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Inspections and Human Medicines Pharmacovigilance Division

Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency

Launch phase closure report

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Table of contents

1. Executive Summary

The Agency undertook an extensive review of the processes, outputs and stakeholder feedback generated in the first six weeks of the Medical Literature Monitoring (MLM) service. A number of process updates have been made and continuous improvement will be demonstrated throughout the lifetime of the service.

The Agency will continue to work with its contractor to ensure measurable results are observed in the execution of search strategies with increased precision over time and continuous improvement throughout the lifetime of the service.

The Agency remains confident that the MLM service will, over the coming months, provide industry with the anticipated benefits previously communicated. These include but are not limited to:

- A significant reduction in duplicate literature reports within EudraVigilance;
- A harmonised approach to the entry of adverse drug reactions originating from literature articles;
- An efficiency in Marketing Authorisation Holder (MAH) business processes by holding the Agency accountable for the resource intensive screening and reviewing of literature;
- A gradual streamlined pharmacovigilance function as literature review and case processing of articles is transitioned to the Agency.

The Agency understands and acknowledges that these objectives will not be achieved in the short term; however the forecast efficiency and reduced costs may be seen from Q3 2016.

The MLM service entered full production, screening for 300 active chemical substances and 100 herbal substances on 1st September 2015. The full production phase commenced using further refined search strategies which support increased precision. The revised strategies will be published on the dedicated MLM webpage.

The Agency remains committed to seeking constructive feedback from industry. Based on industry feedback, the format and content of outputs have been updated and will continue to be refined as necessary.

The Agency will set up an expert panel to review the search strategy on a monthly basis. We believe this approach will signal the start of the creation of standards of excellence in search strategy definition for the identification of Individual Case Safety Reports (ISCRs).

2. Overview of the 'Launch Phase' service

Between 1 July and 31 August 2015, the Agency and its contractor executed the in-scope MLM service for the top 50 chemical substance groups as listed on the Agency website. These activities included:

1. Daily[1] searching of the scientific and medical literature reference database Embase.
2. A monthly[2] search of the scientific and medical literature reference database International Pharmaceutical Abstracts (IPA) and the Allied and the Complementary Medicine Database (AMED), performed on 3 August 2015 for the month of July 2015.

[1] Daily refers to calendar days with the exception of weekends (Saturday and Sunday)
[2] Monthly refers to updates of the database as issued by the database provider every calendar month.

3. Review and initial assessment (screening) of each literature record resulting from the literature search against the inclusion/exclusion criteria within one day following the conduct of the search (i.e. citation details, abstract and full text article if available).

4. Daily publication of the screening results "sum_screen" and "sum_ICSR" each on the restricted area of the EudraVigilance website.

5. Follow-up of missing information of potential Individual Case Safety Reports (ICSRs), tracking of the follow-up status and outcome as well as publication of the status as part of "sum_ICSR".

6. Entering of valid ICSRs in EudraVigilance for all suspected Adverse Drug Reactions (ADRs) within the EEA and suspected serious adverse reactions originating outside the EEA as an outcome of the screening activities and in line with the timelines specified below:

    6.1. Serious adverse reactions are entered in EudraVigilance immediately and no later than seven calendar days[3];

    6.2. Non-serious adverse reactions are entered in EudraVigilance within 21 calendar days

7. Updating and publishing the "sum_ICSR" tracking sheet and making the ICSRs available for download by MAHs in the MLM EVWEB area or via the EudraVigilance ICSR Export Manager

8. Transmitting electronically the ICSRs entered in EudraVigilance within one calendar day to the National Competent Authorities (NCAs) in EEA Member States in accordance with the reporting requirements of ICSRs as outlined in GVP Module VI[4].

9. Initiating appropriate follow-up of confirmed ADRs and publishing of the updates to the MLM "sum_ICSR" tracking sheet as applicable.

10. Processing of any new follow-up information, maintaining and publishing the "sum_ICSR" tracking sheet accordingly and creating follow-up ICSRs:

    10.1. within seven calendar days for suspected serious adverse reactions;

    10.2. within 21 calendar days following receipt of new information related to suspected non-serious adverse reactions.

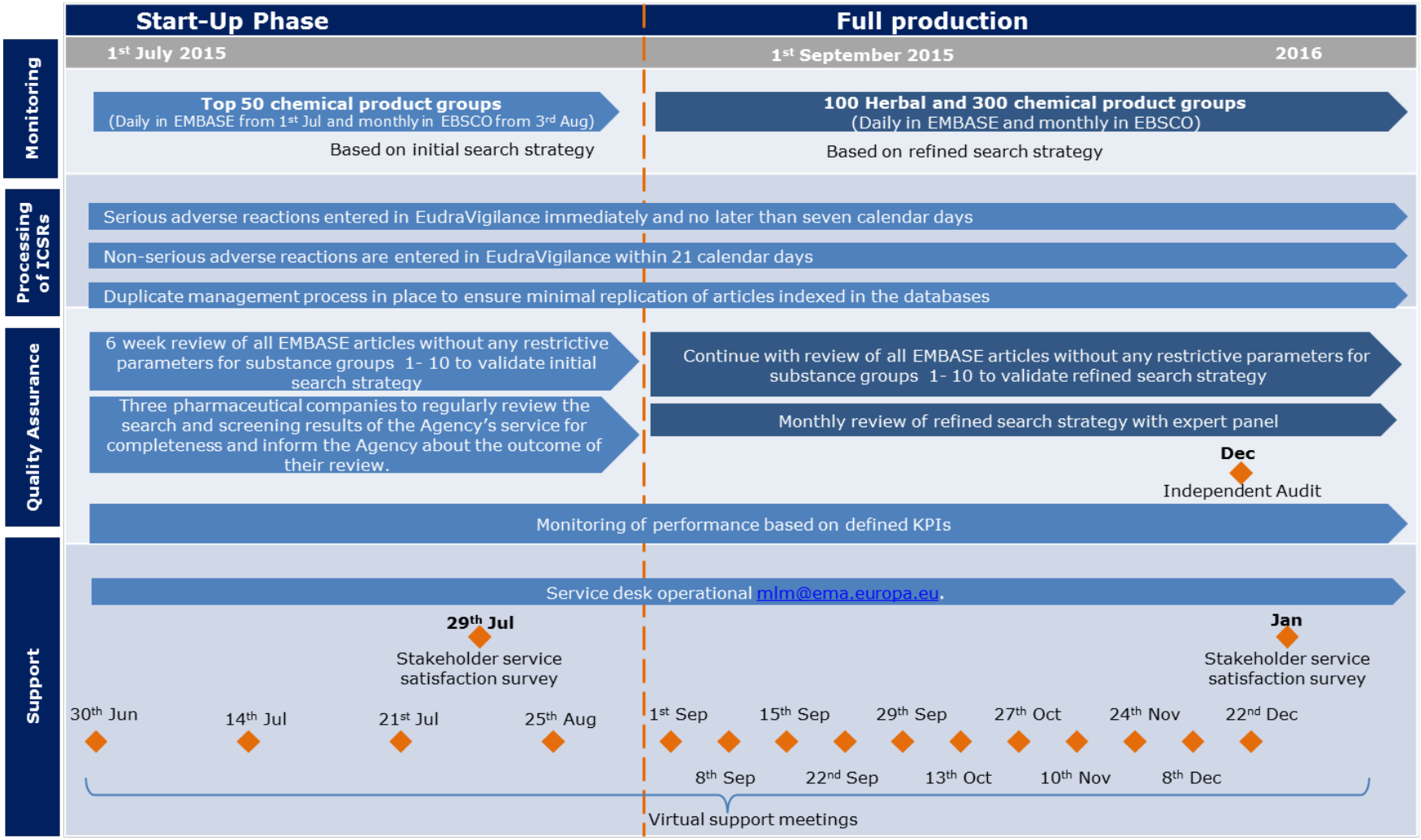
11. Updating the "sum_ICSR" tracking sheet in line with outcome of EudraVigilance duplicate management process[5] and initiation of ICSR processing (including nullification) where applicable.

12. Operating the Tracking Tool to support the tracking of all activities and the creation of the sum_screen and sum_ICSR excel files

13. Operation of the MLM Service Desk (mlm@ema.europa.eu)

[3] Day zero for the timelines related to the entry in EudraVigilance is the date on which the contractor becomes aware of a publication containing the minimum information for an ICSR to be reportable. Refer to GVP module VI, chapter VI, App 2.7
[4] GVP Module VI.B.8 Reporting modalities; GVP Module VI.C Operation of the EU Network; GVP Module VI, Appendix 3 Modalities for reporting and Reporting requirements of Individual Case Safety Reports (ICSRs) applicable to marketing authorisation holders during the interim period (17 October 2013, EMA/321386/2012 Rev.8 or later if applicable)
[5] Process description for managing duplicates in the context of the Medical Literature Monitoring (MLM) service (9 June 2015, EMA/262834/2015)

Figure 1 below illustrates all activities completed in the launch phase and the activities undertaken from 1st September 2015.



2.1. Literature screening and reviewing

The Agency and its contractor have executed daily and monthly searches using the approved and published search strategies. These searches have been screened and reviewed against the inclusion and exclusion criteria outlined in the detailed guide, and assessments have been published in the sum_screen tracking sheet, no later than one day after the search was performed.

By the end of the launch phase, over 12,000 records have been screened for the 50 active substances in scope. This has included using broad search strategies searching only on active substance name with trade names and synonyms for the ten most popular active chemical substances, which is described further in section 5.

2.2. ICSR processing

At the time of this report, more than 100 ICSRs have been created from the MLM service and processed in EudraVigilance.

The contractor processed initial cases in EudraVigilance within the published timelines. Where case corrections have been required following quality assurance measures, cases have been resubmitted which compromised compliance. Details on the compliance Key Performance Indicators (KPIs) are provided in section 3.

Feedback received through the MLM service desk and webinars has been accounted for in quality improvement measures and the Agency are providing direct support to the contractor to further enhance the quality of the ICSRs. Quality assurance processes have been updated to ensure compliance timelines are not impacted by future case corrections.

Significant improvements have been made in ICSR quality since the start of the service, specifically in relation to structured data fields and coding. The Agency and its contractor are committed to ensuring continuous improvement of ICSR submission and quality to ensure the KPIs described in section 3 of this report are routinely met.

2.3. MLM service desk

The MLM service desk (mlm@ema.europa.eu) has been operational since 1st July 2015, with over 300 queries being received and responded to at the time of the report. The mean response time for issues was approximately 20 hours. The types of queries received in the service desk range from feedback on ICSRs and MLM tracking sheets to registrations for webinars and requests for additional clarity on processes.

During the launch phase, the service desk experienced a technical issue with the receipt of some individual emails. This was apparent in feedback from the stakeholder survey in addition to escalation from MAHs not receiving responses to queries. This is further discussed in section 6.

2.4. Quality assurance measures

The contractor is performing quality assurance across all aspects of the service (searching, screening and reviewing articles, creation and follow-up of ICSRs, operation of the service desk) to ensure conformance to specification and identification of process areas for improvement.

In addition the Agency is providing quality assurance measures, including 100% quality assurance of ICSRs processed since 1st July 2015, quality assurance of screening and reviewing of articles and of

helpdesk activities. The Agency is also monitoring compliance with timelines for all KPIs and the duplicate management and the adherence of MAHs and National Competent Authorities (NCAs) as to the new rules regarding transmission of MLM service ICSRs to EudraVigilance.

The quality of the reviewing of articles and creation of ICSRs has improved markedly over the first six weeks of operation of the service, and the proportion of cases requiring correction fell significantly from the first two weeks of operation of the service.

3. Key performance indicators

The critical success factor for the MLM service is to ensure timely and adequate daily screening and tracking of the medical literature with publication in EudraVigilance. Once identified, the ICSRs are to be processed in a timely manner, with appropriate follow-up performed as described in the detailed guide. The contractor will ensure responses to all queries received through the MLM service desk to facilitate openness and transparency.

Below are KPIs and initial performance during the launch of the MLM service. These KPIs will continue to be used by the Agency and its contractor to monitor performance based on continuous assessment throughout the service.

Table 1. Key Performance Indicators during the launch phase

Key Performance Indicator	Target performance	Performance to date	Comments
Daily screening of all 50 active substance	100%	100%	
Publication of search and screening results (MLM Search Results) by 9am CET the following day	100%	90%	There were four occurrences where the spreadsheets were not uploaded on the EudraVigilance webpage by 9am as a result of human error. In all cases this was remedied within a few hours. Further training has been provided by the EMA and contractor and processes refined to prevent this occurring again. In the month of August no delay was observed in the publication of the search and screening results.
Response to all emails in MLM Service Desk within two business days	95%	83%	The mean response time for all emails successfully received through the MLM service desk is 20 hours, including Agency review and approval of all responses before sending out. Recent performance against the service level agreement (SLA) has improved where the weekly compliance is approximately 95% on a consistent basis. Of the issues

Key Performance Indicator	Target performance	Performance to date	Comments
			that have not been answered within 48 hours, most have been where an additional level of investigation has been required and the SLA has been marginally missed.
Consistent and accurate assessment of literature references	>99%	99.8%	A total of 25 out of over 12,000 literature references were not correctly assessed. As a result of consistent feedback, additional exclusion criteria have been added to exclude toxicology and animal studies that do not meet the original inclusion and exclusion criteria.
Timely Entry of Serious ICSR in EudraVigilance within seven calendar days	100%	83%	Due to case corrections initiated as a result of feedback and amendments from quality assurance activities, absolute case compliance was low, as reflected in the KPI due to resubmissions occurring after day seven. The Agency and its contactor's measures on quality will ensure the KPI improves to 100%.
Timely Entry of non-serious ICSR (occurrence within the EEA) in EudraVigilance within 21 calendar days	100%	100%	
Daily provision of listing of ICSRs generated following literature screening and publication on EudraVigilance website	100%	90%	There were four occurrences where the spreadsheets were not uploaded on the EudraVigilance platform as a result of human error. In all cases this was remedied within a few hours. Further training has been provided by the EMA and contractor and processes refined to prevent this occurring again. In the month of August no delay was observed in the publication of the search and screening results.
Correct and timely follow-up of all suspected adverse reactions	>99%	100%	All follow-up has been conducted in line with the detailed guide and the business process documents.

4. Overview of business processes

The Agency has approved business process documents developed by the contractor in support of the activities in scope of the MLM Service. These include Standard Operating Procedures (SOPs) on

literature screening and review, and ICSR processing and detailed Work Instructions (WINs) covering all activities performed by the contractor as part of the MLM service. A summary of these documents is included in table 2.

Table 2. Summary of business processes.

SOP / WIN Title	Content description
MLM/SOP/001	A complete description of the process by which medical literature is searched, screened and reviewed. The purpose of this SOP is to ensure these activities are performed in an efficient and consistent way and by doing so support pharmacovigilance at the European level.
MLM/SOP/002	A complete description of the process by which ICSRs originating from the medical literature are processed. The purpose of this SOP is to ensure these activities are performed in an efficient and consistent way and by doing so support pharmacovigilance at the European level.
MLM/WIN/001	Detailed guidance on performing literature screening in reference databases and tracking of the search results
MLM/WIN/002	Detailed guidance on performing review of literature references to determine ICSRs, including assessing full text articles
MLM/WIN/003	Detailed guidance on processing and submission of MLM ICSRs to EudraVigilance and National Competent Authorities
MLM/WIN/004	Detailed guidance on initiating follow-up for MLM ICSRs with primary authors
MLM/WIN/005	Detailed guidance on the management of the MLM service desk in providing responses to standardised queries and investigating service related issues
MLM/WIN/006	Detailed guidance on the management of duplicates originating from the MLM service
MLM/WIN/007	Detailed guidance on the quality assurance activities undertaken by the Agency and its contractor to ensure quality and continuous improvement

The business process documents have been published on the MLM webpage.

5. Search Strategy Methodology

The Agency and its contractor published the search strategies for the 50 in scope active substances (EMA/403865/2015) on 29th June 2015, which had undergone review and approval with industry working groups and Project Maintenance Group-1 (PMG-1). The methodology was developed in accordance with GVP module VI, chapter VI.App2.3.2 to ensure appropriate levels of precision and sensitivity to detect articles meeting the inclusion criteria pertaining to ICSRs or potential ICSRs. The search strategy also includes all associated trade names and synonyms from the Article57 database.

The searches have been deployed each calendar day since 1st July using Embase, and the same searching principles were conducted on 3rd August 2015 in EBSCO. Stakeholder feedback through the

service desk has been continuously assessed and monitored in support of the search strategy definition, such as MAHs highlighting articles that were not retrieved in the MLM search but which were retrieved as part of their own routine surveillance activities either for the in scope compounds or while conducting surveillance on other compounds.

Please refer to section 5.2 for details on search refinement.

5.1. Analysis of search strategy precision and sensitivity

During the launch phase of the MLM service, the Agency and its contractor committed to performing a broad, systemic review of the medical literature using only active substance names, brand names and synonyms for substance groups 1-10 without use of any targeted safety parameters to increase search precision. This review has been conducted over the first six weeks of service in order to assess and validate the methodology applied. The results are presented in table 3.

In total, 16 ICSRs have been created and processed in EudraVigilance across the substance groups, while only 13 of these ICSRs were identified when utilising the targeted, safety specific search. Further information on next steps to be taken by the Agency and its contractor in further defining and improving the search precision is provided in section 5.2.

Table 3. Analysis of broad and targeted search strategies for substance groups 1-10 during first 6 weeks of MLM service

Substance Group	No of articles retrieved using broad search parameters	No of articles retrieved using targeted search parameters	No of ICSRs identified in broad search	No of ICSRs identified in specific search
Paracetamol	606	259	3	3
Hydrochlorothiazide	308	102	1	1
Ibuprofen	398	99	2	1
Omeprazole	283	71	0	0
Amlodipine	218	81	2	2
Simvastatin	922	90	1	1
Diclofenac	406	24	3	2
Ciprofloxacin	527	181	1	1
Pantoprazole	154	34	1	0
Lidocaine	347	101	2	2
Total	**4,169**	**1,042**	**16**	**13**

5.2. Revised search methodology

Based on the provisional analysis of the launch phase, the Agency and its contractor propose to continue to study the impact of performing a safety specific search strategy for all in scope products along with broad searches for chemical substance groups 1-10 until December 2015.

Simultaneously, the Agency and its contractor are engaging with subject matter experts from the literature database providers and key stakeholders, who have provided commentary and proposed missing articles since 1 July 2015, to further refine and improve strategy to enable increased sensitivity and precision of the search.

We have identified a number of terms for inclusion in the specific search that will prevent any problems arising as a result of indexing, to ensure the broadest possible coverage without compromising specificity. This review will be urgently expedited with analysis presented to all MLM stakeholders as soon as possible.

Based on stakeholder feedback, the Agency and its contractor have determined that a disproportionately large number of articles being retrieved for screening and review had a date of publication prior to 2015 as they get added to the literature reference database. As the effective date of the service is July 2015, the Agency has determined that date of publication on searches should be limited to 2015 to minimise the volume of articles previously searched by MAHs prior to 2015. This date of limitation will be included for the duration of the MLM service.

The Agency and its contractor encourage MLM service participants to provide commentary on and suggested enhancements to the search methodology published on the EMA website via the MLM service desk in order to facilitate continuous improvement of the service. An expert panel has been established to formally review strategies which may require updates based on the results of the extended validation of the search methodology and any relevant feedback. This panel will meet monthly or on an ad-hoc basis if urgent review of the strategies is required.

Any amendments to the search strategy will be communicated and published on the dedicated MLM webpage.

6. Summary of issues and resolutions during the launch phase of the service

All issues associated with the MLM service have been investigated and resolved where possible on high priority. Issues have been escalated to the MLM service team through the service desk, webinars, and direct feedback to EMA personnel and the stakeholder survey conducted during the launch phase.

6.1. MLM service desk

It was apparent during the launch phase that several users had issues successfully sending emails to the service desk, but this issue has since been resolved.

6.2. MLM tracking sheets

The MLM tracking sheets have been found to be a common source of feedback. Stakeholders expressed challenges with using the spreadsheets and interpreting the data that they require in collaboration with ICSRs being downloaded from EudraVigilance. An example of this is the sum_icsr spreadsheet not containing day zero of the ICSRs identified from screening literature. The Agency and its contractor have initiated discussions around a proposed revised format for the spreadsheet to be presented to industry and key stakeholders with potential implementation of a revised format of MLM outputs from January 2016.

From 1st September 2015, an amendment to the spreadsheet was made to publish the day zero on the sum_icsr spreadsheet to assist MAHs in managing download and onward transmission of ICSRs within compliance timelines. The user manual has been updated in line with this change.

One of the key aspects of the tracking sheets was transparency of the assessment of each literature reference article against the inclusion and exclusion criteria. The criteria were coded outputs to the

tracking spreadsheet; however, some articles retrieved did not fit within these exclusion and inclusion criteria in the detailed guide, such as articles relating to in vitro or toxicology studies, or studies in animals. Updated criteria have been added to the tracking sheet outputs which has increased transparency and reduced the number of questions raised on why articles were assessed against inaccurate criteria.

Errors made in tracking have been corrected following feedback from industry and where this has impacted an assessment, a clarifying footnote has been used to highlight the discrepancy.

Updates to the tracking tool have been made to ensure conformance to the Vancouver reference style and, since two weeks after go-live, the Vancouver style has been uniformly adhered to.

Additional clarity has also been added to the tracking spreadsheets to state where no literature references have been retrieved in the daily or monthly searches.

There were several incidents where the publication of the daily tracking sheets was delayed due mostly to human error. These were all resolved within a few hours and additional training and refinement of processes has ensured that compliance with the 9am publication timeline is routinely met.

The ordering of the archived spreadsheets, which has been a common source of feedback in webinars from end users, was inconsistent. The Agency has made changes to ensure the ordering of the archived sheets is logical and consistent and the data that users require is easy to find.

6.3. MLM ICSRs

Since early July, the MLM ICSRs have been available for MAH downloading from EudraVigilance. One of the main discussion points is quality and compliance of ICSRs that have been processed as part of the MLM service, as previously described in section 3.

Initial quality concerns were identified from stakeholder feedback with suggested areas for improvement in case processing and submission, including case narratives and event and product coding. Also, there were concerns that ICSRs were appearing in the tracking sheet, but were not available for downloading on the same day.

Since the initial phase of the service, a week on week improvement has been observed in the structured data fields (i.e. coding of drugs, events, medical history) and the case narrative through quality assurance measures taken by the contractor and additional training and feedback provided by the Agency. In addition, the EMA has made technical amendments to the Eudravigilance system to ensure that ICSRs transmitted on a given day are always available for download the following day, which is the same day that they are published in the tracking sheet. As part of the continuous improvement measures, ICSR quality will be continuously monitored and the Agency appreciates the feedback of its stakeholders in contributing to the evolution of the service.

7. Summary of stakeholder survey and pertinent feedback

As part of the commitment from the Agency and its contractor to continuously improve the MLM service, the first stakeholder survey was circulated on 29 July 2015. The survey provided industry stakeholders with an opportunity to express their views, opinions and perceptions of all aspects of the MLM Service. The request to participate went out to all MAHs affected by the launch phase of the MLM Service, via Eudralink.

In total, 307 responses were received with aggregated results summarised in Figure *1: Summary of survey responses*. A summary of each aspect of the service is presented below.

7.1. Background of participants

The vast majority of respondents to the stakeholder survey, as anticipated, were MAHs and worked in Pharmacovigilance. Other stakeholder groups represented included contract resource organizations and service providers, with other respondents working in the industry sectors including Regulatory and Medical Affairs.

7.2. MLM outputs

Over 85% of respondents agreed that the MLM service staff are proficient in the screening and reviewing of literature. Some respondents highlighted that too much data is provided on a daily basis making it difficult to track for users and, while there is appreciation of the transparency this provides, perhaps it is not necessary for the needs of the MAHs. This comment was also repeated from other stakeholders who find the daily outputs difficult to align with their standard weekly review of literature as they must consult multiple spreadsheets. The Agency and its contractor have initiated discussions around a proposed revised format for the spreadsheet to be presented to industry and key stakeholders with potential implementation of a revised format of MLM outputs from January 2016.

Additionally, several stakeholders identified that the archive of spreadsheets was not easily searchable. Several comments were received on the literature references Vancouver styling, which over the course of the service to date has improved and is now in full conformance. A number of comments were made in regards to the large number of potential ICSRs that are provisionally assessed but then are subsequently omitted upon receipt of the full text article. The contractor will continue to process potential ICSRs in line with the detailed guidance for performing review of literature references and will review the process during Q1 2016.

The Agency and its contractor have made improvements to the tracking sheets during the launch phase, which have been considered helpful based on stakeholder feedback. A common source of feedback was the addition of a day zero header in the mlm_icsr spreadsheet, which has since been incorporated.

Additional suggestions on the information contained in the tracking sheets and general management of the literature information will be reviewed by the Agency and its contractor as part of continuous improvement measures.

7.3. MLM ICSRs

Over 78% of respondents responded positively that cases are reported on time, with 73% of respondents considering the ICSRs received through the service to be of good quality.

The respondents re-iterated that the timelines of seven and 21 days for case submission pose logistical issues for them to receive ICSRs and submit to third parties outside of the EEA. This is further compounded when day seven falls on a Friday or weekend, as occasionally cases may be made available for download on a Friday, however, the spreadsheet detailing that is only observed on the following Monday. The contractor will continue to process ICSRs in line with current business processes. Situations where ICSRs have been updated following quality assurance measures or stakeholder feedback result in an updated version being published after the defined timelines which have impacted MAH compliance.

Several areas have been identified as causing quality issues, including incorrect assessment of seriousness, inappropriate coding of drugs as concomitant / co-suspect, and the case narratives not explicitly stating the reason for a new version of an ICSR. The Agency and its contractor acknowledge that improvements in case qualitywere required and have been working continuously with stakeholders through the webinars and service desk to identify cases of inappropriate quality and trends in quality deficiencies. The Agency are now providing 100% quality assurance review of ICSRs created from the MLM service and where necessary the contractor is updating cases of lower quality and resubmitting with updated information. Quality assurance measures are in place and the Agency and its contractor are observing quality improving on a week to week basis.

The stakeholders accessing MLM ICSRs via EVWEB and export manager experienced some challenges, with 63% stating the export manager provides easy access to the ICSRs with 73% retrieving cases easily from EVWEB. The main sources of feedback included suggestions on advanced filtering and delays in cases being made available for download. Some stakeholders also requested updates to the user manual information to provide an additional level of detail to ensure ease of access. With regards to these requests, the user manual was updated to provide the additional required detail.

7.4. MLM Service Desk

The MLM service desk was the central component for routine feedback and escalation. The stakeholder responses indicated high awareness of this being the channel for correspondence relating to the MLM service. The majority of stakeholders who used the service found that the responses were of good quality (77%) and clearly presented (82%).

During the course of the launch phase, the Agency was notified of instances of no response from the service desk. Upon investigation, all emails received by the service desk had been responded to meaning certain users experienced issues in successfully sending emails. This issue has since been resolved. The Agency has set up an improved automated response to be sent from the mailbox acknowledging receipt of the email.

7.5. Stakeholder impact

A common theme of feedback was that the 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. The same theme was evident from other service users who remarked that their literature process was complicated by the involvement of screening for non-serious ICSRs outside the EEA to enter in their database and searching of local literature was still a requirement for complete coverage.

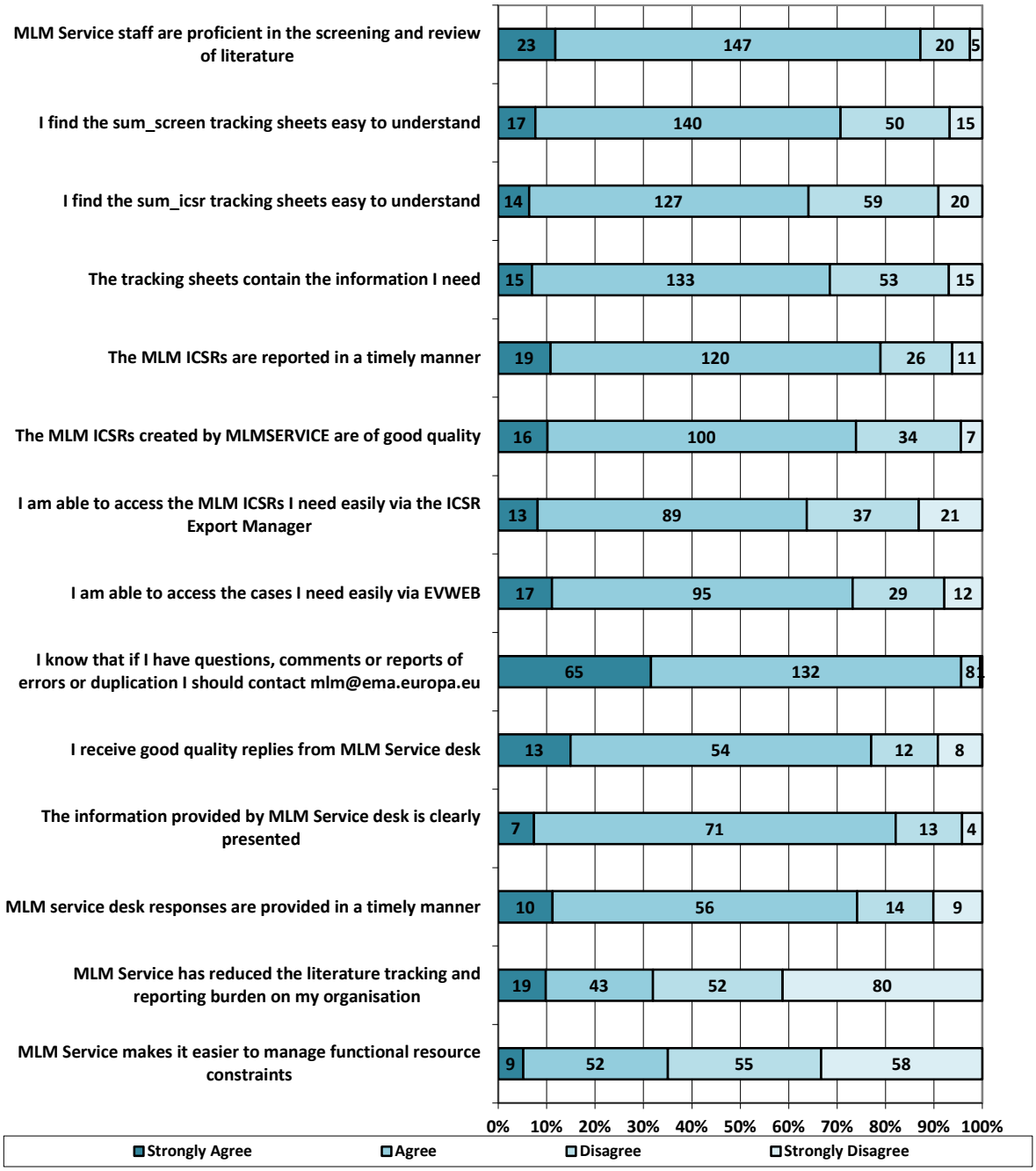
Several responses detailed the process to be laborious and did not reduce workload but replaced that with reconciliation and daily checking of EV and the tracking spreadsheets. MAHs have struggled with the concept of day zero due to time constraints and the additional layer of activity to check whether the article has been identified previously or from another source.

Several respondents commented positively on the helpfulness of the webinars as a forum to address questions, while a refreshed Q&A document published on the MLM website would be appreciated with the experiences of the launch phase. An updated Q&A document was published on 1st September on the EMA website.

The stakeholder impact findings are understandable given the process is new to users and the process improvements that have been identified and are in need of implementation. It is believed that further benefits of the system will be realised in due course, once it is well established. The Agency and its

contractor encourage users to consistently feedback issues and suggestions through the service desk, the dedicated MLM webinars and in future iterations of the stakeholder survey.

Figure 1: Summary of survey responses



8. Next steps

The MLM service increased its scope of activity to full production with 300 chemical and 100 herbal as of 1st September 2015.

The Agency and its contractor will continue to host regular stakeholder webinars until December 2015 following the increase to 400 active substances. The purpose of these meetings is to communicate progress and help provide solutions and guidance to any user problems experienced. The meetings will also include an overview of issues and challenges faced, a summary of pertinent feedback received

through the MLM service desk, and any amendments to process taken as corrective and preventative action.

Due to the potential large numbers of attendees at the webinars, the meetings will be independently moderated to ensure minimal disruption to conversation. For those interested in participating, please request an invite through the MLM service desk. The dates and times can be found on the MLM dedicated webpage.

The medical literature monitoring activities will undergo a two yearly, independent audit of the contractor's internal quality management and control systems and of the services provided to assess their effectiveness with a view to bringing about continuous improvements. The first audit is scheduled to take place in Q4 of 2015.

A customer satisfaction survey will be sent out to collect feedback on the service early in January 2016.

Figure 2 below summarises the MLM service optimization activities which have been implemented and those which are to be implemented from 2015