



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Highlights of the EMA MLM Stakeholder survey

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8<sup>th</sup> Industry stakeholder platform





# Outline

## Survey

- Overview
- Responses

Service improvements

Independent audit update

Workshop

## Survey overview

MLM satisfaction survey ran from 29 February to 21 March

- Two surveys were run in parallel: one for MAHs & one for NCAs
  - 1,618 individual QPPVs were contacted (representing 2,533 MAHs)
    - 253 replies
      - Marketing Authorisation Holder: 198
      - Contract Research Organisation: 38
      - Other (please specify): 17
  - 31 NCAs were contacted
    - 6 respondents from 5 NCAs
- All questions had multiple choice options plus optional text boxes



## MAH Survey responses

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Summary of responses

Detailed replies at end of presentation

## Summary of replies

### Screening & reviewing

- 83% agree that “MLM Service staff are proficient in the screening and review of literature”
- 65% agree that the tracking sheets contain the information they need

### Case processing

- 67% agree the cases are reported in a timely manner
- 73% agree the ICSRs are of good quality
- 73% agree the quality has improved since launch phase

### Business process adaptation

- 89% of MAHs have adapted their business processes to no longer submit the ICSRs resulting from the MLM Service both to EV and to the concerned NCA in the EEA

## Summary of replies

### Service desk

- 90% of MAHs know that if they have questions, comments or reports of errors or duplication they should contact [mlm@ema.europa.eu](mailto:mlm@ema.europa.eu)
- 71% agree that they receive good quality replies from the service desk
- 86% agree that the MLM Service desk responses are provided in a timely manner
- 86% agree that the webinars are useful
- 90% want the webinars to continue throughout 2016

### Overall perception

- 69% agree that their perception of the MLM Service has improved since the completion of the launch phase (September)

## MAH responses overview

Most MAHs find the service to be of good quality

- All questions regarding quality received 65 – 83% favourable responses

Most MAHs think the service delivers in a timely manner

- All questions regarding timeliness received 67-86% favourable responses

The vast majority of MAHs (~90%) have adapted their business practices

There are still areas for significant improvement

- Most notably ICSR data quality

Most MAHs think the service has improved since the launch phase



## NCA Survey responses

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Summary of responses

Detailed replies at end of presentation

## Summary of replies

### Receipt of ICSRs

- 83% of NCAs were successfully receiving the ICSRs
  - One had experienced a problem when a case was not correctly received

### Business process adaptation

- 100% of respondents had adapted their business processes to not resubmit MLM ICSRs to EV
- 83% of respondents had adapted their business processes to no longer provide MLM ICSRs to MAHs

### Duplicates from industry

- 83% had noticed some reduction in the number of duplicates as a result
- 67% had noticed either a significant or total reduction in the number of duplicates



## Survey summary

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## Survey summary

Most MAHs & NCAs are already realising some benefits from the MLM Service

There are still significant areas to improve, notably ICSR quality

Improvements have been made and more are in progress

**In time all should benefit from the MLM Service**



## Service improvements

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## Changes that have already been made in response to survey

All responses & requests for changes have been reviewed & assessed

The following improvements have already been made:

- Non-serious non-EEA cases included in the service
- Day zero for follow-ups is included in tracking sheet
- Sum\_ICSR tracking sheet now includes potential ICSRs that are downgraded (so no need to switch between sheets to find apparently missing cases)
- MLM Service pre-submission duplicate detection process enhanced

## Changes to be made in response to survey

The following improvements are either in progress or are planned:

- Export manager will be enhanced in future release of EV
- Exclusion criteria terms in spreadsheet to be amended to make them more obviously match inclusion-exclusion criteria document
- Inclusion & exclusion document being updated to provide direct & precise link to exclusion criteria
- Discussions ongoing with other regulators to harmonise day zero
- ICSR data quality is subject to continuous improvement & additional resources have been put into QC & improvements

## Other service improvements already made

- Searching:
  - Search strategy significantly improved
- Screening & reviewing:
  - Tracking sheets improved with extra fields & functionality as requested by MAHs
  - Cumulative tracking sheets added to aid reconciliation & PSUR searches
  - New processes & checks to prevent articles waiting as potential for too long
- Creation & transmission of ICSRs
  - 7-day reporting compliance improved
  - Data quality improved
  - EV upgraded to ensure swifter processing of ICSRs



## Other service improvements already made

- Helpdesk:
  - Technical problems solved & answers all provided within 2 days
- Documentation:
  - Q&As updated
  - User manual updated
  - Detailed guide updated



# Independent audit update

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Current status & next steps

## Independent Audit Update

- Independent audit fieldwork conducted Jan & Feb 2016
- Interim report provided to Agency
- Improvement Action Plans provided to auditors
- Follow-up fieldwork to be conducted mid-August
- Final audit report expected to be delivered to EMA late August/Early September
- Report to be published shortly after on EMA MLM webpage
  - Communication will be sent to all affected MAHs to inform them when it is published



## EMA-Industry workshop on scope of MLM Service

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## EMA-Industry workshop on scope of MLM Service

- It is clear from your responses to the surveys that the service does not cover sufficient activities to replace MAH literature searching activities
- Therefore the aim of reducing the duplication of effort & administrative burden on industry may not be possible with the service as it currently is
- Therefore the EMA will investigate the possibility of increasing the scope of the service
- To better understand industry's needs, we will hold a joint EMA-Industry workshop at the EMA in mid-September

## EMA-Industry workshop on scope of MLM Service

- There will be up to 80 places available on a first-come first-served basis
  - If we are over-subscribed, we will limit the numbers from each organisation to try and get the greatest plurality of voices possible & understand each different type of stakeholder's requirements (originators, generics, multinationals, SMEs, CROs)
  - Webinar & tele-participation will also be available
- The purpose will be for the EMA to listen, learn and fully understand what literature searching activities MAHs need to do
- Following this, the EMA and our contractors will review what changes can be made, considering procurement rules & budgetary concerns & then present a proposal to the participants & to industry generally via a short online survey



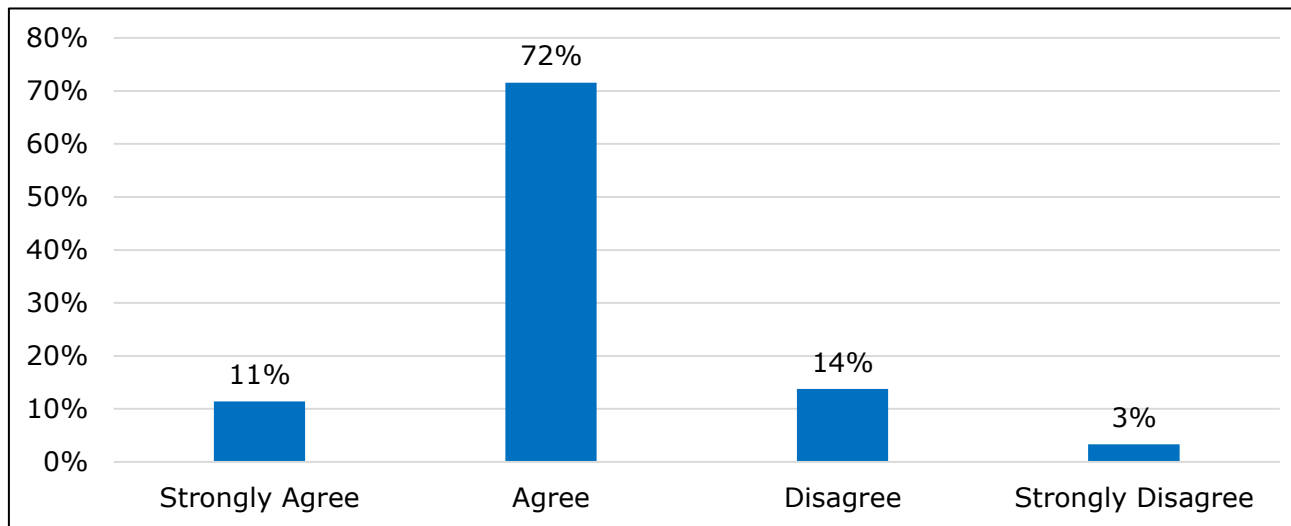


## MAH survey Detailed responses

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Full data on the reply to each question

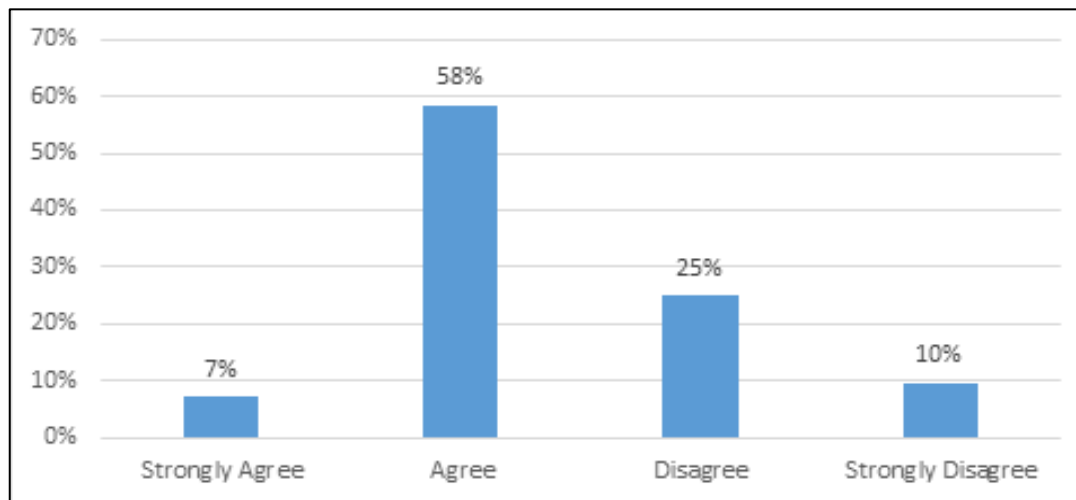
# MLM Service staff are proficient in the screening and review of literature



Respondents commented on:

- Timeliness of MLM Service
- Missing cases
- Interpretation of results
- Poor quality
- Duplicate cases
- Product scope of MLM Service

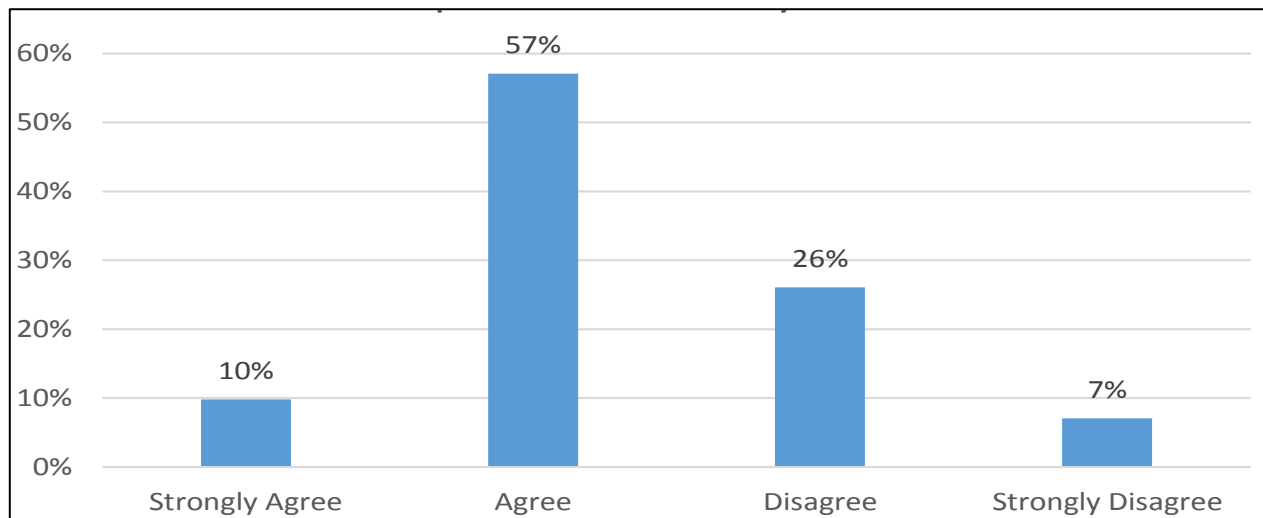
# I find the sum\_ICSRs and sum\_screen tracking sheets contain the information I need



Respondents commented on:

- Spreadsheet configuration is not user-friendly (information spread across worksheets)
- Need clarity on reasons for exclusion
- Too much unnecessary information / Simplify the tables
- Recommend to include day zero for Follow-up information in sum\_ICSRs
- Include Correction performed date for ICSRs for internal quality errors

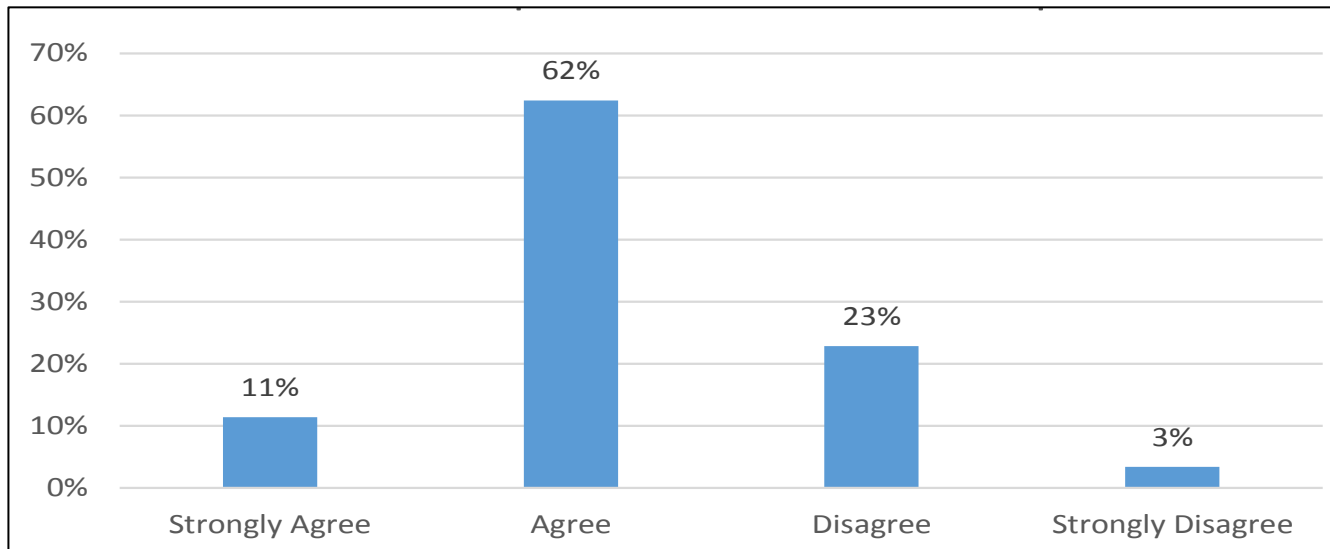
# The MLM ICSRs (serious cases and non-serious) are reported in a timely manner



## Respondents commented on:

- For international reporting obligations the MLM timelines for case processing are too long
- Issues with Export Manager
- There is a lot of variation in reporting times
- Cases identified in PubMed are not indexed in Embase quick enough
- Timelines for ICSR generation by EMA MLM are longer than those in agreements with PV business partners

# The quality of the ICSRs generated by the MLM Service has improved since the launch phase

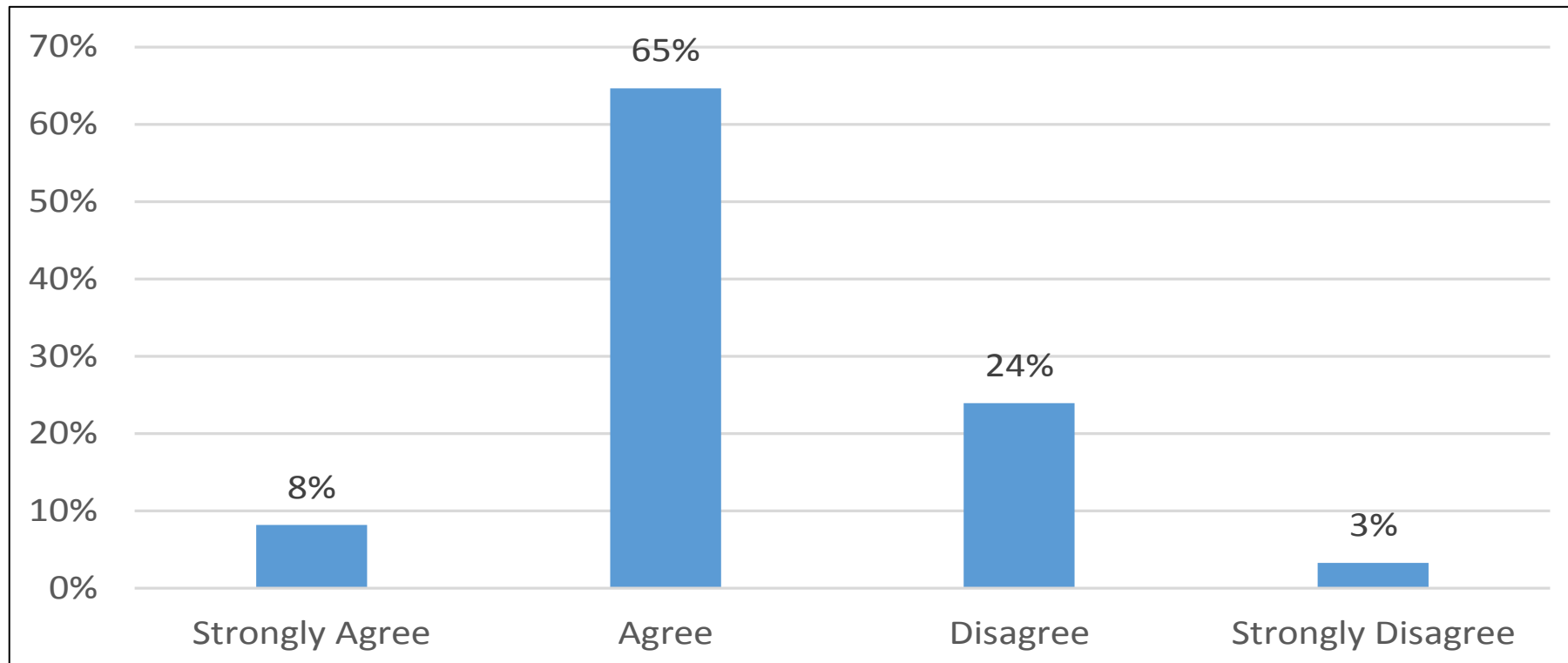


Respondents commented on:

- Data completeness and quality needs to be addressed
- Assessment of seriousness and causality still posing issues
- Include medical history and test in the structured part for completeness



## The MLM ICSRs created by MLM Service are of good quality



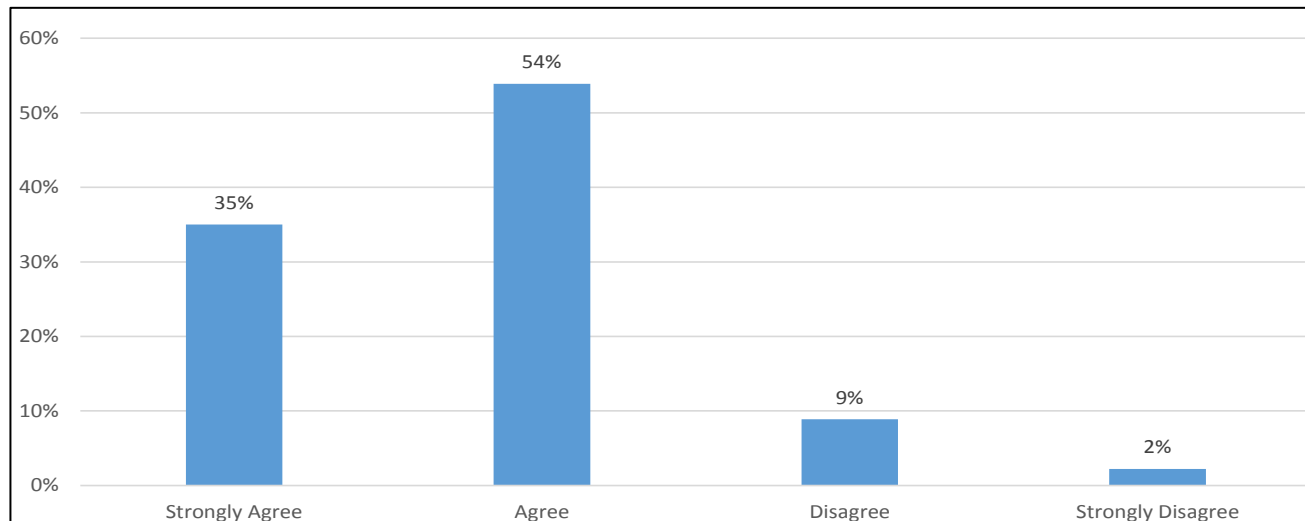
## The MLM ICSRs created by MLM Service are of good quality

Respondents commented on:

- Quality is acceptable but we do not always agree with the approach
- MLM ICSR narratives are too succinct
- MLM ICSR narratives contain irrelevant information
- Product identification/Drug Coding quality issues
- Events incorrectly attributed to some drugs
- Missing information in ICSRs
- English to be improved
- Inconsistencies regarding medical review
- Delayed corrections



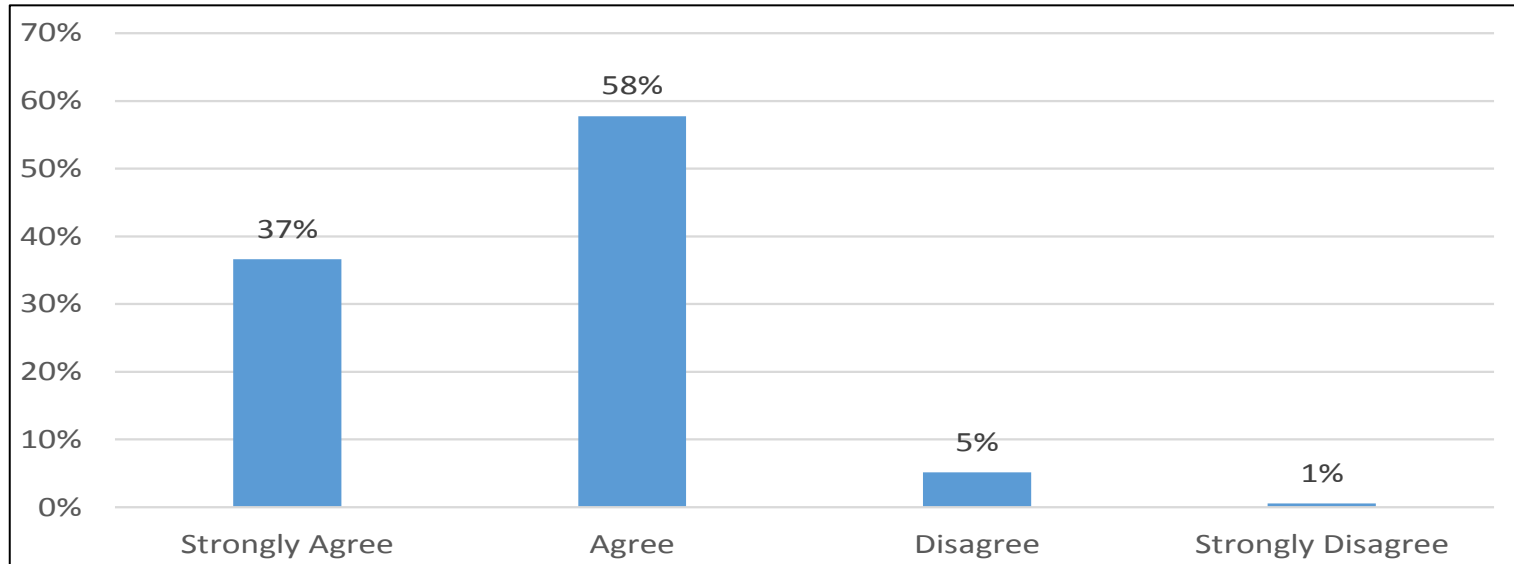
My organisation's business processes have been adapted to no longer submit the ICSRs resulting from the MLM Service both to EV and to the concerned NCA in the EEA



Respondents commented on:

- We have incorporated this into our literature search SOPs
- A lot of additional effort is caused by the MLM service and duplicate literature screening processes
- Timeliness of MLM services impacts our ability

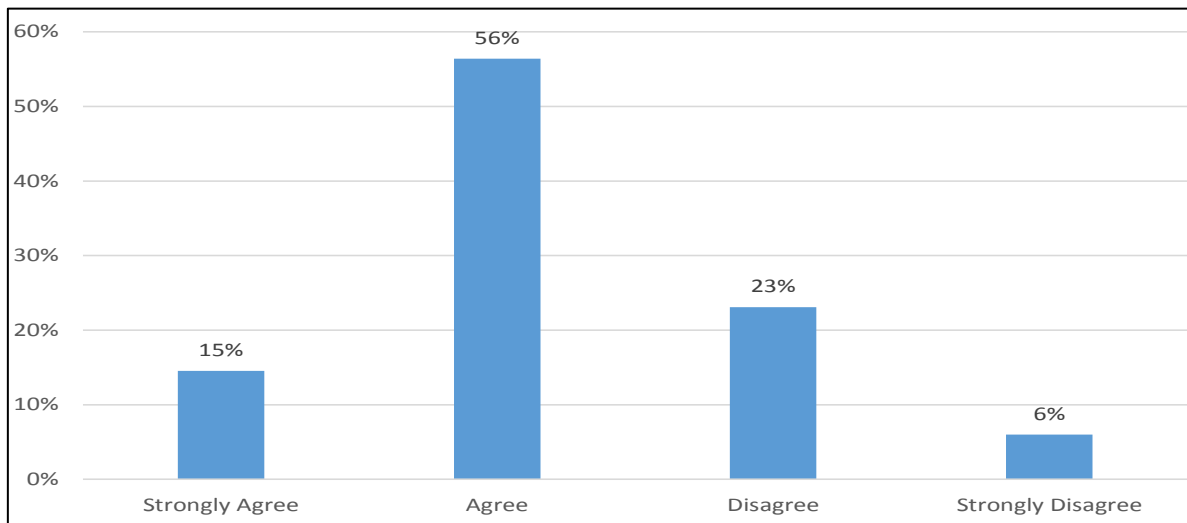
I know that if I have questions, comments or reports of errors or duplication I should contact [mlm@ema.europa.eu](mailto:mlm@ema.europa.eu)



Respondents commented on :

- Current tools are not useful for checking duplicates
- Answers have not been received for all queries
- Despite notifying the helpdesk duplicate cases are being created

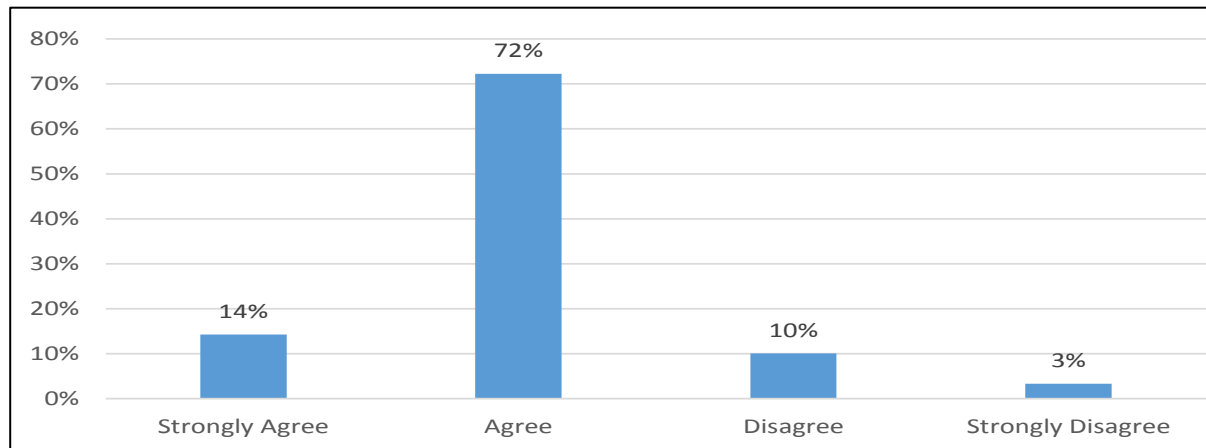
## I receive good quality replies from MLM Service desk



Respondents commented on :

- General responses to specific questions
- Responses not received/Follow up responses not received
- Timeliness of MLM Service replies

Since the full resolution of the technical issues in late September, the MLM Service desk responses are provided in a timely manner



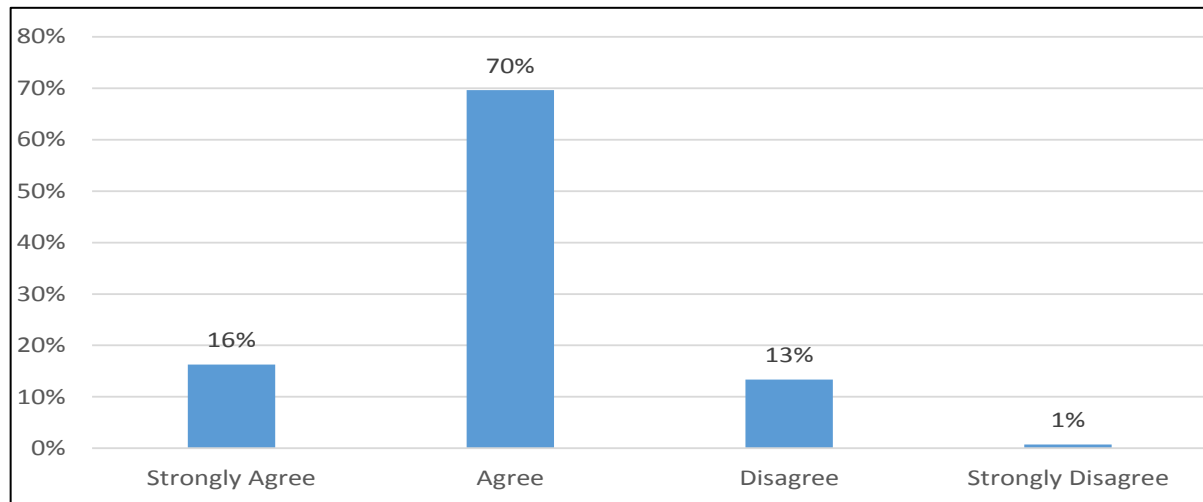
Respondents commented on :

- Timely manner is not sufficient, quality and relevance is needed first
- Response not received
- Timeliness of MLM Service replies
- If the question relates to a serious case which may require reporting outside of the EU, a turnaround of no more than 2 working days would be appreciated

# The MLM Service support webinars are a useful platform to attain additional information and ask questions



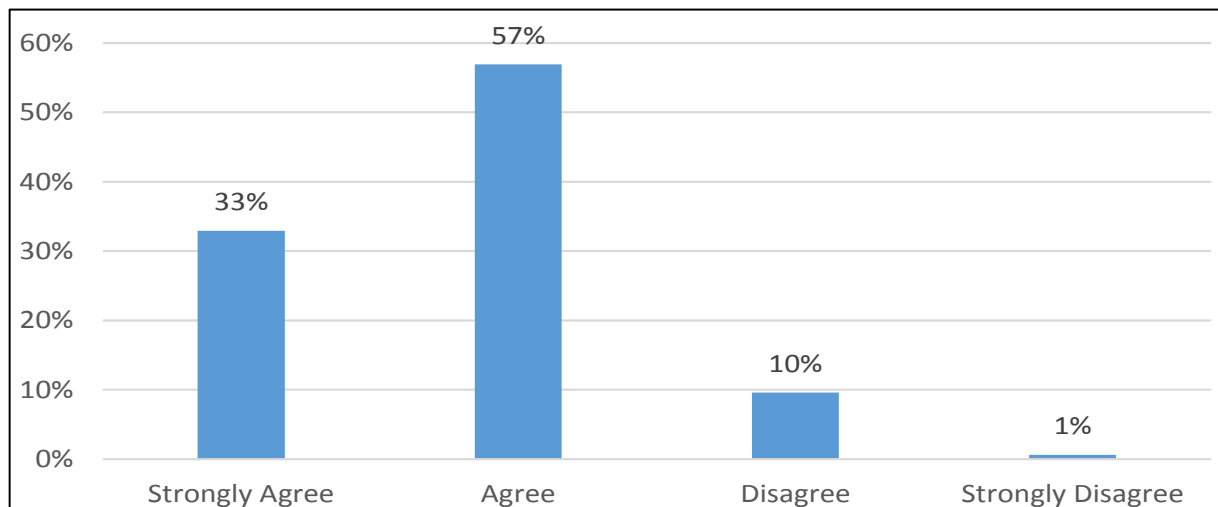
EUROPEAN MEDICINES AGENCY



Respondents commented on :

- They were useful originally but less so now
- Focus has been on EMA point of view and not MAHs
- Uncertainty over webinar schedule
- Invitation not received
- Q&A documents need to be updated after each webinar

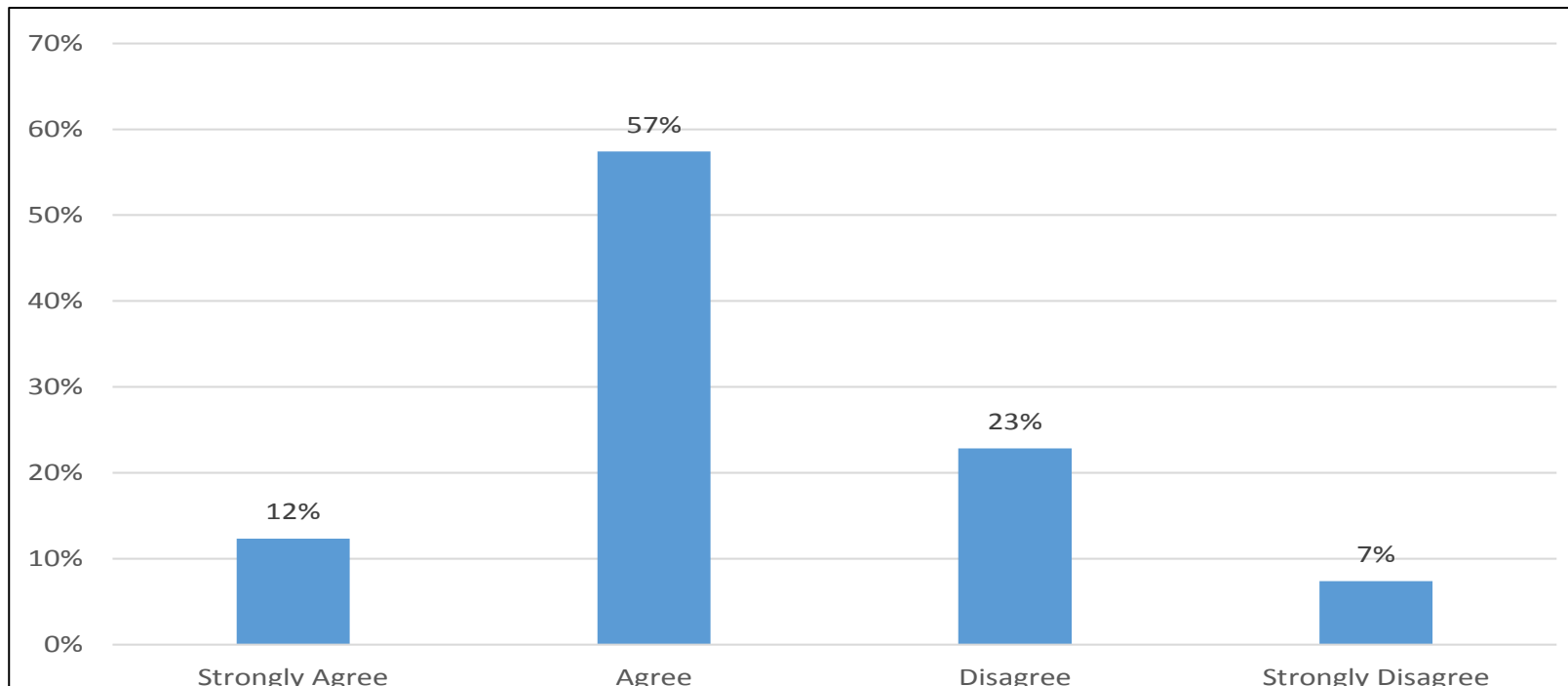
## I would like the support webinars to continue through 2016



Respondents commented on :

- Q&A components are appreciated
- Useful to have a forum to share concerns / issues
- If the webinars provide more advice to MAH
- Webinars in local language would be useful and enhance the applicability of new concepts
- No need to have a webinar every month, but only when new information is available

## My perception of the MLM Service has improved since the completion of the launch phase (September)



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Respondents commented on :

- The updates to the tracking spreadsheets to add Day zero and highlight what has been transmitted and what will be removed has been useful
- The MLM Service process has created additional workload for our department
- MAH has other requirements and needs to run their own searches
- The quality does not comply to our business standards
- Experience has uncovered additional complexities
- Downloading is still a challenge
- Data is missing

## Additional feedback

- Overall, we are satisfied and we hope it continues the same way
- Expand the service to cover additional products
- MLM service increases our workload
- MLM service is only focussed on detection of ICSRs, and therefore literature must still be monitored by MAHs for routine safety surveillance activities in signal detection and periodic reports - Expand scope to cover all aspects of global literature review
- Search for non-serious cases outside EEA
- Reduce volume of data in tracking sheets
- Changing clock start date to date of availability of XML file would resolve a lot of problems at MAH site, especially the problem of assigning clock start date for FDA reporting
- We acknowledge and appreciate the process set up in a short time-frame, as well as the huge work provided in literature search by EMA MLM

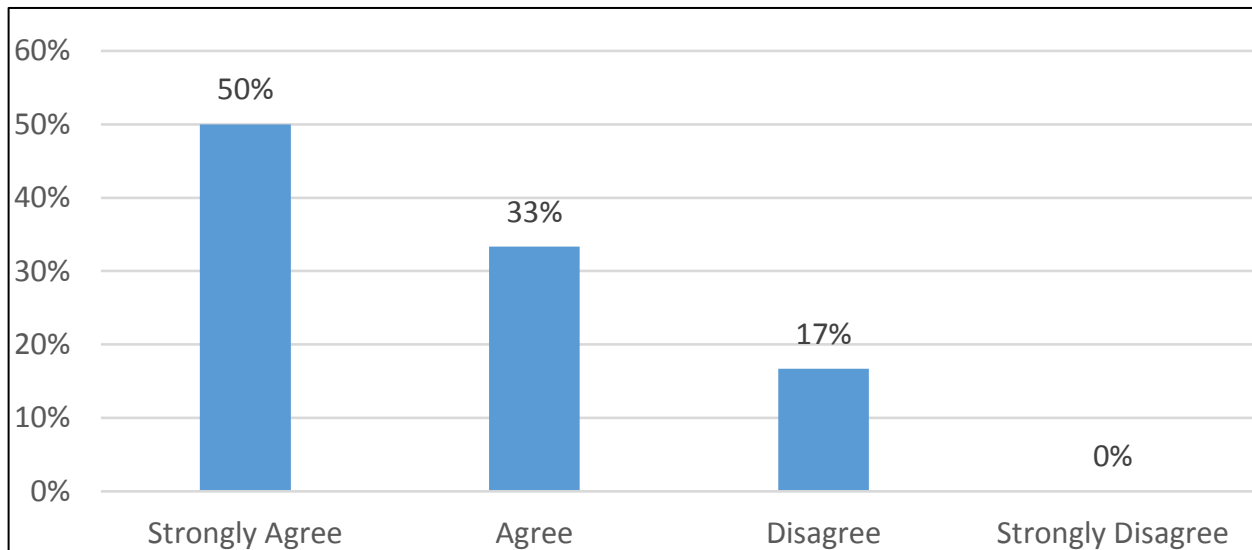


## NCA survey Detailed responses

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Full data on the reply to each question

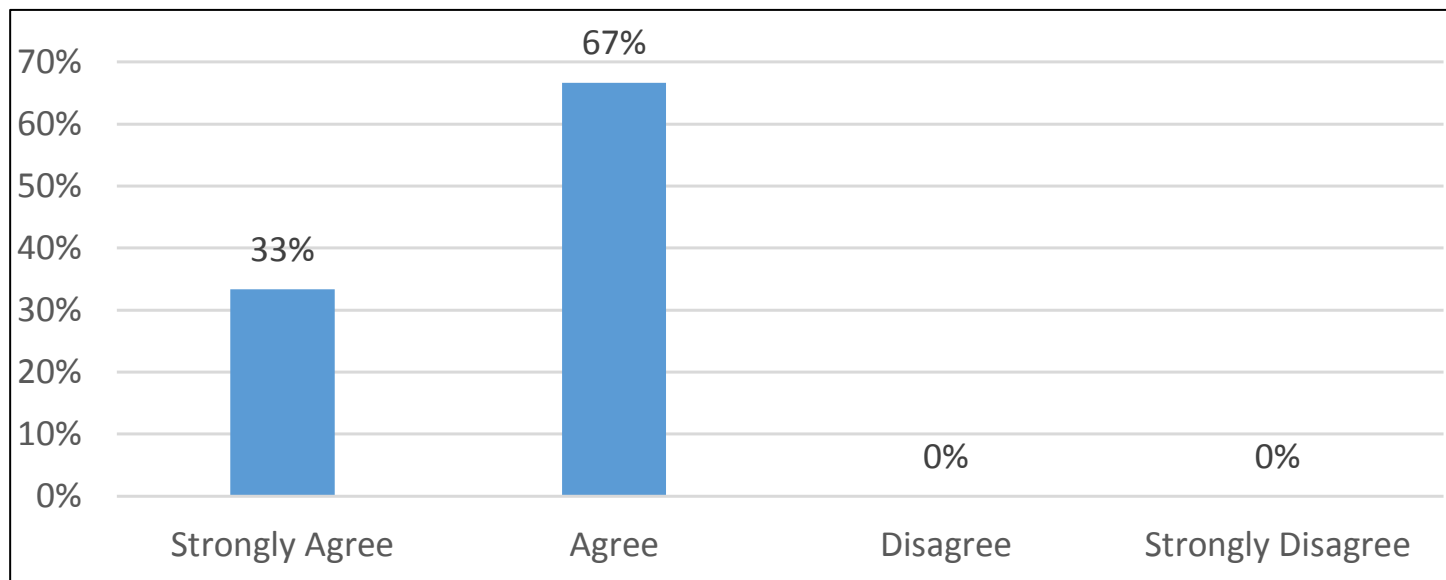
I am successfully receiving the relevant ICSRs generated by the MLM Service transmitted to my NCA



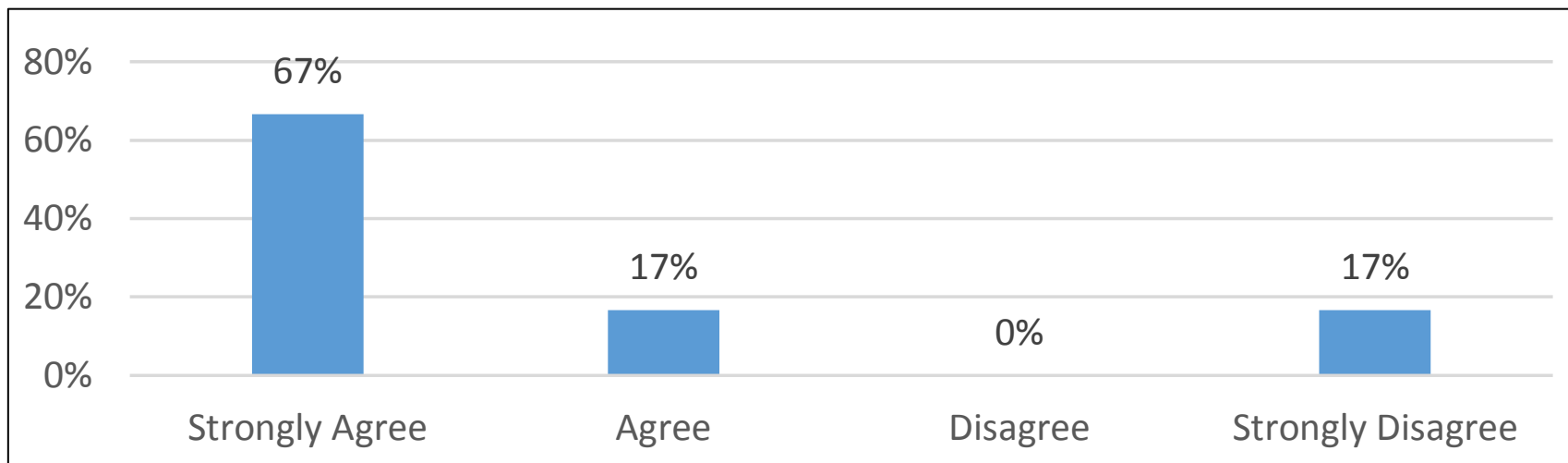
Respondents commented on :

- Follow up with MLM helpdesk was required
- Data completeness has impacted report submission

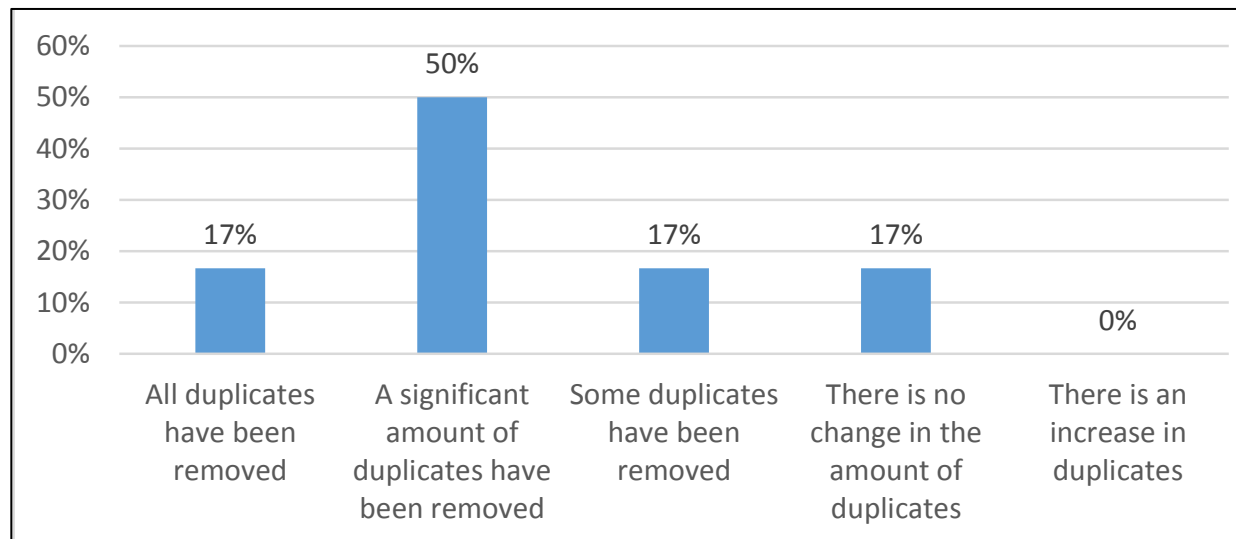
My agency's business processes have been adapted to no longer re-submit the ICSRs resulting from the medical literature monitoring service to EudraVigilance



My agency's business processes have been adapted to no longer provide the ICSRs resulting from the medical literature monitoring service to the concerned marketing authorisation holders, since they can download those ICSRs from the EudraVigilance download area



For the substance groups in scope, I have stopped receiving duplicate ICSRs from industry since the launch of the MLM service



#### Respondents comments:

Small number of duplicates initially received from industry since the launch of the MLM service. NCA followed up with the MAHs to ensure their procedures are updated to take into account the changes to literature reporting requirements as a result of the MLM service