Evaluation of the "EUropean DAtabank on MEdical Devices"

11 October 2012

Introduction

The European Databank on Medical Devices - Eudamed - is a secure web-based portal acting as a central repository for information exchange between national Competent Authorities and the Commission in accordance with the Medical Devices Directives.

First provisions on Eudamed were introduced in the Medical Device Directives in 1998 by Directive 98/79/EC on *in vitro* diagnostic medical devices[1] (IVD). Eudamed's legal basis is included in the three applicable Directives, Council Directive 90/385/EEC on active implantable medical devices [2], in particular Article 10b, Council Directive 93/42/EEC concerning medical devices [3], in particular Article 14a, and Directive 98/79/EC on *in vitro* diagnostic medical devices[4], in particular Article 12.

Directive 2007/47/EC[5] amended the existing provisions on Eudamed, introducing the obligation for the Commission to implement Eudamed no later than 5 September 2012 and to evaluate the operational functioning and the added value of the databank no later than 11 October 2012. These provisions were introduced in Article 14a (4) of Directive 93/42/EEC.

Commission Decision 2010/227/EU[6] fulfilled the first of these obligations. It implemented Eudamed and made its use mandatory as of 1 May 2011. With the present evaluation report the Commission fulfills the second of its obligations under Article 14a (4), to evaluate the operational functioning and the added value of Eudamed.

The Eudamed implementation and evaluation ran in parallel with the revision of the Medical Device Directives. Proposals to review the Medical Device Directives were adopted by the Commission on 26 September 2012[7]. These proposals also foresee a number of substantial changes in relation to Eudamed. These changes were proposed by the Commission based on the experiences collected with Eudamed so far and feedback received from Member States, notably through discussions in the Eudamed Working Group[8] and other forums.

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[1] OJ L 331, 7.12.1998, p. 1.
[2] OJ L 189, 20.7.1990, p. 17.
[3] OJ L 169, 12.7.1993, p. 1.
[4] OJ L 331, 7.12.1998, p. 1.
[5] OJ L 247, 21.09.2007, p. 21.
[6] OJ L 102, 23.04.2010, p. 45.
[7] http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm.
[8] The Eudamed Working Group is chaired by the Commission and advices on all issues related to the implementation of the Eudamed database. The participants are the national competent authorities, the industry and the notified bodies.

The present evaluation confirmed the appropriateness of the suggested changes included in the Commission proposals to review the medical device regulatory framework.

The evaluation is focused on two aspects: the operational functioning of the databank and the added value it brought to the strengthening of market surveillance and transparency in the field of medical devices.

The evaluation report consists of two different parts.

The first part is the result of an internal analysis based on the data contained in Eudamed on the 30th of June 2012 and aims at providing a description of the main Eudamed elements and data stored, as well as the current technical issues.

The second part is based on information provided by the national Competent Authorities via an electronic survey.

The survey was submitted to the EU Member States, the EFTA countries, Switzerland and Turkey.

1. Internal analysis

1.1 Technical Issues

Eudamed has been technically developed over the last 10 years, with the first data being entered by Member States in 2003. Since then Eudamed has been technically adapted and improved on various occasions. A major step was the changeover to Eudamed 2 in 2009, which brought a new Eudamed interface, based Eudamed on a new flash based (Flex) technology, this provided for new access management and user login, introduced the new clinical investigation module and brought new features for devices and certificates.

Eudamed, as it stands now, is functional for the tasks required under the Medical Device Directives. However, in order to better meet the needs of users and to address technical issues arising with the increased use of Eudamed, technical improvements constantly take place.

Changes to the application are decided in co-ordination with the Eudamed Working Group. They are planned well in advance and are introduced through releases. Special attention is paid to the fact that changes to Eudamed in most cases, and especially to the xsd scheme for the upload, may require changes at national level as well.

The IT developments during 2012 focused on a release implementing numerous improvements agreed within the Eudamed Working Group.

The more significant upgrades implemented are:

- changes to business rules, including clarification on mandatory data,
- new business rules for certificates, *In Vitro* Diagnostic (IVD) devices and Clinical Investigation (CIV) devices,
- new xml validation rules,
- a better identification of IVD devices,
- significant improvements in the CIVs module,
- new non mandatory fields in the CIVs and National Competent Authority Reports (NCAR) modules,
- improvement of the e-mail notifications,
- a review of the user interface,
- the alignment between the user interface and the XML Schema,
- addressing identified inconsistencies in the database,
- the resolution of issues raised by the users, and

- the update of the User Guide.

The main technical problems encountered were related to the download, upload and search functionalities.

1.2 Information on users

The number of Eudamed users within the national Competent Authorities on the 30th of June 2012 was 334 and covers all EU Member States. 48 different national Competent Authorities have access to Eudamed and 15 of them do not enter data but only use their access rights to consult Eudamed.

The number of users varies from one national Competent Authority to another mainly depending on the internal organization of each participating country.

Most of the national Competent Authorities have between 1 and 5 users, followed by those with between 5 and 10 users. A few have more than 10 whereas in one national Competent Authority the number of users goes up to more than 100.

The Eudamed system administrator is the Commission and users can have 4 different roles: Confirmer, Proposer, Fat Viewer and Slim Viewer with decreasing access rights.

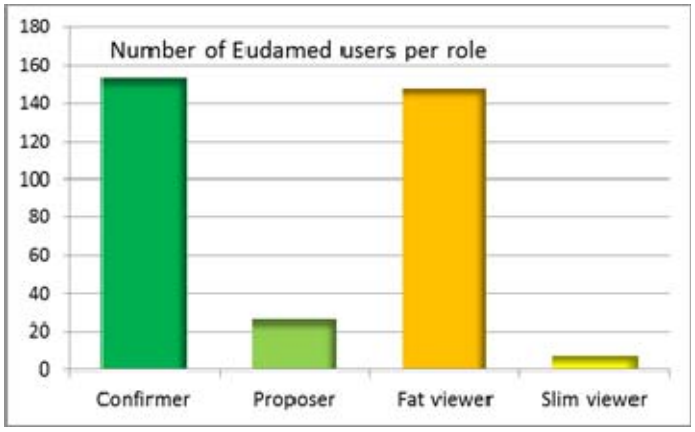
Data entered in Eudamed follows a two-step registration process: the first is "proposed" and the second is "confirmed".

The table below summarizes the Eudamed user rights in relation to the different profiles:

EUDAMED USERS RIGHTS		ROLES			
		Slim Viewer	Fat Viewer	Proposer	Confirmer
Medical Device Management					
Confirmed Data	View all confirmed data	✓	✓	✓	✓
	Create new versions of confirmed data from your own Competent Authority	✗	✗	✓	✓
Proposed Data	View Proposed data from the own Competent Authority	✗	✓	✓	✓
	Create/Update/Delete Proposed data from your own Competent Authority	✗	✗	✓	✓
	Confirm Proposed data from your own Competent Authority	✗	✗	✗	✓
Advanced Search:					
Perform Advanced Searches		✓	✓	✓	✓

Download/Upload:				
Uploads	✗	✗	✗	✓
Downloads	✓	✓	✓	✓

The distribution of users per role highlights that the number of "confirmers" is the largest part of the overall users, followed by the “fat viewers” users.



Eudamed offers its users the possibility to subscribe to automatic e-mail notifications for National Competent Authorities Reports (NCAR) and CIV modules. So far, 44% of users from 32 different countries receive e-mail notifications on NCARs and 33% of users from 28 different countries receive e-mail notifications for Clinical Investigations.

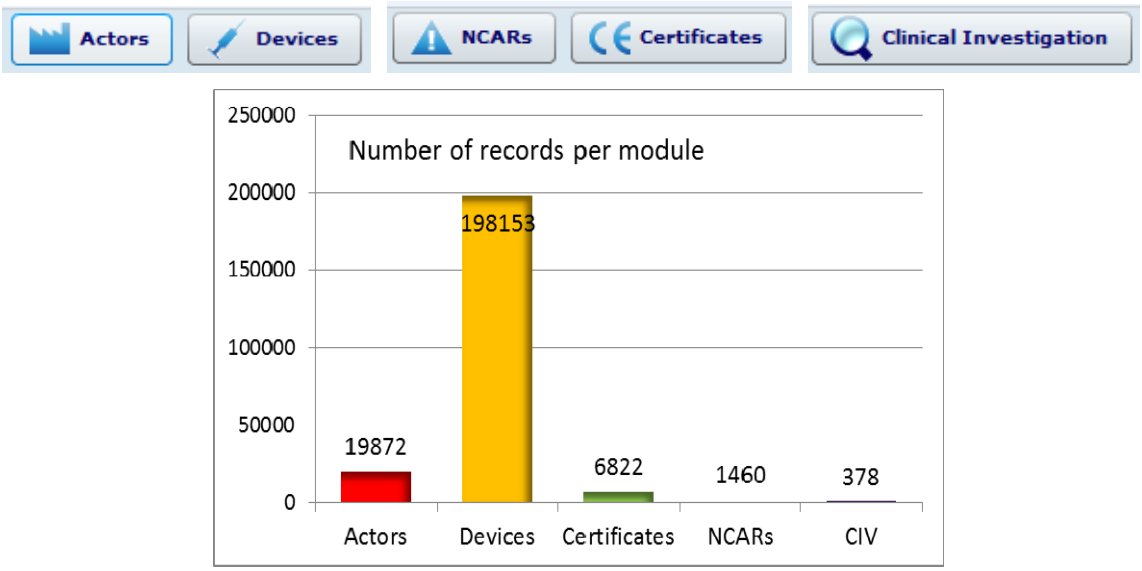
Eudamed gradually replaces NCAR mailing system used before to share NCAR information. Improvements to the e-mail notification were implemented in 2012 to ensure that users receive all required information. The high number of users receiving e-mail notifications on NCAR concerning incidents linked to medical devices shows the importance of the system to spread the sensitive NCAR information.

1.3 Information on Data

The following overview of information encoded in Eudamed has to take account of the fact that different modules became available at different times and that data entry on a voluntary basis was already possible long before it became a legal obligation. Differences in the number of entries between Member States does therefore not necessarily allow for conclusions to be drawn regarding the situation in these Member States, but might be simply due to the varying usage of the application.

The first operational Eudamed modules were actors (ACT) - which encompass competent authorities, manufacturers and authorized representatives - and devices (DVC) in 2003, followed by Vigilance National Competent Authorities Reports (NCAR) and Certificates (CRF) in 2004 and the last implemented module was Clinical Investigations (CIV) in 2011.

2003 2004 2011



The device module is clearly the most used module. Device entries into Eudamed can come either through registration data for class I devices, through certificate data when a device belongs to IIa, IIb or III risk class, as well as through NCAR entries. The current legal provisions and the structure of Eudamed will not allow Eudamed to provide a complete picture of the EU market for medical devices, the number of devices entered is therefore not representative of the Union's medical device market. Overall it is estimated that there are about 500 000 devices on the market.

As regards certificates, those which are issued as of 1st of May 2011 as well as decisions on certificates, must be entered into Eudamed. There is no obligation to enter certificates retrospectivly. The number of certificates above therefore does not provide a comprehensive picture of the number of existing certificates in the EU.

1.3.1 Data per module

The amount of data registered into Eudamed and provided by the different national Competent Authorities per each module, varies from one to another country according to the following:

- **Actors module** (data from 28 countries)

  - 11 Countries recorded between 1 and 100 Actors;
  - 11 Countries recorded between 101 and 500 Actors;
  - 2 Countries recorded between 501 and 1000 Actors;
  - 2 Countries recorded between 1001 and 5000 Actors;
  - 1 Country recorded between 5001 and 10000 Actors;
  - 1 Country recorded has more than 10001 Actors.

- **Devices module** (data from 26 countries)

  - 4 Countries recorded between 1 and 100 Devices;
  - 6 Countries recorded between 101 and 500 Devices;
  - 4 Countries recorded between 501 and 1000 Devices;
  - 8 Countries recorded between 1001 and 10000 Devices;
  - 2 Countries recorded between 10001 and 50000 Devices;
  - 2 Countries recorded more than 50000 Devices.

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- **Certificates module** (data from 19 countries)

- 8 countries recorded between 1 and 50 Certificates;
- 4 Countries recorded between 51 and 100 Certificates;
- 5 countries recorded between 101 and 500 Certificates;
- 1 country recorded between 501 and 1000 Certificates;
- 1 country recorded more than 4000 Certificates.

- **NCARs module** (data from 15 countries)

- 8 countries recorded between 1 and 5 NCARs;
- 2 countries recorded between 6 and 100 NCARs;
- 5 countries recorded more than 101 NCARs.

- **CIV module** (data from 14 countries)

- 8 countries recorded between 1 and 20 CIV;
- 2 countries recorded between 21 and 50 CIV;
- 4 countries recorded more than 51 CIV.

The information above underlines that, while the number of countries performing the registration of Actors and Devices in the respective modules is very high, the entry of data concerning CIVs, NCARs and CRF modules is limited to few countries.

While these differences are, to some extent, linked to market size, it is also indisputable that, in order to increase the effectiveness of Eudamed and to strengthen its role in the medical devices market surveillance, participating countries still need to increase their efforts.

1.4 Statistics on data quality based on sampling

The criteria for the samples selection are:

1. Data entered after the 1st May 2011;
2. Minimum one data set of each active national Competent Authority.

The criteria for the data quality analysis are:

1. The consistency of data;
2. The completion of mandatory fields;
3. The use of optional fields;
4. The use of the attachments possibility.

The 5 modules consolidated results show this picture:

Consistency of data	Data is accurate in 92% of samples.
Completion of mandatory fields	All Mandatory fields are completed in 100% of samples. 6% had fulfilled one or more mandatory fields with "NA"
Use of Optional fields	92% of optional fields are completed at least once. The average use of optional fields is 42% of the total number of optional fields available
Attachments	30% of samples have attachments.

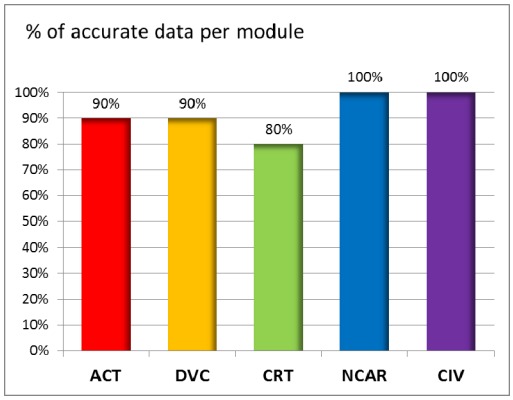
However, the variations between the modules are significant. While data entered in the NCAR and the CIV modules is more complete, with data appropriate in 100% of samples

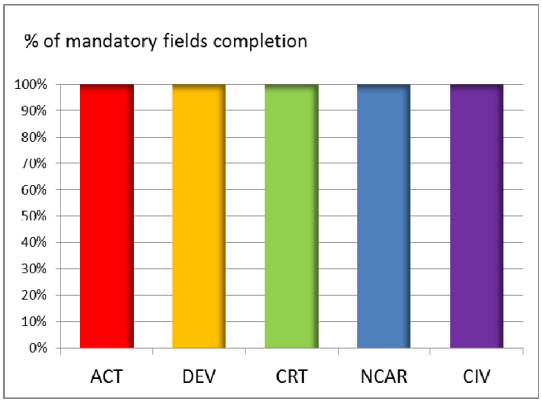
and a high use of optional fields - up to a maximum of 80% - data entered in the CRF module is appropriate in only 80% of samples and the completion of optional fields is very low.

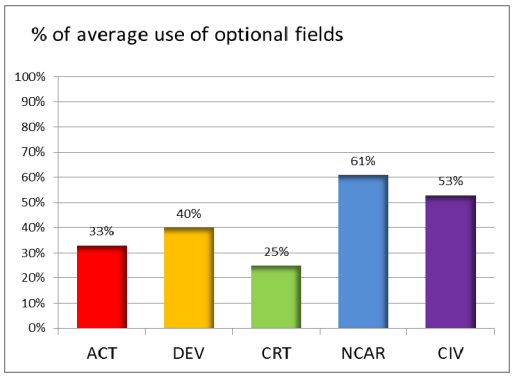
For the DVC and ACT modules, data is appropriate in 90% of samples and in 20% of samples optional data is inconsistent or appears in a wrong place.

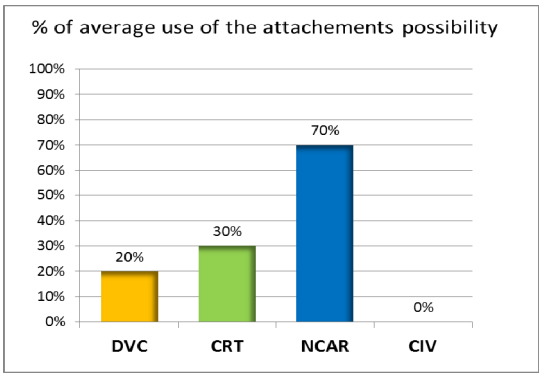
The option for attachments is mainly used in the NCARs module, with Field Safety Notices being the most frequently attached document.

The sampling analysis show that data contained in Eudamed is reliable at a very high level and all countries entering data comply with the Eudamed Decision obligations on mandatory data, however there is still room for improvement since the Eudamed ambition is to collate 100% of consistent and reliable data.









2. Eudamed survey results

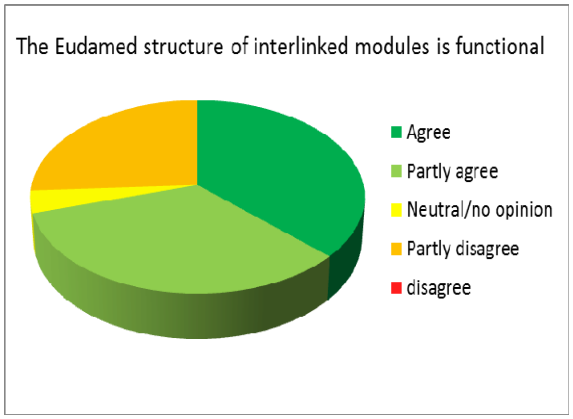
2.1 Operational Functioning

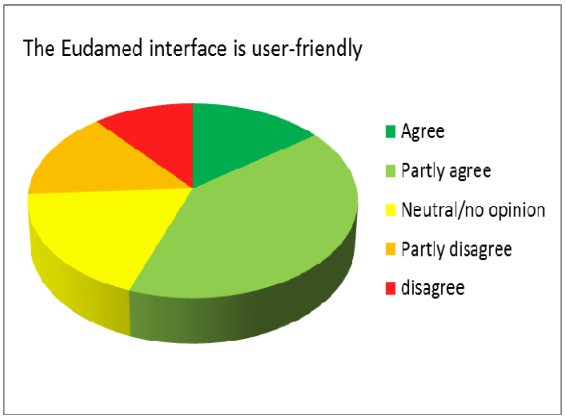
This second part of the report is based on the information provided by the countries using Eudamed further to an electronic survey to which 85% of consulted countries responded.

The successful participation in the survey allowed the gathering of a large number of consolidated opinions from the national Competent Authorities and having a complete overview of both the Eudamed operational functioning and the added value it brought in terms of transparency and market surveillance in the medical devices sector.

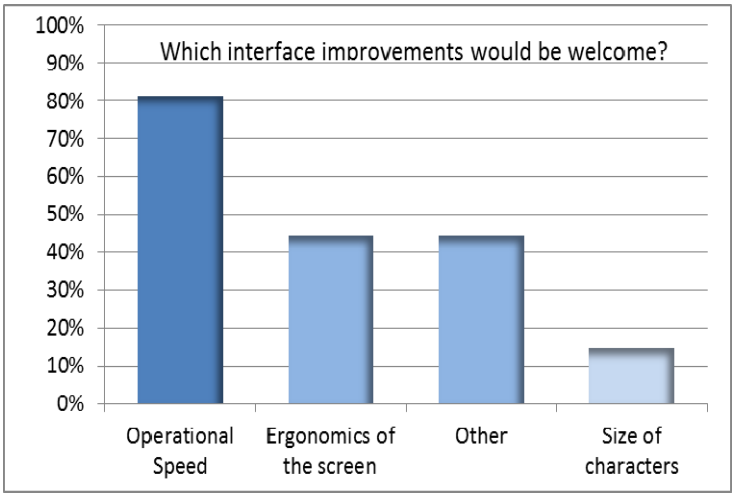
As regards the Eudamed operational functioning, the replies reveal an overall positive opinion.

In particular, most of the consulted countries consider the structure of the interlinked modules to be functional and give a positive opinion as to the user friendliness of the interface.





The survey suggested the following three interface improvements: operational speed, ergonomics of the screen and size of the characters. Most of the responses stressed the need to increase the operational speed of the application. The "other" proposals mainly focused on the need of improving the way of displaying information.



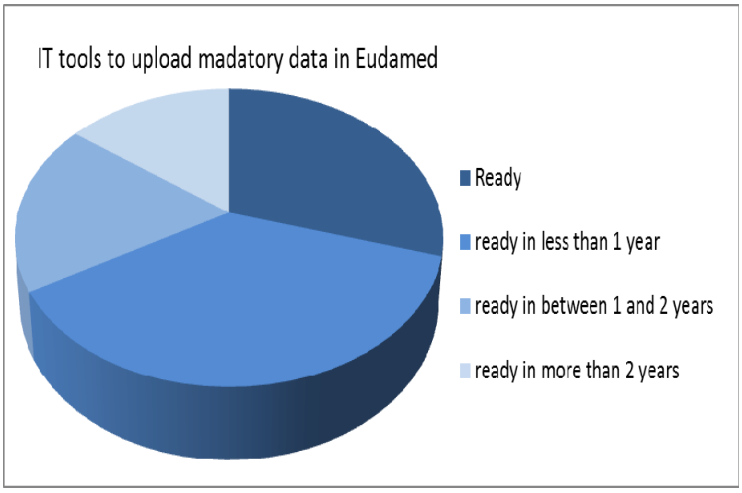
Concerning the Eudamed download and upload functionalities, while the overall operational functioning is satisfactory, the analysis of the responses also reveals that improvements still need to be made as to their use of the different modules.

Indeed, while the download functionality is used by around 50% of countries with reference to the Actor, Device and NCAR modules, the downloading of Certificates and Clinical Investigations remains low. Several countries suggested improvements to the download functionality.

As regards the upload functionality, it is used by more than 55% of countries in the Actor and Device modules and by 25% for Certificates. Upload in the NCAR and Clinical Investigation modules is used by around 10% of countries.

Nevertheless, the trend towards an increasing use of both download and upload functionalities together with the expectation of those countries (on average less than 10 per each module) that did not yet complete the development of IT tools for the upload of mandatory data into Eudamed to do that very shortly, is a positive indicator for the future improvements in this field.

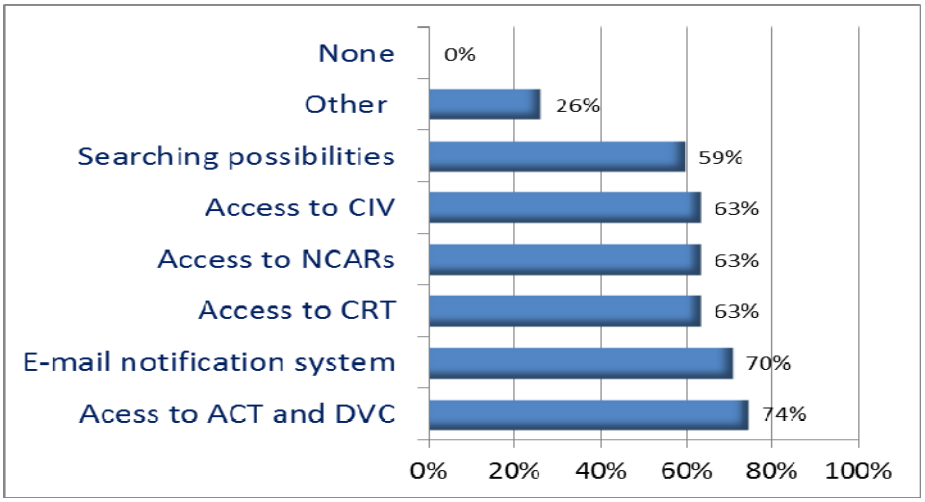
In order to benefit from the upload and download functions in Eudamed, Member States must have compatible national IT systems in place. Here, differences between Member States exist.



2.2 Added value

The analysis of the added value section of the questionnaire shows that that Eudamed represents a very important tool for the transparency and market surveillance enhancement in the medical devices sector.

The responses to the question "Where do you see the **main Eudamed added value**" show a high level of satisfaction.

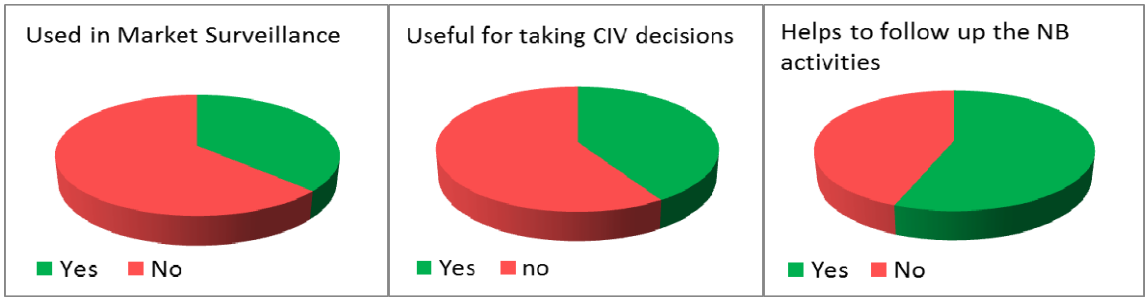


Eudamed is perceived by the great majority of consulted countries as a tool bringing a significant added value in terms of information on registered actors and devices but results are also satisfactory with reference to the other modules, e-mail notification system and the search capabilities.

The responses on the **use of Eudamed in the market surveillance** area indicate that Eudamed does not yet fully address the needs in this area.

Nevertheless, according to the opinion of the majority of countries, available information on Certificates is considered to be helpful in allowing Competent Authorities to better follow up on the Notified Bodies' activities. Information on Clinical Investigations is

considered to help Competent Authorities, of a still limited number of countries, to make decisions in this field,



The countries using Eudamed in market surveillance basically use the application for vigilance issues, checking certificate validity and for high class device searches.

The main arguments of those not using Eudamed for market surveillance are that:

- they prefer using the national databases (which are considered to be more reliable),

- the data contained in Eudamed is incomplete or insufficient,

- the data entries are too limited to allow a complete overview of the national distribution of the devices,

- not all national available information is entered in Eudamed.

Some countries suggest the creation of a specific module dedicated to market surveillance.

Concerning Clinical Investigations, the national Competent Authorities that do not use Eudamed to help to take decisions, they argue that the data in Eudamed is partial (see point 1.3.1: only 14 countries enter CIV data), the information insufficient, the national systems are adequate and that there is a need for more advanced searching tools for CIV.

Eudamed is more widely used in the follow up of Notified bodies activities; however, the national Competent Authorities regret again that the data is incomplete and that most of the data on certificates is not recorded (see point 1.3.1: only 19 countries enter data on certificates and point 1.4: the lowest average use of optional fields is in the CRF module with only 25%). Additionally, certain national Competent Authorities do not enter certificates issued by their national Notified Bodies for manufacturers/authorised representatives in other countries which leads to an overall lack of information.

The responses to the questionnaire also gave important indications as to the **frequency of the data entry/updating activity** carried out by the national Competent Authorities.

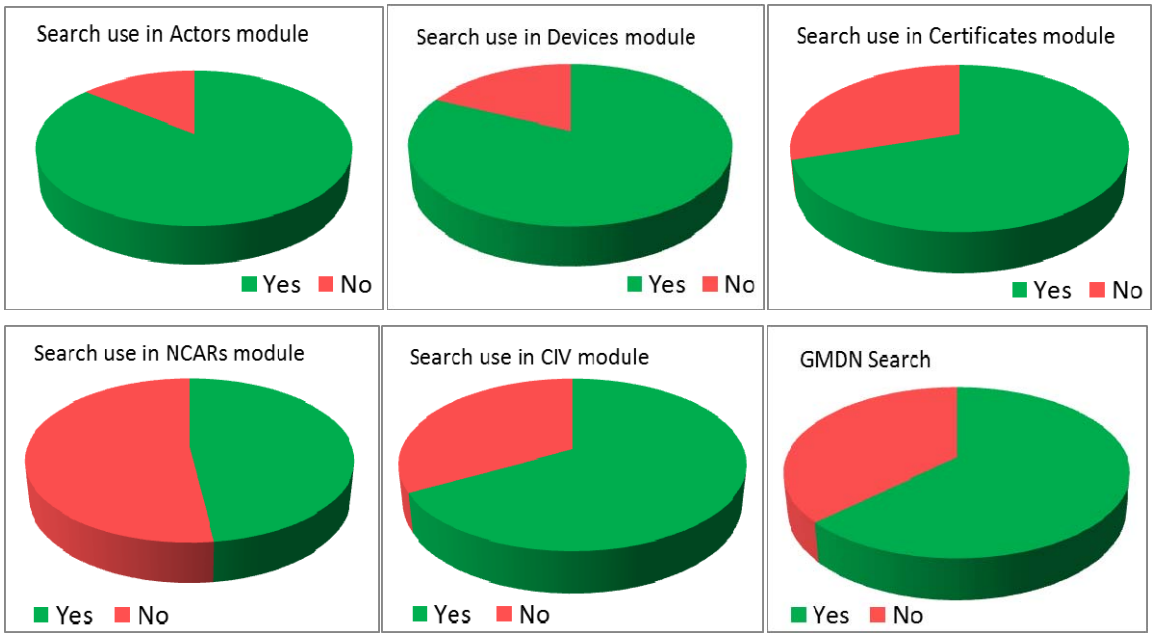
The analysis of the results shows that data on Actors and Devices is entered/uploaded with higher frequency when compared to those on Certificates, NCARs and Clinical Investigations.

In particular, data on Actors and Devices are, overall, updated/entered between one and a few times a month, whereas the majority of countries updates/enters data on Certificates, NCARs and Clinical Investigations less than once a month. Almost 40% of the replies declared to enter/update data with a frequency of less than once a month.

While an upload of registration data in predetermined intervals is useful, the purpose of sharing information on NCAR's, decisions in relation to certificates and on decisions taken in relation to CIV is to allow a swift information exchange between authorities. This type of data should therefore be entered as soon as possible.

While improvements still need to be made with specific reference to the **development of advanced searching tools**, the use of Eudamed reporting functions and the exploitation

of the modules for searching purposes, show a positive opinion on the overall added value brought by Eudamed to ensure a better market surveillance and to provide information mainly through the actors and devices modules.



Almost 70% of responses show that participating countries are satisfied with the current search scope, 60% use the reporting functionality and 80% do not need additional reports, however free text searches, search by generic name, storing and reprocessing searches facilities, additional ad hoc advanced reports specific for vigilance and clinical investigation and search queries would be welcome.

Structural Problems with Eudamed and proposed changes in the Revision of the Medical Device Legislation

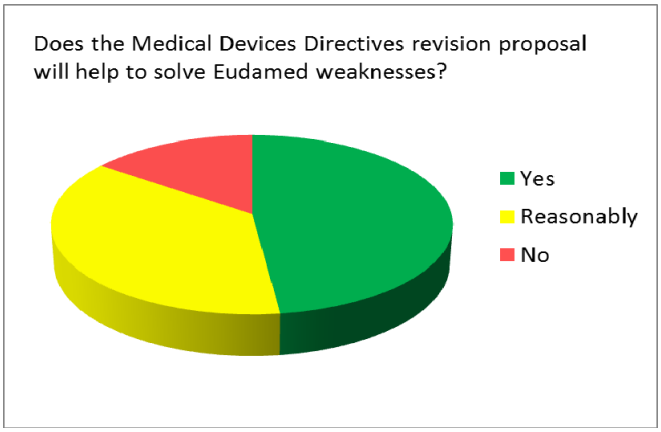
The shortcomings identified throughout the evaluation and in the experiences with Eudamed overall relate to a number of basic shortcomings in the legislative framework.

Eudamed does not provide a complete overview of actors and devices on the EU market. The reason for this is mainly that the current legislative framework does only foresee a registration requirement for class I devices, the requirements for higher class devices are left to national rules. In addition, the current rules do not provide for sufficiently coherent rules as to the detail of registration data, leading to a situation in which the data available in the various Member States is not homogeneous. The current system also foresees data entry by CAs, which is intensive work and creates a data triangle, with data submitted by the manufacturer to the authority and from the authority to Eudamed. The basic ownership rule in Eudamed is that whoever enters data becomes the data owner in Eudamed. Taking the example of a medical device, several authorities might need to enter data for this device, one might be the registered place of business of the manufacturer, the other might have an incident to report and yet another might need to enter the certificate. The current ownership rules in Eudamed can lead to multiple data entries in these cases, again leading to the result that Eudamed does not provide a reliable overview of what is on the market and that the different data is not interlinked, a clear deficiency for the market surveillance use.

The evaluation results confirmed that the main Eudamed weaknesses are, first the fact that Eudamed does not provide a complete overview of actors and devices on the EU market, second the fact that Eudamed does not yet lead to transparency as there is no public access, third the data entry by CAs is work intensive, in particular as regards data

on certificates and manufacturers, and finally the current ownership rules lead to multiple data entries.

The responses to the final question concerning the Medical Devices Directives Revision proposal of a central registration databank providing for direct data entry by manufacturers and other actors in relation to registration data but also for direct data entry on certificates by Notified Bodies and with part of the information publicly available show a positive appreciation of the Medical Devices Directives revision proposals for Eudamed.



In this respect, the large majority of interviewed countries consider that the future databank providing for direct data entry by manufacturers and other actors in relation to data registration and also for direct data entry on certificates by Notified Bodies, will substantially enhance the effectiveness and usefulness of the databank.

The feedback received in response to the submitted questionnaire finally provided a set of valuable and constructive suggestions to further improve the functioning and usefulness of Eudamed and will be used as a basis for future discussions in the framework of the European Eudamed Working Group.

Conclusions

The evaluation showed that Eudamed, as it now stands, works and is able to meet the current legislative requirements. It brings a clear added value for the participating countries.

Further improvements can and should be made in the current framework. Increased and more frequent and timely use of participating countries is necessary to reap the benefits of Eudamed in the short term.

In the framework of the "Eudamed Working Group" activity, the Commission monitors and reminds the Member States to correctly use Eudamed. In addition, the Commission reserves the right to undertake the appropriate measures against those Member States which do not comply with their legal obligations regarding Eudamed.

However, in the long term, the evaluation showed that Eudamed is not fully able to meet today's expectations about a European databank in terms of completeness, data quality, interlinkage and transparency. The transposition of the current Medical Devices Directives into national law is heterogeneous; consequently, the national information systems show heterogeneous data which translates into heterogeneous data in Eudamed.

The evaluation confirmed that the changes foreseen in the Proposals for Regulations on the revision of the Medical Device regulatory framework are appropriate to overcome these shortcomings and to develop Eudamed into a comprehensive and transparent information system on medical devices.