premises.
- A secure Network will be used (TESTA II, , IDA PKI certificates,...) in order to access the system. At a first instance only public data will be handled, so no special security measures should be taken. For reliability reasons it is preferred to start from the beginning with the full-scale TESTA infrastructure. At a second instance Initial reports will be stored in the EUDAMED system for vigilance purposes. This type of reports is not public and increases the security level to be applied on the system. The use of initial reports is generally seen as one of the major benefits of the EUDAMED system.
- Quality of service must be guaranteed: performance, backup, availability 24 hours/day & 7 days/week, security.
- State-of-the-art technology will be used such as that proposed by the Commission standard product list and the Architecture Guidelines of IDA. ([www.ispo.cec.be/ida/ida.html](http://www.ispo.cec.be/ida/ida.html))
- Access to the EUDAMED system will be based on Web technology.
- Data quality management will be performed by the National CA or by an external contractor via a open call for tender procedure. IDA will not finance this initiative.
• Logging and monitoring will be activated in order to guarantee Data integrity.

2. Assignment of Roles and Tasks

• DG ENTR Unit G4: project owner, contact point for external bodies.
• DG ENTR Unit R3: project manager (analysis & development done by external experts hired through a Commission framework contract) running the system.
• The EUDAMED WG: part of the MDEG group functioning as project steering committee. They use the CIRCA system to communicate and exchange documents and information.
• CA Member States: end-users responsible for data entry in the EUDAMED system, guaranteeing data-quality.

3. Expected Benefits

• Today, information of manufacturers and medical devices is spread over all Member States. The information is received either directly from manufacturers (Class I devices) or through certificates issued by Notified Bodies. EUDAMED will concentrate them all in one data base. The national Competent Authorities will greatly benefit from the common European database in the case vigilance or other Europeanwide investigations. Safety or hazard notices sometimes recommend stopping using a particular device. In such cases, a complete list of manufacturers of groups of products would help ensure alternative products are available and prevent notices from interfering clinical practice.

• Today IVD medical devices have to be notified in all member States. EUDAMED will require only one notification. This is essential point both for the IVD manufacturers and national Competent Authorities. It saves the manufacturers the extra cost they should cover in the case of doing notifications in an every Member State. It also makes the launching of the new products on the market easier. One of the principles in the new approach directives is to avoid the negative impact of regulation on new innovations.

• Vigilance reports today are to be distributed by the receiving Competent Authority (CA) to all other CAs. EUDAMED will make vigilance reports immediately available to all Member States. The database is very helpful when taking a decision on action that needs to be taken with reference to a particular device. This will shorten the time between the incident and the final report and that way the EUDAMED database increases the safety of the patients.
4. Scheme for equitable sharing of operational and maintenance costs

4.1 Expected costs for the development and validation phase

A total amount of 390k€ is requested for the complete development and validation phase. The calculation of the mentioned total amount is based on a set of three profiles.

- A **Senior Analyst** profile for the functional analysis of the EUDAMED system. The basis for the functional analysis is the descriptive document as discussed and agreed during the EUDAMED Working group meetings. This document describes the actual existing situation of information flows. A pre-analysis will be completed in a vision document collecting all the user requirements laid down in so called Use Cases. (The latter document is under discussion with the working group participants by extensively using CIRCA newsgroups.) When the Commission framework contract is used the cost for this profile will be 575€/day.

- An **Analyst Developer** profile for the development and implementation work. The implementation work will cover also the testing and the training. In the above mentioned contract the cost for this profile will be 500€/day.

- A **Senior Analyst Developer** profile will be used for the development of the reporting. Following the Commission framework contract the cost for this profile will be 520€/day.

The project management will be performed by Commission officials and is not taken into account in the cost estimation.

The cost related to verification of the quality of the data introduced in the EUDAMED system is not covered by this budget estimate. Data quality verification will be the responsibility of the Member State’s competent authorities, and is mentioned in point 4.3. Cost sharing scheme after implementation.

The whole project is partitioned in different phases.

- **Functional analysis** of the complete EUDAMED system, including the Vigilance module.

- **Entity Registration** module performs the registration of Competent Authorities, Manufacturers, Authorised Representatives, and Notified Bodies. The aim is to perform data entry via electronic forms through a Web browser.

- **Device Registration** module enables users to enter device related information for Medical Devices and IVD devices. This module is rather specific due to the fact that it concerns products being totally different from Entities.

- **Certificates module** concerns about the conformity assessment information. The possibility should be foreseen to upload certificate documents in the database with contextual search features.
• **Systems Management** module contains the functions enabling system administration.

• **Vigilance module**

• **Reporting module** concerns about all types of information extraction from the EUDAMED database.

• **Development support** concerns the support to Member State’s Informatics services in order to tune the massive data upload during the start-up phase.
The above picture shows the planning diagram for the project execution. Remark that Development support is spread over the project so that every module receives assistance when it goes in production. The same is the case for the reporting module.

From the above picture the following budget partitioning can be extracted.

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4.2 Costs for the implementation phase

50,000 Euro
  2002: 30,000 Euro
  2003: 20,000 Euro

A distinction is made between Hardware and software licenses. Hardware cost will be foreseen in Unit G4 working plan 2002. Software licenses will be acquired for an estimate amount of 50,000 Euro, 30,000 Euro in 2002 and 20,000 Euro in 2003. This amount include a training plan foreseen by the end 2002 beginning 2003.

4.3 Cost-sharing scheme after implementation

- For corrective maintenance & operational cost an amount of 40,000 Euro must be subscribed in Unit G4 yearly working programme.
- National CA: connectivity between CA & TESTA Gateway.
Annex 1:
Summary of the feasibility study - conclusion, tasks for regular operation

The contractor has developed, installed and made accessible a data base system for the exchange of regulatory data on medical devices. In so far the objectives and obligations laid down in the contract between the Commission and DIMID1 have been entirely fulfilled. In the overall assessment of EUDAMED the difficulty of some Member States with delivering data in time should not discourage from making further efforts to complete the data base with all regulatory data from all Member States.

At the site of DIMDI all technical means are available to speed up data transfer, incorporate them into EUDAMED and offer them to all Member States.

With the new Art. 14a of the MDD 93/42/EEC and the necessity of Member States to transpose these regulations into national law, the implementation of a common European data base becomes more compelling. When the project EUDAMED was set up almost all Member States had agreed to participate in the project on a "voluntary" basis. Maybe due to the difficulties Member States encountered in collecting data from manufacturers and sending them to EUDAMED, the commitment to participate on a European level was not taken too seriously, because the legal foundation did not yet exist.

This may have also been the reason why some Member States did not give the requested feed back to the contractor on their particular situation. For the contractor it has been more difficult during phase 11 to get a clear picture why some countries were not able to transmit data for EUDAMED or why they did not show any reaction.

Considering the experience the contractor has gathered on the situation in Germany and taking into account the efforts by all parties involved to improve the system, it is not surprising that other countries may still have similar problems.

The contractor is optimistic that eventually all countries will have adjusted their national system to a unique system in the regulatory data exchange of notifications and certifications. He also believes that the control and transparency of the European medical devices market can only be achieved by having a unique central data base operated and maintained by one entity.

If the target of having all regulatory data incorporated into EUDAMED by the end of the project has not really been achieved, the continuation of completing and maintaining EUDAMED is strongly recommended. The other option of having for each Member state a different national data base with different structures and features accessible to the other Member States can't be regarded as an alternative.

The proposal made by the contractor in the second report in February 1999 (Report 2.00) on how EUDAMED should be continued after the termination of the project at the end of August 1999, is still valid and does not need to be further amended in this final report.