EMA
EUROPEAN MEDICINES AGENCY

# Compliance Monitoring based on reporting timelines

## Monthly Automated Reports

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20th industry stakeholder platform - operation of European Union (EU) pharmacovigilance

13th November 2025

# Agenda

- Overview
- Rationale
- Key Concepts
- Examples
- Compliance Measurement
- Reports excluded from the reporting compliance
- Different time zones
- Summary

# Compliance Notifications

- **What?** Up to three ICSR compliance reports (for 7/15/90-day timelines), each in separate notification emails submitted through automated reports generated by EVDAS. Within each of these compliance reports are 3 sub-reports constituting 5 outputs altogether including tables and barcharts.
- **Who?** QPPVs/RPs of all sender organisations will be automatically contacted (For Sep/Oct/Nov only top 20 MAHs who sent the most ICSRs to EV & NCAs)
- **How?** By email from donotreply@ema.europa.eu
- **When?** Launched on Wednesday 3rd September 2025
- **How often?** Every month with compliance reports covering the submissions made to EV the previous month. Next notification will be on 29 Oct 2025

# But why?

1. To ensure compliance with the legal basis:
   - Directive 2001/83/EC, Article 107(3) – MAHs 15/90 days
   - Directive 2001/83/EC, Article 107(a)(4) – NCAs 15/90 days
   - Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, Article 42(2) Sponsors 7/15 days
   - Commission Implementing Regulation (EU) No 520/2012 Articles 26(2)(a) and 25(1)(f) of chapter IV
   - Regulation (EC) No 762/2004, Article 24(3) SOPs & Article 11(1)c -quality system
2. To complement your own Quality System and to assist with timely root cause analysis
3. To quickly visualise compliance and comprehend the volume of non-compliant cases
4. To understand the types of cases/timelines that are non-compliant e.g. SUSARs or post marketing cases 7/15/90-day timelines

# Who receives them?

- The compliance reports for a given organization are defined by the batch sender identifier (N.1.3). This data element identifies the origin of the ICSR reports (creator of ICH ICSR batch file), e.g. company name or regulatory authority. The identifier is unique to the receiver. This is the registered organisation ID.
- So if an EV Head Quarter profile has multiple affiliates and virtual affiliates with their own organisation IDs, each sender (which could be an affiliate or a virtual affiliate) will each receive their own set of reports.

# How do the ICSR submissions get divided into three potential ICSR compliance reports?

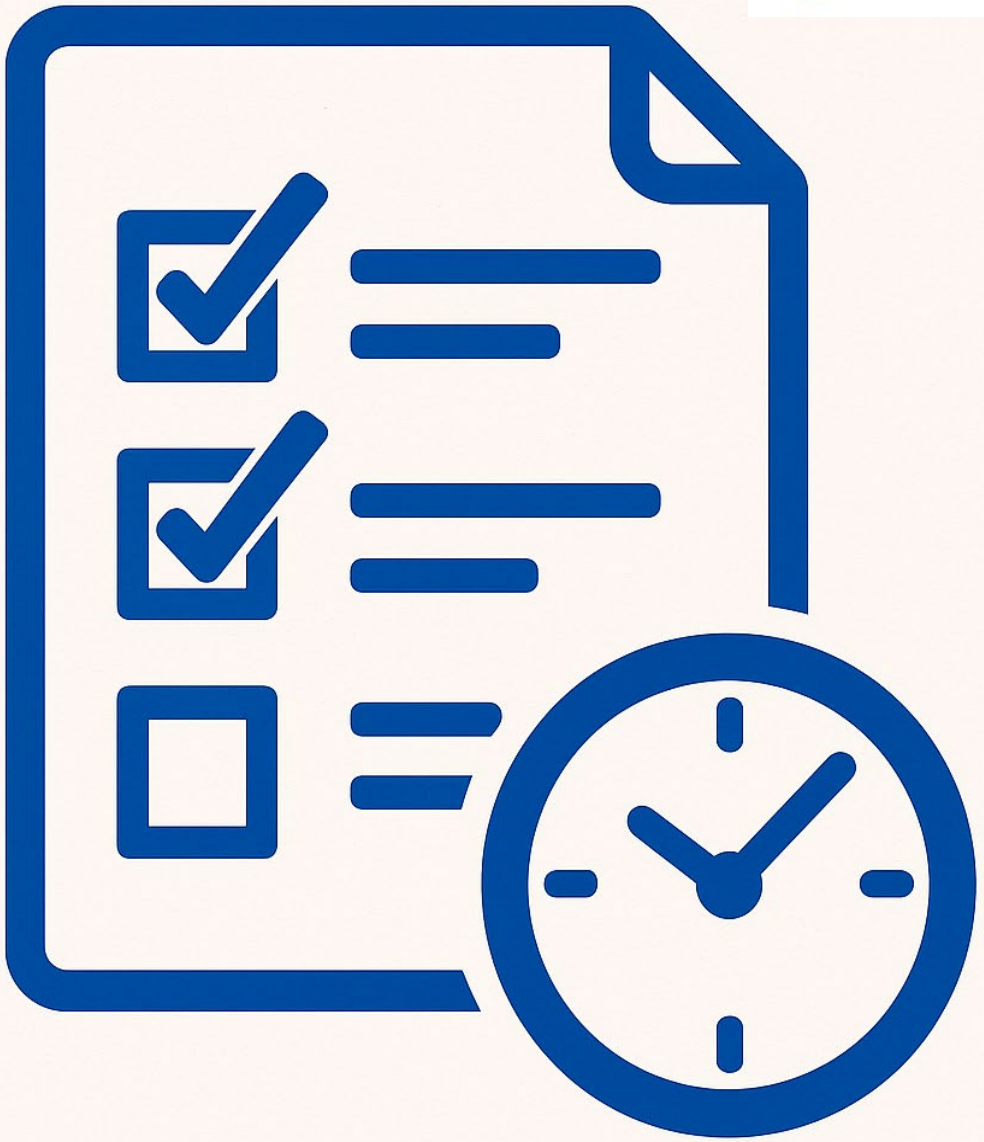
- **EVPM 15 days**
  - If **any** of the **seriousness criteria** at the **reaction level** are selected as **“true”** and the case is submitted EVPM
- **EVPM 90 days**
  - If **no seriousness criteria** are selected as **“true”** at the reaction level (NI or no selected) and the case is submitted to EVPM
- **EVCTM 7/15 days**
  - **Serious fatal or life-threatening ICSRs (7 days)**
    - **at least one suspected reaction** has the seriousness criteria "**Results in Death**" or "**Life-threatening**" selected as “true”
      - A **suspected reaction** has at least one iteration of the section "Drug-reaction(s)/events(s) matrix" (ICH E2B(R3) G.k.9) populated with:
        "1“for "EU **Method** of Assessment" (ICH E2B(R3) G.k.9.i.2.r.2.EU.1)
        AND
        "1“ (**reasonable possibility**) for "EU **Result** of Assessment" (ICH E2B(R3) G.k.9.i.2.r.3.EU.1)
  - **Serious not fatal and not life-threatening ICSRs (15 days)**
    - **no suspected reaction** has the seriousness criteria "**Results in Death**" or "**Life-threatening**" (ICH E2B(R3) E.i.3.2a or E.i.3.2b) selected as “True“; but one or more of of the other seriousness criteria selected as “true”

# What exactly is in each compliance report?

- **Sub-Report 1**: "**Listing of Non-Compliant Individual Cases Submitted to EVCTM/EVPM Outside 7/15, 15 or 90 Days Reporting Period".**
- Lists ICSRs submitted to EVCTM/EVPM beyond the 7/15, 15 or 90 days reporting period for the concerned month and year.
- It is in table format and a column entitled 'reporting time in days' tells you the exact day it was submitted on e.g. day 16, counted from day 0.
- **Sub-Report 2: "Overview of ICSRs Submission to EVCTM/EVPM Within/Outside 7/15, 15 or 90 Days Reporting Period".**
- This report provides an overview of the number of ICSRs submitted to EVCTM/EVPM within or outside the 7/15, 15 or 90 days reporting period for the concerned month and year.
- There are 2 outputs for this overview – a table and a horizontal barchart displaying the percentage and volume of cases within or outside the timelines.
- **Sub-Report 3: "Overview of Submission Timelines of ICSRs to EVCTM/EVPM: 7/15, 15 or 90 Days Reporting Period".**
- This report provides an overview of the number of ICSRs submitted to EVCTM/EVPM for the concerned month and year in relation to their reporting timelines. It shows both initials and follow up and the 'reporting time in days' tells you the exact day it was submitted on e.g. day 6, counted from day 0.
- For SUSARs it shows if the submission was a life-threatening/fatal cases or a non-life-threatening/fatal SUASR.



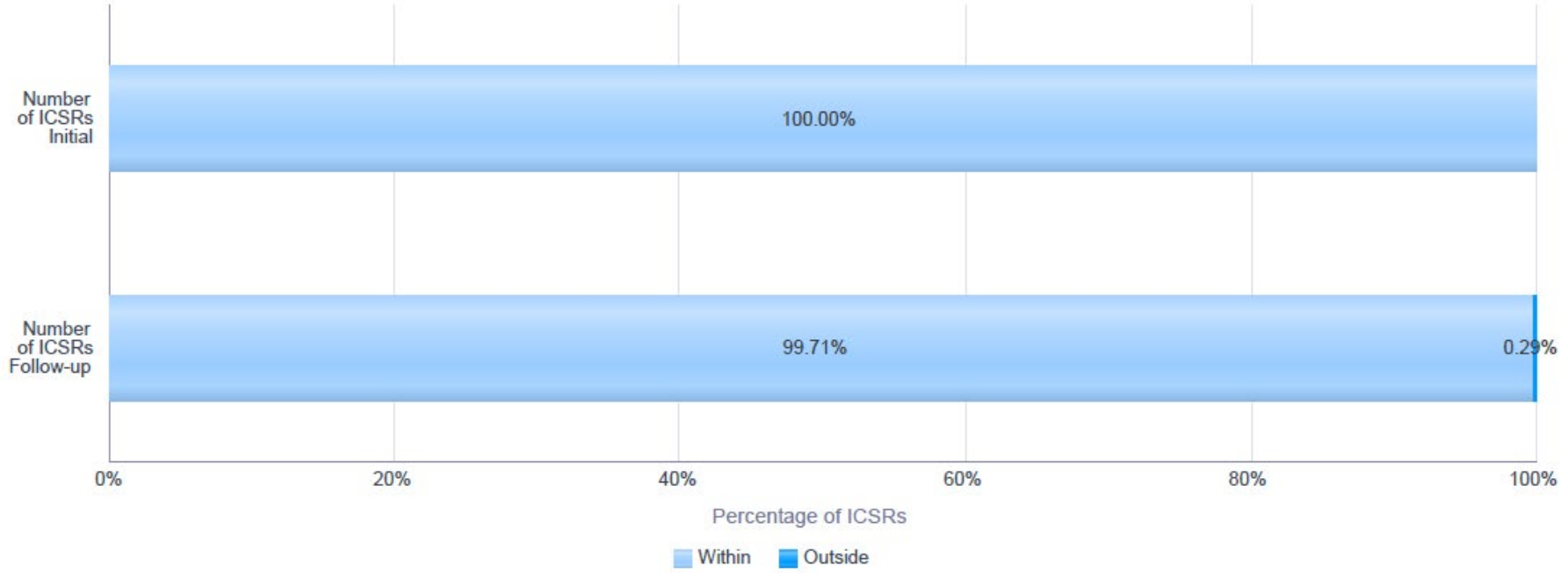
- There are 2 outputs for this overview – a table and a barchart.



# Example: MLM Service – Sub-Report 1

**Organisation Sender ID: MLMSERVICE**
**Organisation Name: EMA MLMSERVICE**

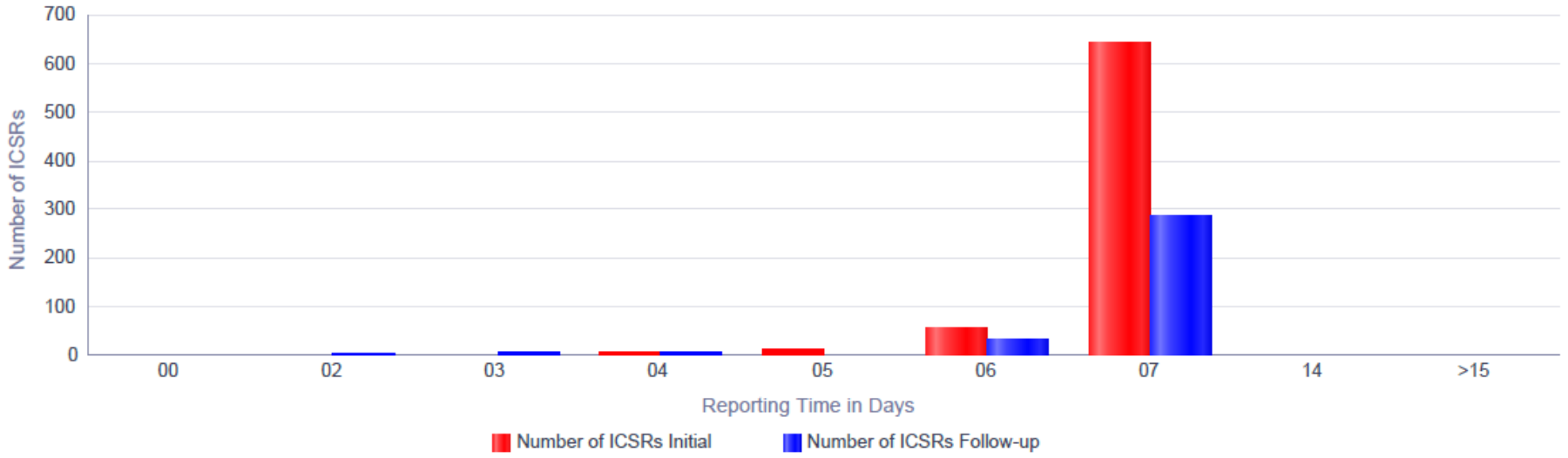
**Overview of ICSRs Submission to EVPM Within/Outside**
**15 Days Reporting Period – August 2025**



# Example: MLM Service – Sub-Report 2

**Organisation Sender ID: MLMSERVICE**
**Organisation Name: EMA MLMSERVICE**

**Overview of Submission Timelines of ICSRs to EVPM: 15 Days Reporting Period – August 2025**



# Example: MLM Service – Sub-Report 3

**Organisation Sender ID: MLMSERVICE**
**Organisation Name: EMA MLMSERVICE**

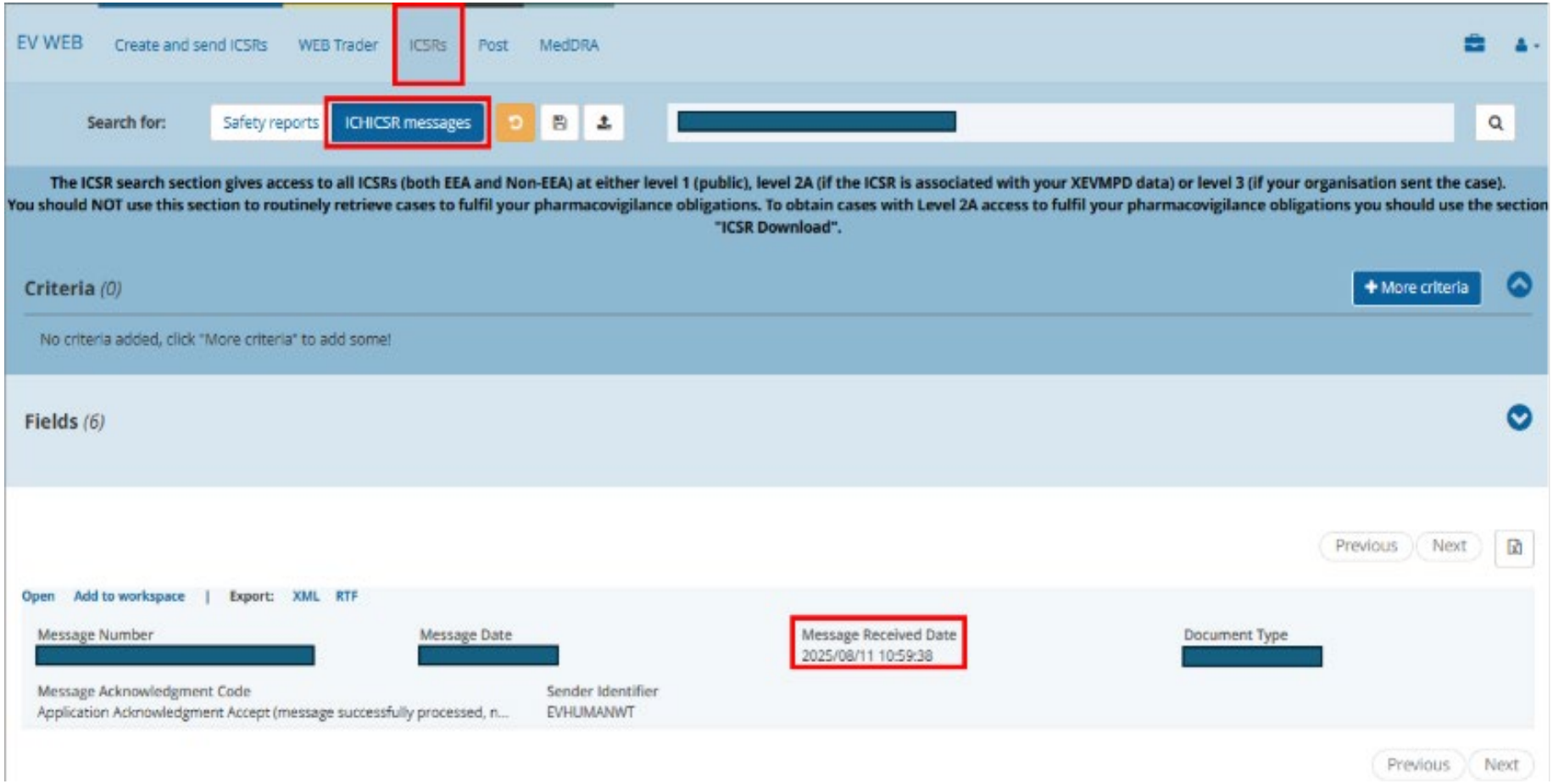
**Overview of Submission Timelines of ICSRs to EVPM: 15 Days Reporting Period – August 2025**

| Reporting Time in Days | Number of ICSRs - Initial | Number of ICSRs - Follow-up |
|---|---|---|
| 00 | 0 | 0 |
| 02 | 0 | 6 |
| 03 | 0 | 8 |
| 04 | 9 | 8 |
| 05 | 12 | 3 |
| 06 | 55 | 32 |
| 07 | 642 | 285 |
| 14 | 1 | 0 |
| >15 | 0 | 1 |

# How is compliance measured?

The compliance is calculated per each ICSR as the difference between the data element "Date (of receipt) of most recent information for this report" (ICH E2B(R3) C.1.5) and the "EudraVigilance Gateway date“.

This image shows how to find the gateway date in EVWEB



# Are any ICSRs excluded from the compliance notification?

Yes:

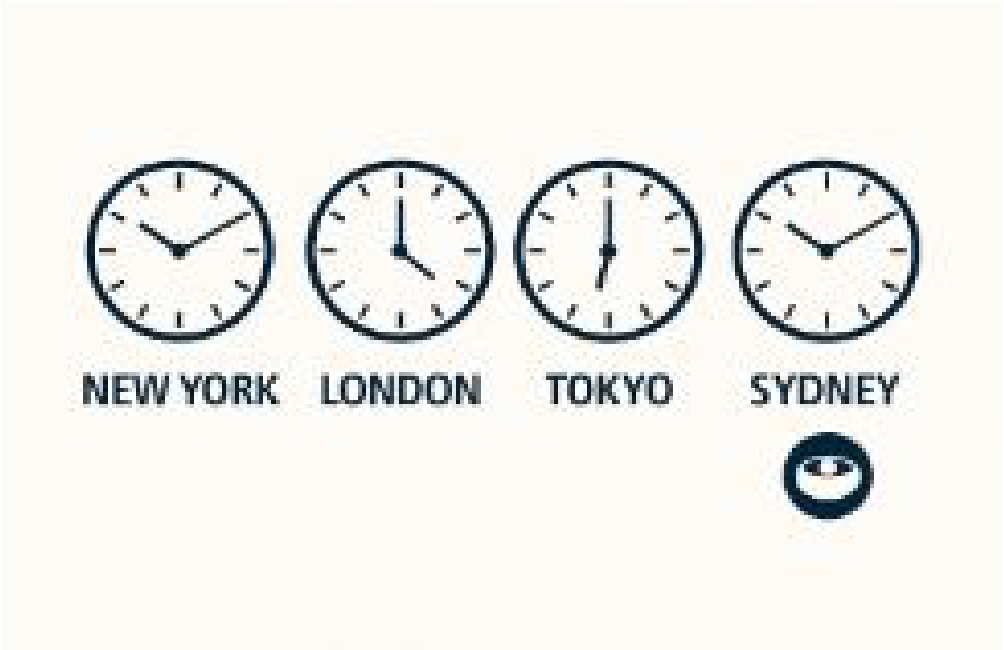
1. "**Error reports":** ICSRs for which the sender received an acknowledgement code "CR" in data element "Acknowledgment Code for a ICSR Message" (ICH E2B(R3) ACK.B.r.6);

2. "**Nullification reports**": ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "1";

3. "**Amendment reports**": ICSRs where the data element "Report Nullification/Amendment" (ICH E2B(R3) C.1.11.1) is populated with "2".

# What about different time zones?

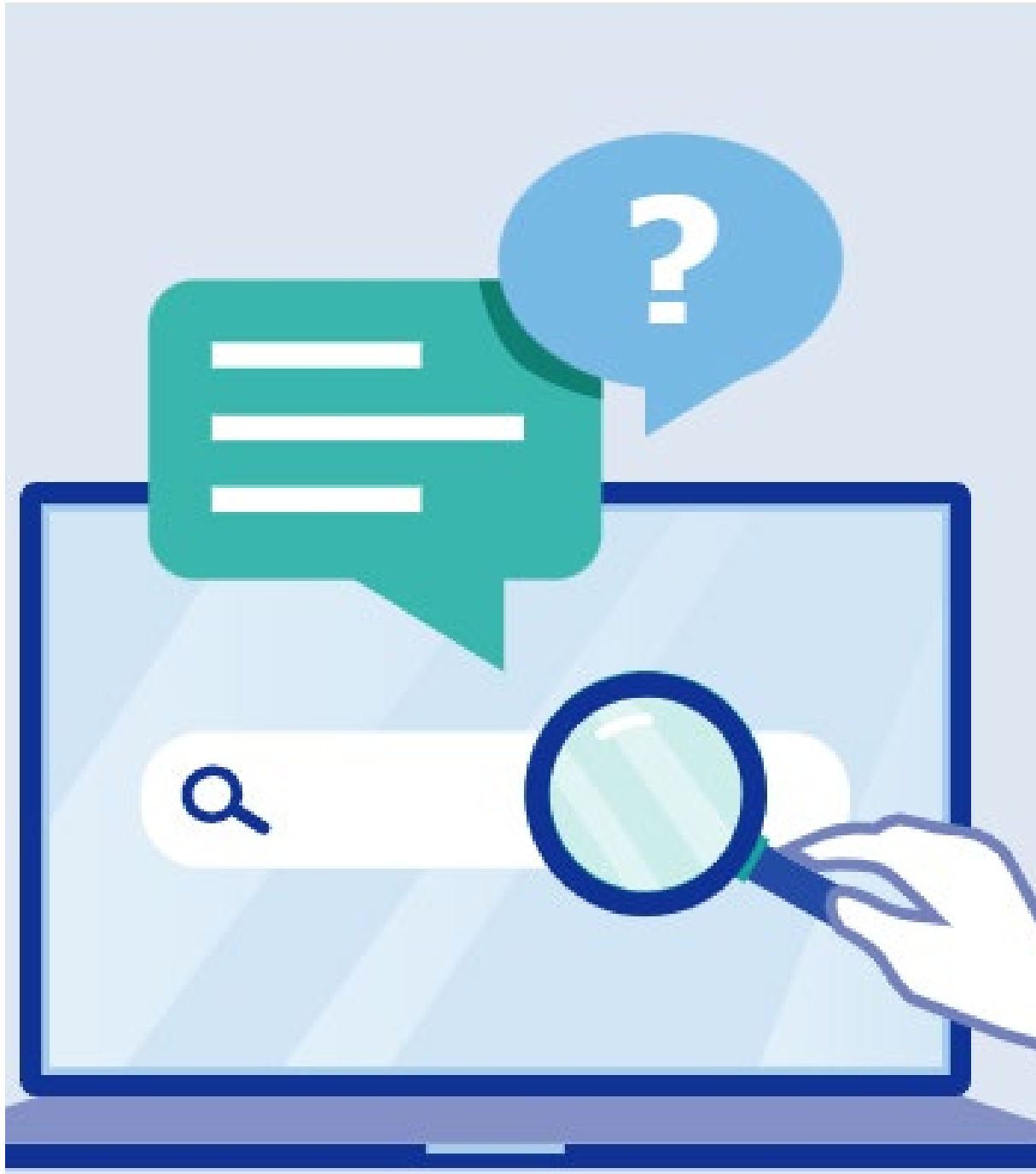
- Please be mindful of potential time zone differences when submitting a case to EV, as close of business in your location could mean the deadline has already passed for EMA.
- The official EV gateway date should be checked
- In ICSR submissions you can include the time_zone from which you are making your submissions.
- We allow 12h (+12:00) exceeding the current CE(S)T time.
- For examples if you are in the UTC +12 time zone and I submit by case to EV at 11:55am on day 16 then it will be on time (if i include the time offset?)



# Questions?

- Please see the FAQ section of the Compliance notifications explanation and Q&A document

- If you still have a question, then you should submit it via the EMA Service Desk: ICSR compliance notification question form



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# Thank you

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