



EASA

European Aviation Safety Agency

European Aero-Medical data Repository (EAMR)

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Your safety is our mission.

An agency of the European Union 

TE.GEN.00409-001



The recommendation



- **Recommendation 5:** The Task Force recommends that national regulations ensure that an appropriate balance is found between patient confidentiality and the protection of public safety.
- The Task Force recommends the creation of a European aeromedical data repository as a **first step** to facilitate the sharing of aeromedical information and tackle the issue of pilot non-declaration. **EASA will lead the project to deliver the necessary software tool.**



Task Force on Measures Following the Accident of Germanwings Flight 9525 Final Report



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Purpose of the EAMR

PUBLIC INTEREST → Civil aviation safety → Basic regulation

➤ **REGULATION (EC) No 216/2008 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

of 20 February 2008

on common rules in the field of civil aviation and establishing a
European Aviation Safety Agency, and repealing Council Directive
91/670/EEC, Regulation (EC) No 1592/2002 and Directive
2004/36/EC

(Text with EEA relevance)

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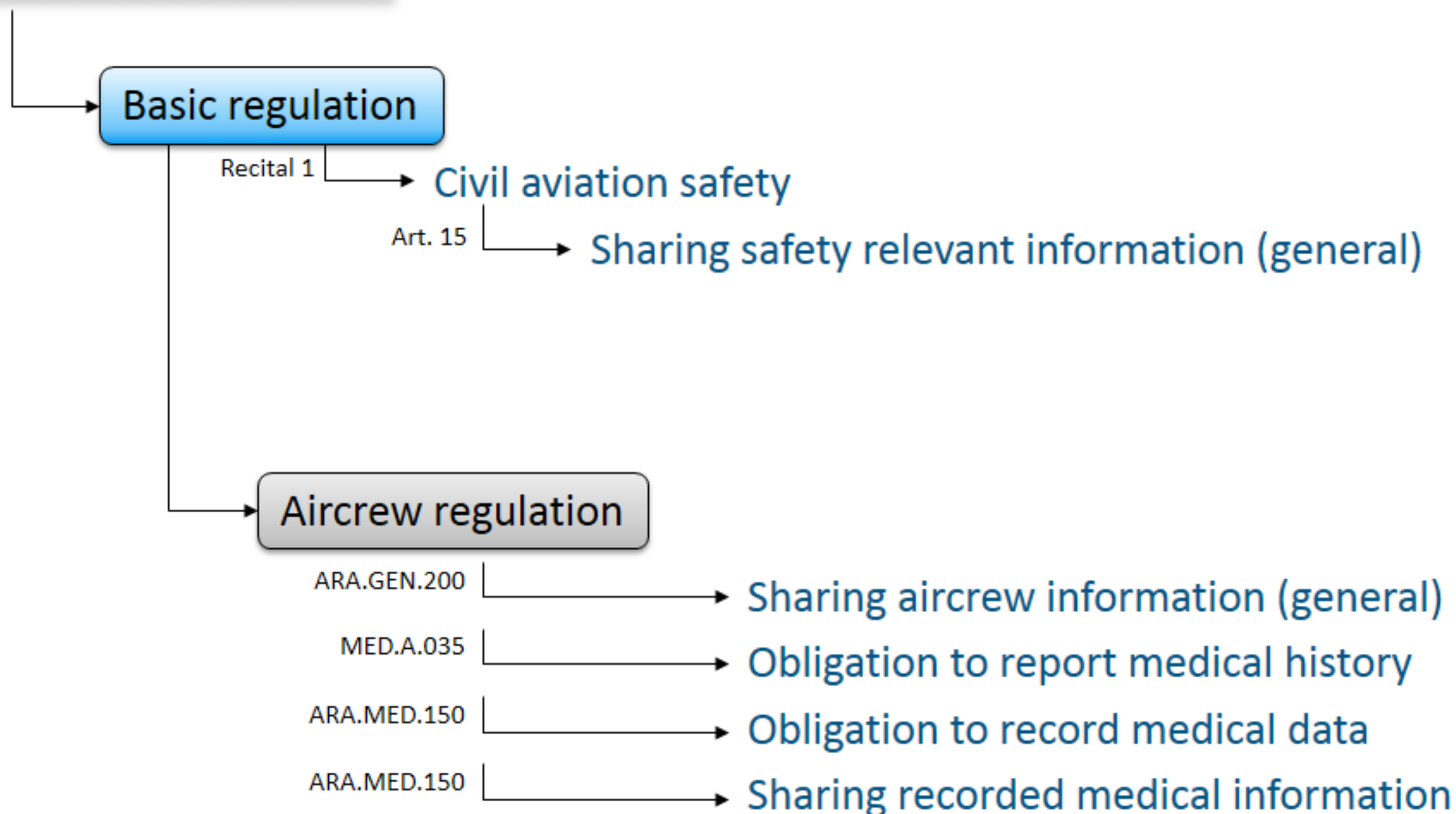
Whereas:

- (1) A **high** and **uniform** level of protection of the European citizen should at all times be ensured in civil aviation, by the adoption of common safety rules and by measures ensuring that products, persons and organisations in the Community comply with such rules and with those adopted to protect the environment. This should contribute to facilitating the free movement of goods, persons and organisations in the internal market.



Overview of the regulatory context

PUBLIC INTEREST





Overview of access levels

Access	Type of data	Example	Access level current situation	Reg. Ref.
Level 1	Personal administrative	<ul style="list-style-type: none"> Name; Date of birth; Nationality; ... 	<ol style="list-style-type: none"> Licensing administration Relevant AMEs/AeMCs Medical assessors of licensing authority Medical assessors of AME/AeMC 	<ul style="list-style-type: none"> 216/2008 → Art.15 1178/2011 → ARA.GEN.200 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150
Level 2	Personal medical certification	<ul style="list-style-type: none"> Date of the medical examination; Place of medical examination; Limitations medical certificate; ... 	<ol style="list-style-type: none"> Licensing administration Relevant AMEs/AeMCs Medical assessors of licensing authority Medical assessors of AME/AeMC 	<ul style="list-style-type: none"> 1178/2011 → ARA.GEN.200 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150
Level 3	Personal medical report/file	<ul style="list-style-type: none"> Blood/urine test results; Possible hormone disorders; Known sleep disorders; ... 	<ol style="list-style-type: none"> Relevant AMEs/AeMCs Medical assessors of licensing authority Medical assessors of AME/AeMC 	<ul style="list-style-type: none"> 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150

Access	Type of data	Example	Access level with EAMR	Reg. Ref.
Level 1	Personal administrative	<ul style="list-style-type: none"> Name; Date of birth; Nationality; ... 	<ol style="list-style-type: none"> Licensing administration Relevant AMEs/AeMCs Medical assessors of licensing authority Medical assessors of AME/AeMC 	<ul style="list-style-type: none"> 216/2008 → Art.15 1178/2011 → ARA.GEN.200 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150
Level 2	Personal medical certification	<ul style="list-style-type: none"> Date of the medical examination; Place of medical examination; Limitations medical certificate; ... 	<ol style="list-style-type: none"> Licensing administration Relevant AMEs/AeMCs → Limited Med. assess. licg authority → Limited Med. Assess. of AME/AeMC → Limited 	<ul style="list-style-type: none"> 1178/2011 → ARA.GEN.200 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150
Level 3	Personal medical report/file	<ul style="list-style-type: none"> Blood/urine test results; Possible hormone disorders; Known sleep disorders; ... 	<ol style="list-style-type: none"> Relevant AMEs/AeMCs Medical assessors of licensing authority Medical assessors of AME/AeMC 	<ul style="list-style-type: none"> 1178/2011 → MED.A.035 1178/2011 → ARA.MED.150



Need to declare

- Impact on aviation safety
 - Medical history → Part of the medical assessment

- **ARA.MED.150 Record-keeping**

.....
(c) For the purpose of aero-medical assessments and standardisation, aero-medical records shall be made available after written consent of the applicant/licence holder to:

- (1) an AeMC, AME or GMP for the purpose of completion of an aero-medical assessment;



Obligation to declare

➤ Impact on aviation safety

➤ Medical history → Part of the medical assessment

➤ **MED.A.035 Application for a medical certificate**

.....
(b) Applicants for a medical certificate shall provide the AeMC, AME or GMP as applicable, with:

.....
(2) a signed declaration:

- (i) of medical facts concerning their medical history;
- (ii) as to whether they have previously undergone an examination for a medical certificate and, if so, by whom and with what result;
- (iii) as to whether they have ever been assessed as unfit or had a medical certificate suspended or revoked.



Obligation to share data (general)

➤ Impact on aviation safety

➤ REGULATION (EC) No 216/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 February 2008

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Article 15

Information network

1. The Commission, the Agency and the national aviation authorities shall exchange any information available to them in the context of the application of this Regulation and its implementing rules. Entities entrusted with the investigation of civil aviation accidents and incidents, or with the analysis of occurrences, are entitled to access to that information.

➤ The **EAMR** will provide the means to comply with such a requirement



Obligation to share data (aircrew)

➤ Impact on aviation safety

➤ **ARA.GEN.200 Management system**

- (c) The competent authority shall establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned including on all findings raised and follow-up actions taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State, but certified by the competent authority of another Member State or the Agency.

➤ The **EAMR** will provide the means to comply with such requirements



Obligation to record data (aero-medical)

➤ Impact on aviation safety

➤ **ARA.MED.150 Record-keeping**

- (a) In addition to the records required in ARA.GEN.220, the competent authority shall include in its system of record-keeping details of aero-medical examinations and assessments submitted by AMEs, AeMCs or GMPs.

➤ The **EAMR** will contribute to ensure compliance with such requirements (medical certificate)



Obligation to share data (aero-medical)

➤ Impact on aviation safety

➤ **ARA.MED.150 Record-keeping**

- (c) For the purpose of aero-medical assessments and standardisation, aero-medical records shall be made available after written consent of the applicant/licence holder to:
 - (1) an AeMC, AME or GMP for the purpose of completion of an aero-medical assessment;
 - (2) a medical review board that may be established by the competent authority for secondary review of borderline cases;
 - (3) relevant medical specialists for the purpose of completion of an aero-medical assessment;
 - (4) the medical assessor of the competent authority of another Member State for the purpose of cooperative oversight;
 - (5) the applicant/licence holder concerned upon their written request; and
 - (6) after disidentification of the applicant/licence holder to the Agency for standardisation purposes.

➤ The **EAMR** will contribute to ensure compliance with such requirements (medical certificate)



Minimising data collection and processing

➤ From ARA.MED.130 (Medical certificate format)

➤ Personal data

1. Licensing authority
2. Surname & forename(s) of applicant
3. Date of birth of applicant
4. Nationality of applicant
5. Applicant identification document incorporating the applicant's photo: {such as a passport or ID card as to which identification is to be used}
6. Applicant's email address: {for notification purposes}

➤ Partial certificate data

7. The date of the medical examination or the date the medical examination was initiated, if process not completed
8. The place of medical examination
9. Any limitations on licence(s)/medical certificate held (No / Yes) → **details not needed**
10. Medical certificates **incomplete**, suspended or revoked by any licensing authority → **denied certificate will not be captured** → status will show certificate incomplete (could be for any administrative or medical reasons)
11. AME/AeMC or medical assessor who issued the medical certificate
12. Competent authority for the AME/AeMC or medical assessor who issued the medical certificate
13. Expiry date of the medical certificate
14. Date of issue of the medical certificate

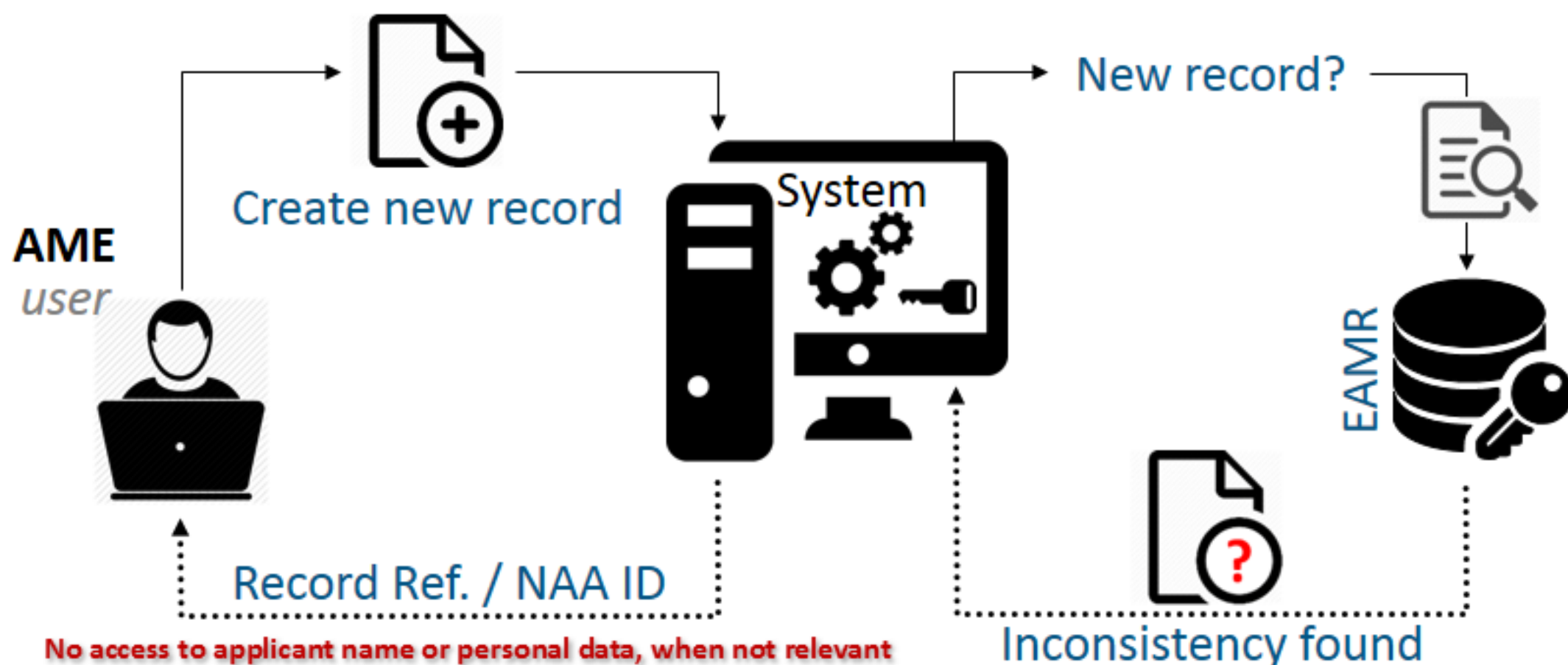


Access to information

- Current accessibility to data → unchanged → *According to ARA.MED.150(c)*
- On a strict need-to-know basis
- Example: → **limited** search function →

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*Consistency checks
performed **by the system**
not by users*





Role of EASA

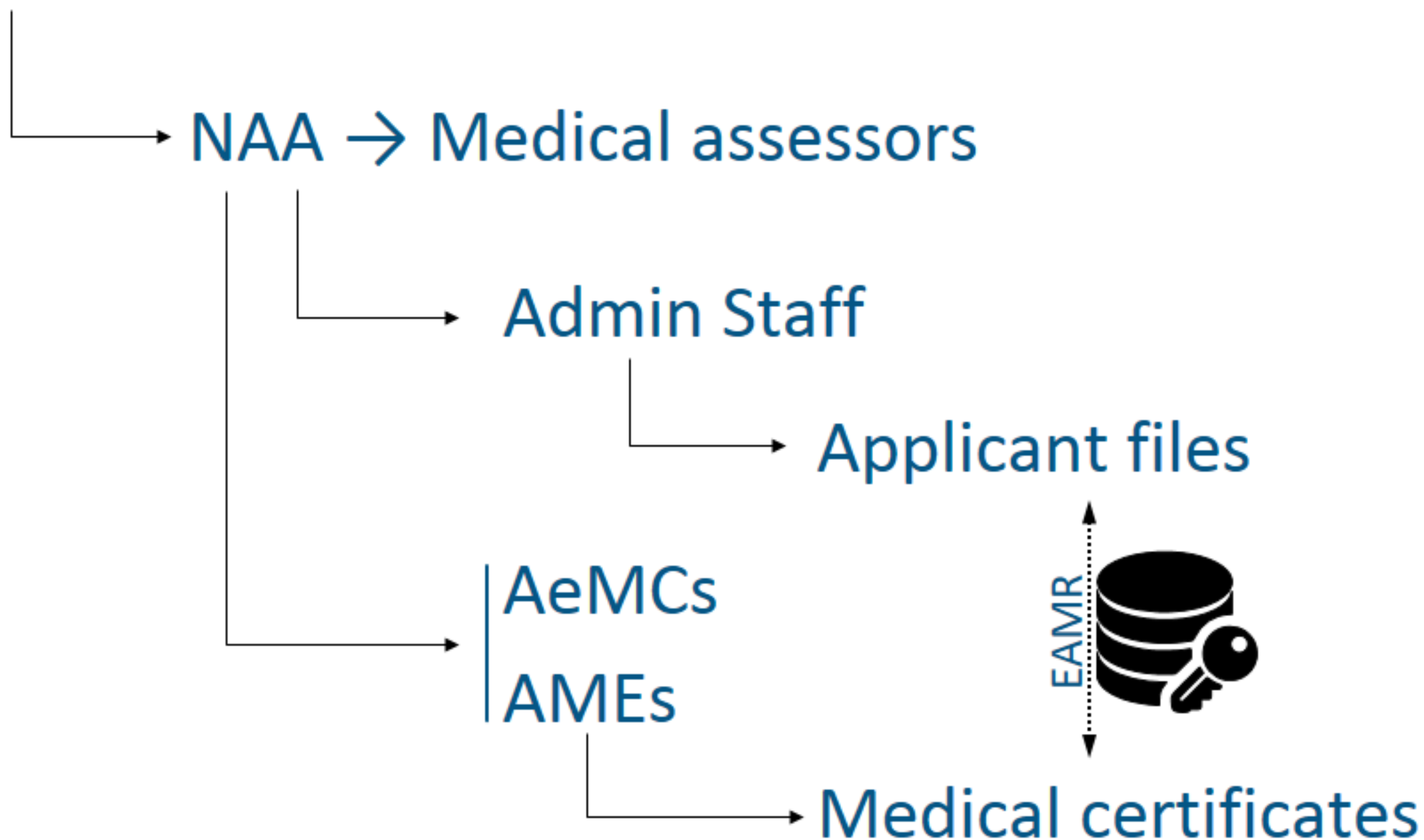


- Deliver tool.
- Initiate the process → List of NAAs to access EAMR.
- Provide a user guide.
- Manage the list of NAAs accessing the EAMR.
- Ensure continuous availability and serviceability of the system



Role of Member States

Member States





Role of the licensing authorities

With regard to applicants

- Each applicant for a Class 1 medical certificate → unique personal record
- Applicant record → before medical certificate data is entered.
- Manage the applicant's record
- Inform applicants about :
 - personal data recorded in the EAMR
 - rights and obligations



With regard to medical practitioners

- AME with privileges to issue Class 1 medical certificates and for each Medical Assessor (MA) → access EAMR → unique AME/MA identification record
 - name of the medical professional;
 - email of the professional {for login purposes}; and
 - unique identifier.
- Manage AME's/medical assessor's record



Role of the AMEs and medical assessors

With regard to applicants

- Identify applicant for a Class 1 medical certificate
- Medical examination initiated → medical certificate record initiated.
- Medical examination completed → record validated.
- Inform applicants about :
 - Certificate data recorded in the EAMR
 - Rights and obligations
- Refer to the relevant licensing authority if data in EAMR inconsistent or missing



Role of the AMEs and medical assessors

- To ensure proper use of EAMR, when performing oversight or in the case of referral, proceed according to basic regulation and implementing rules and in particular:
 - MED.A.025 MED.A.040 MED.A.050
 - MED.B.001 MED.B.005 ARA.MED.125
 - ARA.MED.150 and ARA.MED.245
- Inform applicants about
 - data recorded in the EAMR
 - rights and obligations
- Exercise oversight on AMEs under their responsibility as regards the use of the EAMR.



Role of applicant for Class 1 Med. Certif.

- Contact licensing authority before applying for the first Class 1 medical certificate → This also applies to persons currently holding a Class 1 medical certificate before applying for revalidation/renewal.
- Check correctness of all data recorded when notified by the system, the licensing authority, the AME or the medical assessor.
- Inform the relevant licensing authority, AME or medical assessor about any incorrect, incomplete or inaccurate information recorded based on data received through the notification process.



Essential functionalities of the EAMR (1)

- Notify the user of any plausible suspicion of non-declaration or inconsistency by identifying:
 - the record (not the individual person) and
 - the competent authority to be contacted to clarify the situation.
- Track changes to all records → adequate traceability.
- Systematically notify following persons of any creation, change or deletion of data recorded, related to their identity or medical certificates.
 - Applicants for a Class 1 medical certificate
 - AMEs
 - Medical Assessors
- Regularly run consistency checks to identify possible dual applicant records, dual certificate records or inconsistent records. Appropriate notifications will be generated accordingly.



Essential functionalities of the EAMR (2)

- Generate notifications/warnings indicating dormant certificates or applicant files.
- The system will allow and will track transfers from one licensing authority to another → FCL.015.
- Track suspended, revoked, corrected, reissued, renewed and valid certificates,
- Generate reports to facilitate
 - Oversight of AMEs → Regulation (EC) No 216/2008 and its implementing rules.
 - Standardisation of NAAs under the provision of regulation.
- The system will allow for interoperability with most used databases across the Member States. The objective is to avoid as much as possible duplication of data and undue administrative burden

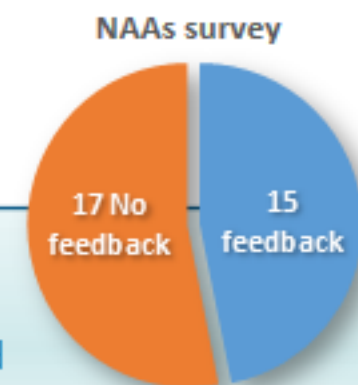
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Feedback on existing medical databases

NAAAs existing tools feedback (15 out of 32)

As of 24 Nov. 2015



► Record tracking	<ul style="list-style-type: none"> ► Computer based (9) ► Paper based (2) ► Mixt (4) - unclear process, further investigation required 	
► Tool <i>(from the 9 computer based)</i>	<ul style="list-style-type: none"> ► EMPIC (3) ► Own tool (6) 	
► Technology <i>(overall)</i>	<ul style="list-style-type: none"> ► SQL/Visual Basic ► Java ► Oracle + Access ► IMAP-POP3 ► C++, Interbase 	<ul style="list-style-type: none"> ► Client Server ► .NET ► JSP ► Delphi
► Access <i>(from the 9 computer based)</i>	<ul style="list-style-type: none"> ► Within the organization (2) ► Within/Outside the organization (7) 	
► Data exposure <i>(overall)</i>	<ul style="list-style-type: none"> ► SQL ► Web services ► Empic applications ► Web interface 	<ul style="list-style-type: none"> ► MSA API ► REST API ► Data base/INTERBASE ► None (2)
► Data export <i>(overall)</i>	<ul style="list-style-type: none"> ► CSV (8) ► PDF (3) ► XML 	<ul style="list-style-type: none"> ► TXT ► MDB ► EML



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Thank you



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