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Standard Operating Procedure (SOP)/Working Instruction (WI)

Name of procedure/Working Instruction	Prioritisation, investigation and management of listed medicines complaints and referrals		
Applicable to	LCS		
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Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0		Original SOP/Policy	Organisational unit/s	June 2020
V2.0		Improvements on guidance to complete RTIC	[redacted]	January 2021

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1 Purpose

To provide guidance and instruction to the Listing Compliance Section (LCS) staff on the prioritisation, investigation and management of external and internal signals of potential non-compliance for listed medicines in the form of complaints and referrals.

2 Scope

This SOP includes procedures for **triaging and undertaking investigations** of potential non-compliant listed medicines referred to LCS by internal and external stakeholders.

This SOP does not cover:

- the establishment of records in Work Management for complaints or referrals
- the establishment of investigations' files in TRIM for complaints or referrals
- the allocation of complaints or referrals investigations to LCS staff
- the prioritisation and management of other types of signals of non-compliance, such as s14 applications or Aristolochic Acids pre-clearance applications.

The processes above are detailed in associated SOPs (please refer to Section 5)

3 Definitions

Term	Meaning
Case file	The set of electronic documents pertaining to a compliance lead including emails, file notes, evidence, copies of labels, etc.
Case record	The electronic record for tracking the details and findings of a compliance lead for workflow management and reporting purposes.
CLP Path	Set of predefined tasks for a CLP in Work Management that define the steps to be undertaken during the progression of a compliance lead. For the purposes of this document, CLP tasks are written in italics, e.g. *CLP –Awaiting investigation.*
CMIb	The Complementary Medicines Inbox (CMIb) complementary.medicines@health.gov.au
Compliance lead	For the purposes of this document, a compliance lead is a signal, either in the form of a complaint or a referral, of perceived or alleged non-compliance of a listed medicine that is evaluated or investigated by the Listing Compliance Section.
Compliance Lead Process (CLP)	Electronic case record for a compliance lead in eBS Work Management.

Term	Meaning
eBS	*Electronic Business Services*, the TGA software application that is opened using the IBM Notes software.
Lead context	A combination of the sponsor and medicine compliance history, and the lead quality and credibility.
Leads Manager	For the purposes of this document, it is LCS' responsible person for overseeing and coordinating compliance leads to ensure that they are all recorded and dealt with in a highly streamlined, consistent, risk-based, timely and efficient manner.
Leads Scientific Officer	For the purposes of this document, it is LCS' default responsible person for undertaking the compliance lead investigation and corresponding action.
Leads Team Officer	Leads Scientific Officer or Leads Manager.
RFI	Request for Information
RTIC	Risk assessment Tool and Investigation Checklist
Work Management (WM)	The part of the eBS application in which case records are created and workflow is managed.
Work Process Manager	Compliance lead owner. Responsible person for managing the overarching workflow of a compliance lead and the associated tasks in WM.

4 Introduction/Background

The LCS receives signals of potential non-compliance related to listed medicines in the form of complaints/allegations from consumers or industry, and referrals from other areas within the TGA or external stakeholders. We refer to these collectively as compliance leads.

The LCS receives approximately 90 compliance leads each year with a third of these pertaining to more than 3 medicines. In approximately 90% of the cases the perceived non-compliance results in a confirmed breach and some of those pose/may pose a risk to consumer safety and/or relate to lack of efficacy of the product. Therefore, a systematic and predictable handling of compliance leads that uses a risk-based selection and timely completion of enforcement actions helps ensure that listed medicines are safe and fit for purpose.

While handling a compliance lead several factors are considered and weighted up in order to assign the right priority, investigation process and subsequent resolutive actions. These factors are:

- the level of risk associated with the alleged breach. It is determined in accordance with the LCS' internal categorisation of the most common legislative breaches;
- the 'lead background', which is combination of the

- (a) sponsor compliance history from previous compliance reviews,
- (b) relative frequency of leads related to that sponsor, and
- (c) number of past investigations into the medicine that is the subject of the lead;

– the credibility or level of confidence in the source of the lead; and

– the level of certainty regarding the breach occurrence (lead quality).

This SOP guides the investigator to interrogate the LCS's databases and gather information related to the factors listed above to inform the investigation process. In the resolution phase, all the factors above are linked through a risk matrix (see TMP0020 Appendixes 1 and 2) which lays out the spectrum of options that are available under the *Therapeutic Goods Act 1989* ('the Act') to enforce compliance.

The following sections describe the steps and relevant information to investigate and action compliance leads.

5 Associated Documents

- POL0003 – LCS TRIM Naming Conventions
- POL0008 – LCS Handling of complaints and referrals (not completed yet)
- SOP0002 - Case and file management of compliance leads in Work Management
- SOP0003 – Case record and file management for Listed Medicine Compliance Reviews
- SOP00XX – SOP for triggering reviews (TBS with Nick)
- TMP0010 – Compliance Review Email Standard words
- TMP0020 – Risk assessment tool and Investigation Checklist
- TMP0023 – Email templates associated with compliance leads.
- TMP0026 – Obligations Notice derived from compliance leads
- TMP0040 - Sponsor compliance history assessment (D20-501611)
- WI0001 - eBS Work Management for case record administration of compliance review and lead processes

6 Roles and responsibilities

6.1 Roles and responsibilities

It is the responsibility of all staff in the LCS to understand and use this document when undertaking a compliance lead investigation.

All staff of the section have a responsibility to identify issues with this document and bring them to the attention of the section's Leads Manager for rectification.

Phase	Stage	Responsible person	Role
Triage	Awaiting investigation	Leads Team Officer	• To enter basic information within the *CLP –Awaiting investigation* task
		Work Process Manager	• To complete the *CLP –Awaiting investigation* task once ready to commence the investigation
Investigation	Investigation & Risk Assessment	Work Process Manager	• To undertake compliance lead investigation using the RTIC • To gather evidence for the compliance lead investigation • If required, to prepare RFIs for external parties, or prepare and send internal correspondence relating to the compliance lead • To file all correspondence-related files and collected evidence/information in TRIM • To enter basic information and complete the *CLP – Investigation & Risk Assessment* task
Action	Referral (if required)	Work Process Manager	• To prepare, seek clearance (if required) and send out referrals • To enter basic information and complete the *CLP –Referral* task
		EL1/Leads Manager	• If required, to review and clear draft referral correspondence
		BISS officer/Work Process Manager	• To save correspondence-related files in TRIM
	Issue Correspondence (if required)	Work Process Manager	• To prepare and assign relevant correspondence for review (e.g. Obligations Notices, responses to a complainant etc.) • To send out correspondence • To enter basic information and complete the *CLP –Issue correspondence* task
		EL1/Leads Manager	• To review and clear drafted correspondence
		BISS officer/Work Process Manager	• To save correspondence-related files in TRIM
	Awaiting Compliance Review (if required)	Work Process Manager	• To enter basic information in *CLP – Awaiting Compliance Review* task • For compliance reviews to be initiated immediately, draft RFI under section 31 of the Act and alert Leads Manager so that a compliance review is appropriately triggered
		Leads team officer	• To complete the *CLP –Awaiting Compliance Review* task

Phase	Stage	Responsible person	Role
Closure	Finalisation	Work Process Manager/ Leads team officer	• To enter basic information within the *CLP –Finalisation* task
		Leads team officer	• To complete follow-up and/or closure tasks (i.e. triggering a compliance review) • To complete the *CLP –Finalisation* task

6.2 Target timeframes

The following table provides a summary of target timeframes for the corresponding activities in the phases detailed above in Section 6.1.

Phase	Task/Scenario	Timeframe
Triage	Progressing to the investigation phase for compliance leads triaged as 'standard'	≤3 business days
	Progressing to the investigation phase for compliance leads triaged as 'urgent'	≤1 business day
Investigation	Completion of the RITC for compliance leads triaged as 'standard'	≤10 business days
	Completion of the RITC for compliance leads triaged as 'urgent'	≤1 business days
	Review of the RITC for compliance leads triaged as 'standard'	≤5 business days
	Review of the RITC for compliance leads triaged as 'urgent'	≤1 business day
Action	Completion of the recommended action and progression to the closure phase based on the priority for action determined in the investigation phase: 1. Low 2. Medium 3. High 4. Critical	1. ≤60 business days 2. ≤20 business days 3. ≤10 business days 4. ≤2 business days
Closure	Completion of closure actions (e.g. triggering a compliance review) and completion of *CLP –Finalisation* task	≤2 business days

7 Undertaking a compliance lead investigation

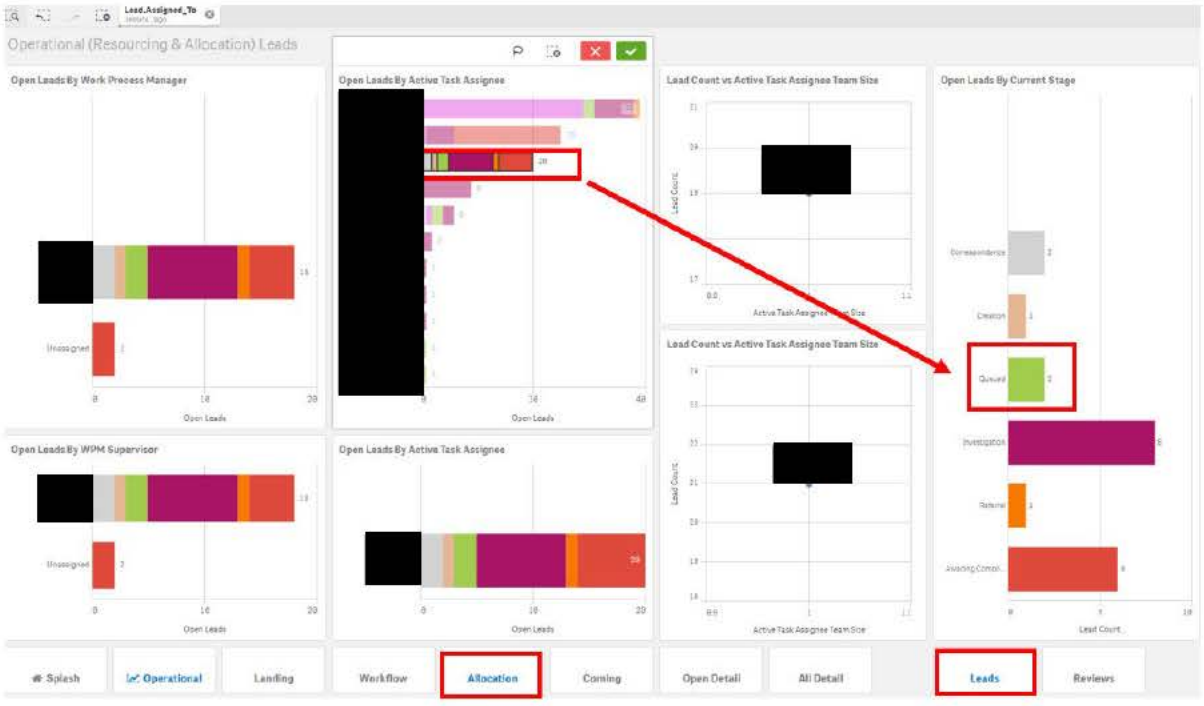
Compliance leads are received either through the complementary medicines mailbox (complementary.medicines@health.gov.au) or via email by the Leads Team. From there, a

member of the BISS team or Leads Team, respectively, establishes a CLP record in Work Management and saves the associated files into a dedicated TRIM folder. A member of the leads team then completes an initial triage of the lead to determine whether it is suitable for investigation, if it is spurious/illegitimate, or if it has been incorrectly designated to the LCS. If the lead is suitable for investigation, it is assigned a priority of 'standard' or 'urgent' depending on matter subject of the complaint/referral, which determines the promptness to initiate and complete the investigation. The process described above is detailed in the associated SOP0002.

If the compliance lead is a referral from Advertising for an evidence assessment, the priority for resolution should correspond to the priority level of the advertising case. An investigation process is not necessary. Progress to section 9.5.

By default, new compliance leads are assigned to the Leads Scientific Officer for investigation. However, in cases where the LCS' officers other than the Leads Scientific Officer are required to undertake a lead investigation, the Leads Manager will liaise with those officers before the allocation occurs. In any case, the officer designated to undertake the investigation becomes the Work Process Manager of that lead.

New compliance leads will appear in the LCS dashboard in QLIK Sense from where Work Process Managers to whom a compliance lead investigation has been assigned will be able to see in their portfolio. Please refer to the example below:



Once the Work Process Manager is notified through email and/or QLIK as indicated above, the investigation should be completed within the timeframes outlined in Section 6.2.

7.1 Update WM case record to reflect commencement of investigation

Stage: [Triage: Awaiting Investigation]
Responsibility: Work Process Manager

1. When ready to commence the assessment, complete *CLP –Awaiting investigation.*

2. Allocate *CLP – investigation and risk assessment* to yourself and proceed to complete the Risk Assessment Tool and Investigation Checklist **(RTIC)** as per Section 7.2 below.

7.2 Completion of RTIC/ Investigation of potential non-compliance

Stage: [Assessment: Investigation & Risk Assessment]
Responsibility: Work Process Manager

During the course of the investigation ensure that summary notes are kept up to date in WM.

The following subsection should be read in parallel to TMP0020 (RTIC) as the guidance below is intended for the completion of sections 1 to 6 of that checklist.

7.2.1 Initial screening of compliance lead- Section 1

1. **Analyse and summarise the compliance lead (Question 1)**

Q1. Details of the compliance lead	Provide brief background of the compliance lead, like the date when it was received, complainant/referee details, information provided and summary of the issues described

In responding to this question, please consider the following factors:

- The type of compliance issue being raised (e.g. manufacturing breach, labelling breach).
- The complexity of the issue raised. For example if a lead is regarding many medicines (e.g. >3) the Leads Manager should be alerted. The seriousness of the issue raised. For example, if the complaint describes a medicine not being manufactured in a licenced facility or a site nominated on the ARTG, it is considered serious and the Leads Manager should be alerted.

Include the date when the complaint was received, the source, what information was provided (e.g. pictures of the label, searches of the internet, laboratory certificates, etc.) and a brief summary of the issue.

If the risk seems to be critical, discuss with the Leads Manager to whether an urgent compliance review (or other appropriate action) is required to be initiated immediately

2. **Check basic information regarding the medicine(s) subject of the complaint (Questions 2, 3, 4 and 5).**

Q2. Medicine name/s (include the ARTG number if relevant)	e.g. [redacted]
Q3. Medicine/s current on the ARTG?	If no, consider whether this investigation is required or if the case should be referred to ECT/Advertising.
Q4. Sponsor/ Manufacturer	
Q5. Is there an open review or recently closed review related to the subject medicine?	If yes, consider whether an investigation is required or if the issue can/should be referred to the evaluator undertaking the review

If the complaint relates to a specific medicine:

- Verify the listing status and sponsor of the medicine via QLIK
- If no ARTG number is available (e.g. the consumer only provided the name of the medicine), search the medicine by its name and try to determine if there is an active listing in the ARTG that could be the subject of the complaint. If there is more than one medicine which could be the subject of the complaint, contact the complainant and request either the AUST L number or else a picture of the label.
- If the subject medicine has been recently cancelled, consider if the compliance lead still requires to be investigated or not (e.g. stock in marketplace within expiry, the compliance lead refers to a medicine that was cancelled but has a re-listed version with the same/similar formulation, the new listing may have the same problem).
- If the subject medicine has been cancelled and appears to remain being supplied or advertised, consider whether further investigation is required or if the case should be referred to ECT/Advertising. (e.g. if there is an active website advertising the medicine, refer to Advertising).
- Determine if the medicine is subject to an open or recently completed compliance review (within the last 36 months) via QLIK (see Appendix 9.4.1 for guidance).
    - If the medicine is subject to an open review, continue filling the RTIC keeping in mind that the compliance lead could potentially be resolved through the undergoing review. If it is the case, consider if it would be more appropriate to allocate the compliance lead to the review owner.
    - If the medicines was recently subject to a compliance review, continue filling the RTIC keeping in mind that the alleged potential non-compliance could have already been resolved through the compliance review. In such a case, no further action will be required after the completion of the RTIC.

If the complaint relates to a sponsor/manufacturer/other issue:

- Determine the affected medicines through a search of QLIK by filtering via the sponsor/manufacturer name and/or any other relevant information, for example, an ingredient (e.g. referral from CMES regarding changes to an ingredient that affect a multitude of listed medicines, referral of GMP non-compliance for a manufacturing site that produces listed medicines or a complaint regarding a range of products marketed by a sponsor).
- Once the affected medicines have been determined, complete the checks outlined above for specific medicines.

3. Determine if there are any compliance leads that are similar/relevant to the investigation? (Question 6)

Q6. Are there any compliance leads that are similar/relevant to this assessment?	Yes ☐ No ☐	Provide details below and consider consistent actioning

Search the compliance leads database via QLIK using relevant keywords (see **Appendix 9.3** for guidance). For example, if the lead relates to a problem with a particular ingredient, search the name of that ingredient. If the lead relates to a specific manufacturer, search the manufacturer name, etc.

If the search indicates that there are related compliance lead investigations (completed or underway), consider the level of risk and the actions taken for resolution.

If there are multiple similar open leads, consider consulting with the Leads Manager to determine if a wider approach to the issue might be more effective.

4. Analyse the source compliance lead (Question 7)

Q7. Source of compliance lead, credibility and quality	e.g. Referral from Laboratories, lab results provide breach has occurred. e.g. Tip off from industry that sponsor may not hold evidence, unable to confirm if breach has occurred. e.g. competitor trying to make false allegations about a medicine

The source, quality and credibility of the lead may greatly influence the speed at which the investigation advances as well as the action(s) to resolve the lead. Internal referrals are usually of high quality and easily verifiable, which may enable you to use the information provided as evidence and thereby take direct action. For example, if a referral from Laboratories shows that a listed medicine contains a prohibited substance, the lead can be transitioned to review without needing to request additional information to verify the breach.

On the other hand, tip-offs from another sponsor or general complaints from consumers usually cannot be immediately verified and further research is required, for example by requesting evidence from the affected sponsor or further detail from the complainant.

5. Request further information if required (Questions 7a and 7b)

Q7a. Is further information required from the sponsor/complainant to progress the lead?	Provide what information is being requested. Yes ☐ No ☐	Provide the date RFI sent	**Q7b. Requested information provided?** Yes ☐ No ☐

In some cases, it is appropriate to request further information to progress the investigation, including:

- *When a complainant/referee has indicated that he/she holds supporting material*

  It is not unusual that complainants indicate that they hold further evidence to support their complaint. In those cases, it is advisable to contact the complainant to request such information. Please see TMP0023 for guidance on such request.

Please note that in the standard complaint form (see example below) there is a question that provides whether the complainant holds supporting material. If yes, the information may be requested if relevant.

- *No relevant evidence is available to verify a breach*

There are several scenarios where you may need to contact the affected sponsor to request information that enables to verify the existence or inexistence of the alleged breach.

Examples of scenarios where an RFI could be warranted include (this is not an exhaustive list):
-A company insider or competitor indicates that there is certain misconduct in the manufacture of a product (manufacturing data should be requested);
-A referral/complaint refers to a medicine with a suspicious name that suggests the product may be being advertised for indications other than the ones in its ARTG entry (label and link to sponsor's website should be requested);
-A consumer complains blatant advertising but upon a cursory internet search the advertising is not found (it may be necessary to request label and link to sponsor's website from the sponsor);
-A competitor or Regulatory affairs person complains about a product which lacks evidence to support indications (evidence could be requested upon discussion with the Leads Manager).

If an RFI is deemed necessary, it must done under Section 31 of the Act and following the template: TMP0023. See SOP0002 for further guidance on the management of correspondence if required.

7.2.2 LCS Investigation – Section 2

1. Evidence gathering

Any relevant documents and correspondence relevant to the lead should be filed in the associated TRIM container (and if already in TRIM, then saved as 'alternatively within' the lead container). This may include:

- communication with the complainant/referee,
- communication with the sponsor,
- communication with other areas of the TGA,

and any type of evidence based on the type of breach as described in the table below.

Type of breach	Type of evidence commonly used to confirm a potential breach
Ineligibility for listing **e.g.** lack of warning required by 26BB, indications on label/website breaching the requirements of the Permissible Indications Determination	*ARTG record summary* *Copy or pictures of the label* *Website Captures*
Advertising	*Website Captures (appropriately dated)*

e.g. restricted representation on website, advertised claims inconsistent with the ARTG	*Website domain*
Labelling	*Copy or pictures of the label*
Manufacturing e.g. Manufacturer not having clearance	*ARTG record summary (to determine the nominated manufacturers)* *Relevant manufacturing documentation if provided by the complainant/referee or requested to the sponsor.* *MQB compliance assessment if an issue has been referred to LCS as a result of a GMP compliance signal/issue (This can be found by searching 'form 10.2a' and the manufacturers name in TRIM).* *Example: 'Form 10.2a* [redacted]
Failed lab testing e.g. prohibited substance detected	*Referred lab report*
Evidence in support of therapeutic claims	*Evidence breaches are usually unable to be confirmed without requesting information from the sponsor.* *However, compiling information such as the type of indications (e.g. Specific Scientific), consistency between the advertised indications and the ones included in the ARTG and/or the targeted population, is an important step of the evidence gathering process.* *In addition, if the sponsor's compliance history in regards to previous evidence reviews is available, this should also be saved within the lead container.*

In cases where a compliance lead has been referred from another area of the TGA, the Work Process Manager should carefully read all the relevant material provided (e.g. PSAB usually provides a link to their own investigation TRIM folder) before continuing with the investigation. Sometimes those other areas may have already requested relevant information from sponsors.

During the evidence gathering process, it is not uncommon to note other issues that are not the subject of the compliance lead. Although compliance lead investigations should be kept within the scope of the original issue, if those other issues are safety/efficacy-related, these must be added to the case and taken into consideration during the investigation.

2. Recording material considered during investigation and assessment of the existence/inexistence of alleged breach (Question 8)

Q8. Summary of LCS considerations during the investigation.	Provide a brief description of the breach and/or a summary of reasons and evidence used to determine whether there are verifiable breach or if unable to verify the breach based on information held. Use this section to include website links, TRIM links to copies of labels, advertising captures, ARTG summaries, lab testing results and any other relevant evidence.

Outline the information considered within the investigation and describe your assessment of the potential breach, which must correspond to an actual breach under the Act.

In assessing unclear or complex issues, detailed commentary should be provided as to the nature of the issue and potential applicable legislation or reasoning for why the alleged breach does not constitute a breach under the Act. Please provide links to TRIM files used during the assessment, for example file notes where information was compiled.

Examples of breaches related to legislation not relevant to the TGA may include:

- Issues with the storage of a medicine in a pharmacy (to be referred to state authorities);
- Inappropriate use of the 'Made in Australia' Logo (please see D20-163665 and determine if referral to ACCC is required),
- An issue related to a cosmetic (to be referred to NICNAS); and
- A complaint regarding a specific health professional (to be referred to AHPRA)

3. Determining the outcome of the investigation actions (Question 9)

Q9. Outcome of investigation?	**Potential breach of TG Act identified** ☐ **Progress to Section 3** **Potential other breach** ☐ **Likely to be referred, Progress to Section 5** **No breach identified** ☐ **Progress to Section 5**

Based on the information gathered and the assessed made in, decide whether there is:

- Potential breach of the TG Act: progress to **section 7.2.3**
- No breach identified: progress to **section 7.2.5**
- Potential other breach: progress to **section 7.2.5**

7.2.3 Determining the risk from non-compliance – Section 3

The 'Risk from non-compliance' relates to the potential issues with a medicine determined in the sections above and the risk it may pose if the non-compliance is verified. Under current LCS' framework, the following levels of risk are used to rate non-compliance:

- Low risk, when none of the deficiencies identified are safety or efficacy-related, and generally corresponds to a 'minor' compliance deficiency.
- Medium risk, when there is at least one efficacy-related deficiency.
- High risk, when there is at least one safety-related deficiency.
- Critical risk, when there is at least one safety-related deficiency that is likely to result in significant or imminent risk to consumers.

Section 3 of the RTIC provides the following table which includes common breaches for each risk category:

Low ☐ Minor deficiencies only	Medium ☐ ≥ 1 efficacy deficiency (no safety deficiencies)	High ☐ ≥ 1 safety deficiency	Critical ☐ ≥ 1 critical safety deficiency
Minor inconsistency with the medicine name on the label Ingredient names on label are incorrect according to the AAN requirements The name of the dosage form is incorrect or missing from label The quantity of the goods is not included on the label Incorrect or missing batch/expiry date/storage conditions/supplier details/AUST L number Label legibility requirements not met Advertising breach that does not mislead to the proper contents, identification or use of the medicine. (e.g. endorsement, untruthful non-therapeutic claim) --- **Other deficiency that meets the definition of minor, please describe:**	Sponsor does not hold evidence to support indications or claims Formulation of the medicine is different to the formulation on the ARTG Dosage form of the medicine is different to that on the ARTG Indications or claims are different to that on the ARTG Quality control standards not met for dissolution rate, uniformity of weight, disintegration, preservative content assays, ingredient quantification, conduct of relevant tests and limits Advertising that is likely to impact the consumer's ability to appropriately use the medicine in line with their intended purpose --- **Other efficacy related deficiency, please describe:**	Ingredient requirements or quantity restrictions not met Contains an ingredient or substance (impurity or contaminant) included in a SUSMP schedule Manufacturer not entered in the ARTG or GMP licence/clearance are not held by the manufacturer Mandatory label warning statements are incorrect or missing Requirements for child resistant packaging have not been met The medicine refers to a prohibited or unapproved restricted indication or claim Advertising that is likely to impact the consumer's ability to safely use the goods --- **Other safety related deficiency, please describe:**	Contains an ingredient that is not included in 2688 (with known safety issues) Contains a prohibited substance An instance of fraud, misrepresentation of falsification of data, or intentional or reckless contravention of listing requirements Advertising breach that is likely to lead to harm or risk public health --- **Other safety deficiency of a nature or extent that represents an imminent concern for consumers, please describe:**

When a medicine has more than one deficiency, the overall level of risk is given by the deficiency with the highest level of risk. For example, if a medicine has two minor labelling issues (low risk) and an ingredient that exceeds the limit stablished by the Permissible Ingredients Determination (high risk), the overall risk from non-compliance for this medicine would be 'high'.

Record the assessed risk in Section 3 of the RTIC by marking an 'x' on the provided field and progress to **section 7.2.4.**

If the risk is critical discuss with the Leads Manager to whether an urgent compliance review (or other appropriate action) is required to be initiated immediately.

7.2.4 Determining the medicine & sponsor compliance profile – Section 4

Information relevant to the compliance history of the sponsor and the medicine must be gathered to inform the corrective action, the level of stringency of such action and the priority for its initiation.

The factors that can affect the compliance history of a medicine/sponsor comprises at least five aspects:

- previous/current compliance reviews;
- previous/current non-compliance signals in the form of complaints or referrals;
- previous/current non-compliance signals from TGA laboratories;
- previous/current advertising cases; and
- previous/current adverse events/defects/recalls cases

1. **Assessing the medicine compliance history (Question 10 and 11)**

Q10. Are there any previous compliance leads received about this medicine in the last 24 months?	Yes No	☐ ☐	Provide details and links if applicable.
Q11. Are there any other relevant compliance signals for this medicine?	Yes No	☐ ☐	Provide details and links if applicable. e.g. old or current compliance reviews, advertising cases, medicine defect reports or recalls

i) Medicine compliance history based on LCS compliance leads (Question 10)

Search in QLIK for previous complaints or referrals for the same AUST L and do a separate search for the medicine name as cancelled versions of the same medicine are also of interest. Only include complaints or referrals received within the last 24 months. See **Appendix 9.4.2** for guidance on QLIK searches.

If a medicine has been the subject of previous compliance lead investigations, read through relevant material to determine if the previous compliance issue is relevant to the current compliance lead. If it is, this may increase the context rating of the lead and influence the priority of action.

Examples of such situation are:

- Three consumer complaints have been received for a single medicine not having clear ingredient information displayed on the label. The priority for resolution may be increased from low to medium.
- An Obligations notice was issued during a previous compliance lead investigation, however, the new compliance lead indicates that that the breach is still unresolved. A higher level of compliance action should considered (e.g compliance review, P2C).

In cases where a compliance issue from a previous compliance lead is not relevant, consideration should still be given as this may be an indicator of negative compliance behaviour or that a sponsor is unaware of their regulatory obligations.

In the case where a compliance issue from a previous compliance lead was found to be unsubstantiated, this should not impact on the context rating of the current compliance lead.

ii) Medicine compliance history based on LCS compliance reviews (Question 11)

Within section 1 of the RTIC, it was already determined whether there is an open or recently completed compliance review for the medicine. If there was, consider whether the breach(es) within the compliance lead can be addressed through the open compliance review or if it has been previously addressed.

If a medicine has been the subject of a previous compliance review (within the last 36 months), read through the relevant review material (proposal to cancel notice, review checklist etc.) to determine if the compliance issue subject to the complaint was existing at the time of the evaluation.

In the case where the issue subject of the compliance lead was noted during a review and not pursued as a breach, consideration should be given as to the need of the investigation. For example, if a complaint is received regarding a potential breach for a sponsor not holding evidence to support a therapeutic claim, but it is noted that during a recent compliance review such therapeutic claim was found to be supported, it is likely that the issue subject of the compliance lead is not a breach.

On the other hand, where a compliance deficiency is found to exist after it was pursued during a compliance review and then proposed to be rectified by the sponsor, this would potentially be an indicator of negative compliance behaviour and therefore may increase the context rating of the lead.

iii) Medicine compliance history based on factors out of LCS' framework (Question 11)

Additional factors beyond the results of LCS compliance reviews and leads may be taken into consideration when assessing the compliance history of a medicine. These factors include recent/relevant issues such as advertising cases, medicine defect reports or recalls (See sections **9.4.3 & 9.4.4** for guidance on searching for this information through QLIK).

General searches of the medicine name/AUST L in TRIM can also be of use to determine if the subject medicine has been or is being investigated by other areas of the TGA (e.g. GMP, PVI, etc.). In such cases, consider if liaising with that section is relevant for the current lead or if the potential breach is already being actioned by another section.

Any relevant information found through the searches above should be considered to determine its impact on the context rating of the current compliance lead.

Examples of such situation are:

- If a complaint is received regarding a potential breach for advertising indications not included on the ARTG of the medicine and the above check provides that the Advertising Compliance Unit previously issued an Obligations notice to the sponsor for the same matter, this would increase the context rating of the lead.
- It is noted that PSAB have an open investigation into an adverse report that was likely derived from the lack of appropriate allergen declaration on the label. In this case it may be suitable to liaise with PSAB to determine their actions to resolve the issue or if a collaborative effort will be required.

2. Assessing the sponsor compliance history (Questions 12,13 and 14)

Q12. Are there any previous compliance leads received about this sponsor in the last 24 months?	Yes ☐ No ☐	Provide a summary of the details and links if applicable.
Q13. Does the sponsor have any notable/relevant issues detected through compliance reviews?	Yes ☐ No ☐	Provide a summary of the details and links if applicable. e.g. Multiple instances where labs have detected prohibited substances, medicine or range of products repeatedly reported for the same reason, sponsor previously admonished for the same reason
Q14. What is the sponsor's compliance history?	Good ☐ Fair ☐ Moderate ☐ Poor ☐	Provide brief reasons for this outcome.

i) Sponsor compliance history based on LCS compliance leads (Question 12)

Search in QLIK for previous complaints or referrals for the same sponsor within the last 24 months. See **Appendix 9.4.2** for guidance on QLIK searches.

If a sponsor has had numerous compliance leads (including or not leads for related matters), this would potentially be an indicator of negative compliance behaviour and therefore may increase the context rating of the lead.

This information should be considered when responding question 14, described below.

ii) Sponsor compliance history based on LCS compliance reviews (Question 13)

Search in QLIK for previous compliance reviews undertaken on medicines of the subject sponsor within the last 36 months. See **Appendix 9.4.2** for guidance on QLIK searches. If possible, filter for reviews where similar issues were pursued and read through the relevant review material (proposal to cancel notice, review checklist etc.) to determine if the sponsor is being systematically non-compliant with certain aspect(s) of the legislation.

If a sponsor has been pursued for related issues, consider discussing with the LCS' Compliance Assurance Manager as a more strategic approach to rectify the issue may be required. This can potentially be an indicator of negative compliance behaviour and therefore may increase the context rating of the lead.

This information should be considered when responding question 14, described below.

iii) Sponsor compliance history (Additional factors) (Question 14)

The assessment of 'Sponsor compliance history' is determined mainly by examining the outcomes of past compliance leads and reviews (discussed above). However, additional factors beyond LCS' past findings may be taken into consideration. These factors include:

- Recent/relevant issues dealt by the Laboratories Branch, Advertising Compliance Unit and/or PSAB (See **9.4.3 & 9.4.4** for guidance on QLIK searches).
- Recent/relevant issues dealt by other areas of the TGA (cursory searches for the sponsor's name in TRIM may be sufficient to determine if such information exists).

All the information compiled in relation to the compliance history of the sponsor should be considered and summarised on the RTIC.

Example:

Sponsor/Medicine history:

- Product has been on the ARTG since 2014
- No relevant product history (leads, complaints, advertising cases, ADR's, recalls etc.)
- Sponsor has a history of 75% non-compliance from 4 reviews – all broad with no safety issues
- Sponsor has had 5 leads since 2014 – all labelling issues

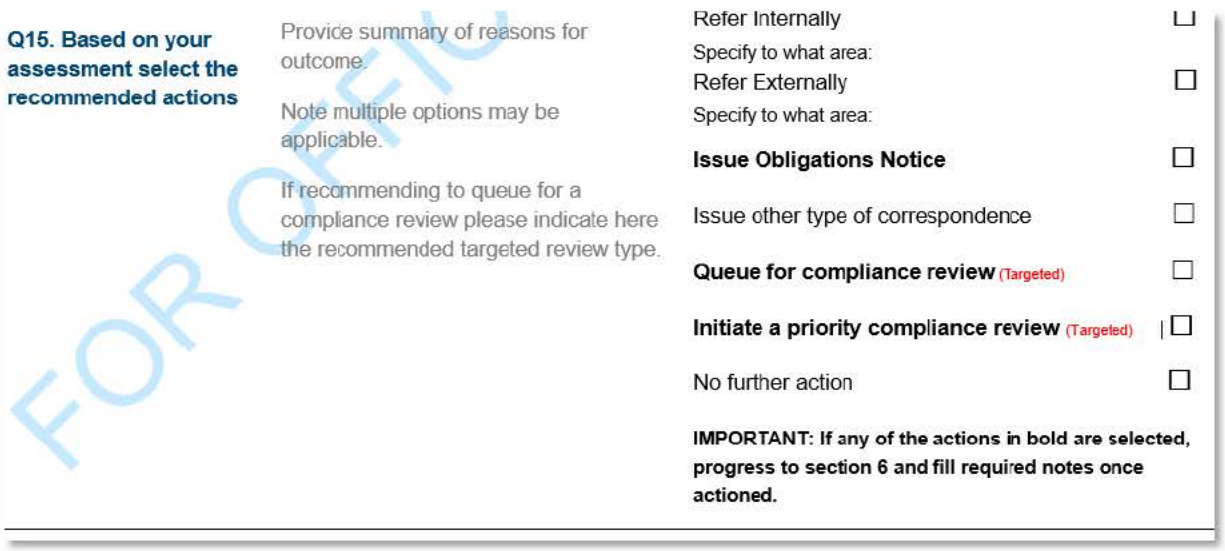
To rate the sponsor's compliance history, please refer to TMP0040 for further guidance.

Rating example:

The sponsor has a 75% rating of non-compliance with all reviews having < 3 deficiencies, with no safety deficiencies noted. The compliance leads have all been minor labelling in nature. None of the medicines listed by this sponsor have been subject to advertising/laboratory/recalls cases, therefore, a compliance history of **moderate** should be assigned.

7.2.5 Determining the required action and priority – Section 5

1. Determining the required action (question 15)



Q15. Based on your assessment select the recommended actions	Provice summary of reasons for outcome. Note multiple options may be applicable. If recommending to queue for a compliance review please indicate here the recommended targeted review type.	Refer Internally ☐ Specify to what area: Refer Externally ☐ Specify to what area: **Issue Obligations Notice** ☐ Issue other type of correspondence ☐ **Queue for compliance review** (Targeted) ☐ **Initiate a priority compliance review** (Targeted) ☐ No further action ☐ **IMPORTANT: If any of the actions in bold are selected, progress to section 6 and fill required notes once actioned.**

The appropriate enforcement action should be selected based on the associated risk of non-compliance and the lead context. Attachments 1 & 2 of the RTIC provide a graphical guide on determining the appropriate action.

Detailed explanatory notes are required to justify the recommended action for the resolution of the compliance lead. These notes should reference the decision tools and details of how such action addresses the identified deficiencies.

Complex leads may require multiple actions or actions not specified in this SOP. Such cases must be discussed with the Leads Manager.

Examples of some typical investigation scenarios are in the table below:

Scenario	Example Action	Associated SOP section
The alleged breaches relate to the advertising material (not including labelling) The alleged breaches relate to a therapeutic good not listed on the ARTG The potential breach is thought to have arisen during manufacture, storage or handling (i.e. a defect of the medicine)	Refer to an internal section of the TGA	***8.1***
The potential breach is related to not holding evidence to support therapeutic claims. Sponsor has a good compliance history	Issue obligations notice	***8.2***

Minor labelling issues noted in an assessment by an internal area of the TGA		
The potential breach is related to not holding evidence in support of therapeutic claims. Sponsor has a poor compliance history The potential breach is related to labelling/presentation (not safety-related) issues for a sponsor with a poor compliance history	Queue compliance review	***8.3***
Testing from the laboratories branch found a prohibited substance in a listed medicine The claims and indications of a medicine (ARTG, label and website) refer to restricted representations and could impact a consumers ability to safely use the goods	Initiate compliance review	***8.4***

If*:*

- Referring to another area of the TGA, see sections 8.1 and 9.1 for further guidance on where and how issues should be referred. The RTIC is finalised at this point. Assign the RTIC for 'clearance' to the Leads Manager using workflow ('clearance') in TRIM and progress to **section 7.4.**
- No potential compliance breach has been identified, no further action should be taken. The RTIC is finalised at this point. Assign the RTIC for 'clearance' to the Leads Manager using workflow ('clearance') in TRIM and progress to **section 7.4.**
- The breach can be appropriately addressed through an educational/obligation notice or a compliance review, progress to point 2 below.

2. Determining the priority for actioning (Question 16)

Q16. Priority for action	E.g. (Low, Medium, High, Critical)

In general, the priority level to initiate an enforcement action is determined on a case by case basis. However, the risk-based activity matrix presented in Attachment 2 of the RTIC provides guidance on the level of priority depending on the non-compliance risk, lead context and enforcement action.

Apart from issues that pose immediate or potential health risks to consumers, the following issues should also be considered of high or critical priority:

- Issues that can be significantly misleading to the Australian public, particularly in a way that could have a negative health impact on vulnerable consumers.
- Issues that are of national or international significance, which may be reflected in anticipated sales volume, knowledge of adverse events, decisions of comparable regulators in other jurisdictions or other intelligence.

- Topics that may attract adverse scrutiny from media or the public, such as inaction in response to specific complaints or concerns raised directly or indirectly with the TGA about listed medicines.

Once the priority for action has been determined, assign the RTIC for 'clearance' to the Leads Manager using workflow ('clearance') in TRIM and progress to **section 7.4.**

7.3 Review of Risk assessment tool & investigation checklist

Stage: [Assessment: Investigation & Risk Assessment]
Responsibility: Leads Manager

Once you receive an email notification that the RTIC has been assigned to you in TRIM for clearance, follow the below actions:

1. Review the RTIC including your comments and editions in track changes.
2. If further work is required, assign the RTIC for amendment to the Work Process Manager using workflow ('amendment required') in TRIM.
3. Repeat steps 1 and 2 as necessary.
4. Once satisfied with the RTIC and recommended action(s), sign and date the checklist, then complete the 'clearance' action in TRIM.
5. Assign the RTIC to the Work Process Manager using workflow ('for completion') in TRIM.

7.4 Complete CLP – Investigation & Risk Assessment in WM

Stage: [Assessment: Investigation & Risk Assessment]
Responsibility: Work Process Manager

1. Once the investigation has been completed and RTIC cleared, under *CLP – Investigation & Risk Assessment* ensure that all the task specific fields are filled as per Figure 1 below.
2. The CLP pathway in eBS WM includes a variety of action tasks by default given that multiple actions can be necessary to handle a complaint or referral. Depending on the recommended action(s), remove the applicable tasks as follows (please note that it is guidance only, you must consider if deleting the suggested actions is appropriate):

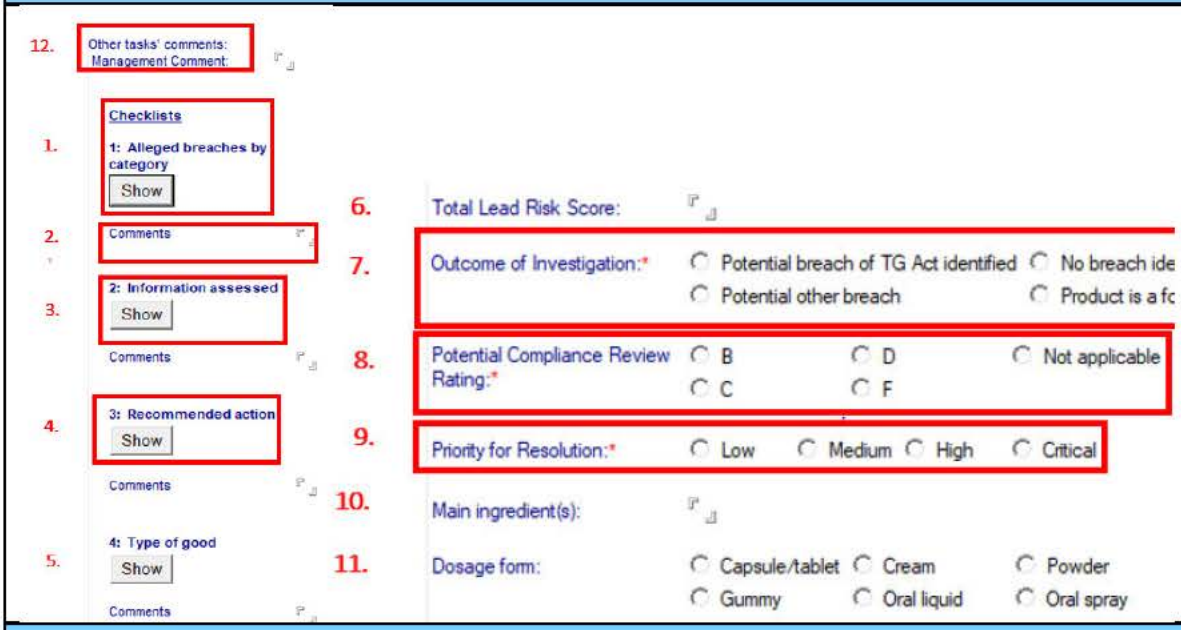
Recommended Action	Task(s) that should be removed
Refer Internally/Externally	*CLP –Issue Correspondence;* and *CLP – Awaiting Compliance Review*
Issue Correspondence/Obligations Notice	*CLP –Referral;* and *CLP – Awaiting Compliance Review*
Initiate/Queue Compliance Review	*CLP –Referral;* and *CLP –Issue Correspondence*
No Further Action	All subsequent tasks up to and including *CLP – Awaiting Compliance Review*

Multiple actions (e.g. Refer & Queue Compliance Review)	Remove the unneeded tasks (e.g *CLP –Issue correspondence*)

3. In the next inactive task, enter the name of Work Process Manger in 'Assigned to'. Save and close. If the next inactive task is *CPL- Finalisation*, assign it to the Leads Team Officer.
4. Complete *CLP – Investigation & Risk Assessment* task. Progress to section 8.

Figure 1. CLP – Investigation & Risk Assessment guidance table

Task Specific Fields – *CLP- Investigation & Risk Assessment* (Numbers correspond to the field numbers in the table below)



Field usage and guidance summary

Field	Usage	Does this field need to be completed?
1. Alleged breaches by category	As determined within the assessment of the compliance lead (Section 7.0)	Yes
2. Alleged breaches by category (comment)	Enter relevant keywords that describe the compliance leads Example: 'Restricted Rep', 'Microbiological testing', etc. **This field is searchable within QLIK to help identify similar leads and provide guidance for consistent action.** Carefully consider the keywords most relevant to the lead.	Yes
3. Information Assessed	As determined within the assessment of the compliance lead (Section 7.2.1 and 7.2.2)	Yes
4. Recommended Action	As determined within the assessment of the compliance lead (Section 7.2.5)	Yes
5. Type of Good	Not applicable for complaints and referrals	No
6. Total Lead Risk Score	Not applicable for complaints and referrals	No

7. Outcome of Investigation	As determined within the assessment of the compliance lead (Section 7.2.2)	Yes
8. Potential Compliance Review Rating	As determined within the assessment of the compliance lead (Section 7.2.3) For low, mark B For medium, mark C For high, mark D For critical, mark F	Yes
9. Priority for Resolution	As determined within the assessment of the compliance lead (Section 7.2.5)	Yes
10. Main ingredient(s)	Not applicable for complaints and referrals	No
11. Dosage form	Not applicable for complaints and referrals	No
12. Management Comment	Include brief notes that indicate the status of the assessment. Example: Risk assessment and investigation checklist completed. TRIM: D19-XXXXX	Yes

8 Actioning the compliance lead

Depending on the outcome of the investigation (Section 7), progress to the relevant section:

Referring the compliance lead: **Section 8.1**
Issuing correspondence/Obligations notice: **Section 8.2**
Queueing the compliance lead for compliance review: **Section 8.3**
Initiating priority compliance review: **Section 8.4**

8.1 Referring the compliance lead

This action is frequently used if the compliance lead cannot be resolved by the LCS and should be referred to an internal area within the TGA and/or an external agency. However, please note that in some cases an LCS action in addition to the referral may be necessary.

8.1.1 Draft and send the referral email

Stage: [Action: Referral]
Responsibility: Work Process Manager

1. Draft a referral email (associated templates 'TMP0023' for referrals can be found in **section 5**). If necessary, seek clearance from your supervisor.
2. Send the referral email to the internal or external stakeholder through your personal mailbox or the CMIb, respectively, attaching all relevant information and requesting a read receipt to have certainty that the referral was received. Ensure that the sent correspondence and read receipt are filed in the relevant TRIM folder.

   See **Appendix 9.1 and 9.2** for a list of the most commonly used contact emails for internal and external referrals.
3. Progress to section 8.1.2.

8.1.2 Complete CLP – Referral in Work Management

Stage: [Action: Referral]
Responsibility: Work Process Manager

1. Once the referral email has been sent, under *CLP – Referral* ensure that all the task specific fields are filled as per Figure 2 below.
2. In the next inactive task, enter the name of the Work Process Manager in 'Assigned to'. Save and close.
3. Complete *CLP – Referral*
4. If additional actions are required, please refer to sections 8.2, 8.3 or 8.4 accordingly. If not additional actions are require, progress to section 8.5.

Figure 2. CLP – Referral guidance table

Task Specific Fields – *CLP - Referral* (Numbers correspond to the field numbers in the table below)

Field usage and guidance summary

Field	Usage	Does this field need to be completed?
1. Referred to	Select the most appropriate option in the checklist. Example: If referring to ECT- select 'TGA – Regulatory Compliance Section'	Yes
2. Management comment	Example: Referral sent to ECT (TRIM: D19-XXXXX.) Acknowledgment received (TRIM: D19-XXXXX.)	Yes

8.2 Issuing correspondence

This action is used if the compliance lead can be resolved through either issuing an Obligations notice, sending general correspondence such as an educational email or other types of correspondence such as Cease and Desist letter. This task can also be used to indicate formal response to a complainant/referee.

8.2.1 Draft the correspondence

Stage: [Action: Issue Correspondence]
Responsibility: Work Process Manager

8.2.1.1 Draft the obligations notice

1. Based on the breaches and deficiencies you identified in the investigation of compliance lead, draft an Obligations notice using the associated template 'TMP0026' and save it in the relevant TRIM folder.
2. Assign the notice for signature to the Leads Manager/EL1 using workflow ('signature' action) in TRIM. Amend document as required.
3. Once the letter has been signed, progress to **section 8.2.3**.

8.2.1.2 Draft the general correspondence

1. Draft the email correspondence. If necessary, seek clearance via email from your supervisor/Leads Manager otherwise progress to **section 8.2.3**.

8.2.2 Review the correspondence

Stage: [Action: Issue Correspondence]
Responsibility: Assistant Director/Leads Manager

8.2.2.1 Review and sign the obligations notice

Once the Wok Process Manager has drafted the obligations notice, you will receive an email notification that it has been assigned to you in TRIM for signature. Then, the following actions should be followed:

1. Review the Obligations notice including your comments and editions in track changes.
2. If further work is required, assign the obligations notice to the Work Process Manager using workflow ('amendment required') in TRIM.
3. Repeat steps 1 and 2 as necessary.
4. Once satisfied with the obligations notice, sign and date the letter, then complete the 'signature' action in TRIM.
5. Assign the obligations notice to the Work Process Manager using workflow ('for completion') in TRIM.

8.2.2.2 Review the general correspondence

Stage: [Action: Issue Correspondence]
Responsibility: Assistant Director/Leads Manager

1. Review the drafted email correspondence. Reply via email to the Work Process Manager with any required amendments/clearance.

8.2.3 Send the correspondence

Stage: [Action: Issue Correspondence]
Responsibility: Work Process Manager

8.2.3.1 Sending the obligations notice

1. Draft an email using the relevant correspondence template (associated templates can be found in **section 5,** e.g. 'TMP0010'), attach the signed Obligations notice in PDF format, select the options to request a delivery and read receipt, and send it to the sponsor through the CMIb.
2. File the sent correspondence together in the relevant TRIM folder.
3. Once the obligations notice has been issued, under *CLP-Issue Correspondence* place the task on a stop clock for two weeks (or as otherwise indicated in the notice). Save and Close.
4. If a response is received before the date for response has lapsed, update Section 6 of the RTIC to indicate that a response was received and under *CLP-Issue Correspondence* re-start the clock. Progress to **section 8.2.4**.
5. If no response is received within the date for response, under *CLP-Issue Correspondence* re-start the clock and update Section 6 of the RTIC to indicate that no response was received. Progress to **section 8.2.5**.

8.2.3.2 Sending the general correspondence

1. Send the drafted correspondence through CMIb ensuring that the LMP number is included in the subject and the options to request a delivery and read receipt are selected.
2. File the sent correspondence in the relevant TRIM folder. Progress to **Section 8.2.5**.
3. If a response is expected, under *CLP-Issue Correspondence* stop the clock and Progress to **section 8.2.4**. If no response is received within the date for response, re-start the clock and progress to **Section 8.2.5**.

8.2.4 Reviewing the correspondence/Obligations notice response

Stage: [Action: Issue Correspondence]
Responsibility: Work Process Manager

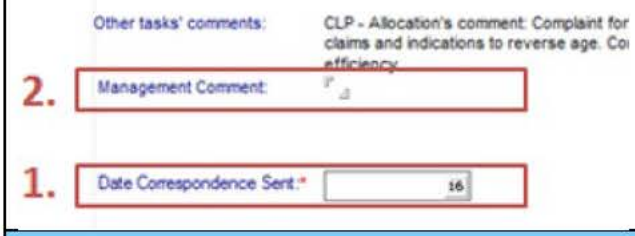
1. UUpdate commentary in WM to indicate that a response was received.
2. If the sponsor provides additional information to demonstrate that the potential breach(es) described in the obligations notices never occurred, consider whether the information provided refutes the breach, does not provide evidence to refute the breach or indicates acceptance or corrective action.
3. Inform the Leads Manager about the response and consider if the Compliance Assurance Manager or the Intelligence Manager need to be informed.
4. Progress to **Section 8.2.5.**

8.2.5 Complete CLP- Issue correspondence in WM

Stage: [Action: Issue Correspondence]
Responsibility: Work Process Manager

1. Under *CLP – Correspondence* ensure that all the task specific fields are filled as per Figure 3 below.
2. Under the next inactive task, enter the name of the Work Process Manager in 'Assigned to'. Save and close.
3. Complete *CLP – Correspondence.*

Figure 3. *CLP – Issue Correspondence* guidance table

Task Specific Fields – *CLP - Issue Correspondence* (Numbers correspond to the field numbers in the table below)


Field usage and guidance summary		
Field	**Usage**	**Does this field need to be completed?**
1. Date Correspondence Sent	The date the correspondence is relayed to the sponsor.	Yes
2. Management Comment	Example: Obligations notice sent to the sponsor (TRIM: D19-XXXXX). Please include any details of the response to the ON, if applicable. Also, add comments in relation to any discussion held with the Leads manager and describe any further action required, if applicable.	Yes

8.3 Queued for compliance review

Stage: [Closure: Awaiting Compliance Review]
Responsibility: Leads Team

This action is used if the compliance lead can be resolved through a non-priority compliance review. Therefore, it is important that any deficiency detected through the compliance lead investigation **is not safety-related or poses a risk to the TGA (please consider the aspects raised in point 2 of section 7.2.5).**

1. Under *CLP – Awaiting Compliance Review* and *CLP – Finalisation* (inactive at this point), enter the name of the Leads Team Manager in 'Assigned to'. Save and close.

At this point, the Work Process Manager's job is completed. Please ensure that ***CLP – Awaiting Compliance Review*** remains active. Ensure that the compliance lead WM and TRIM records are up to date.

All investigations that are queued for review (i.e. the active WM task is *CLP-Awaiting Compliance Review*), remain queued together with other medium priority leads that LCS receives on a daily basis. The LCS leadership team will select to initiate new reviews from the medium priority pool as capacity arises within LCS.

2. When an EL1 has selected a new review to be initiated and alerted the leads team, the leads team will assist him/her by completing the steps outlined in section **8.4.2** and then progressing to section **8.5.1.**

8.4 Initiate a priority compliance review

Stage: [Action: Awaiting Compliance Review]
Responsibility: Leads Team

This action is used to resolve compliance leads investigations where the found deficiencies:

- may result in an immediate or potential health risk to consumers;
- could significantly mislead the Australian public, particularly where there is a health impact;
- involve a new or emerging issue of concern;
- are likely to become widespread if we do not intervene;
- are the subject of public or media scrutiny and concern;
- are of national or international significance; and/or
- could lead to a loss of stakeholder confidence in the Government's regulatory scheme or in therapeutic goods (amongst others).

8.4.1 Request for a review to be triggered

Stage: [Action: Awaiting Compliance Review]
Responsibility: Work Process Manager

1. Once the Work Process Manager and Leads Manager have agreed on the need to initiate a priority compliance review, request the Leads Team Officer to trigger and allocate an ARTG Work Process in WM for the subject medicine. Progress to **section 8.4.3**.

8.4.2 Initiation and allocation of compliance review

Stage: [Action: Awaiting Compliance Review]
Responsibility: Leads Team

1. Trigger an ARTG Work Process in WM. If the compliance lead relates to more than one medicine, each medicine should have a separate process.
1. Allocate the review owner as indicated in the review request. Follow the video instructions in D19-5525877.
2. Under the new ARTG Work Process' *CRP-Allocation* task, enter the associated CLP number and TRIM link of the RTIC.
3. Complete Section 6 of the RTIC by providing the date the review was initiated and the associated Compliance Review Process number.
4. Complete task *CLP-Awaiting Compliance review.* Progress to **section 8.5.1**

8.4.3 Drafting and sending a targeted request for information (s31)

Stage: [Action: Awaiting Compliance Review]
Responsibility: Work Process Manager

1. Locate the associated compliance lead RFI template 'TMP0023'.
2. Draft the compliance lead RFI email based on the breaches and recommendations determined in the RTIC. If necessary, seek clearance from your supervisor, this includes if delegation is required.
5. Send the RFI to the sponsor through the CMIb.
6. File the sent correspondence in the relevant TRIM folder.
7. Progress to **section 8.5.1** and continue the compliance review process as per SOP0003.

8.5 Closure

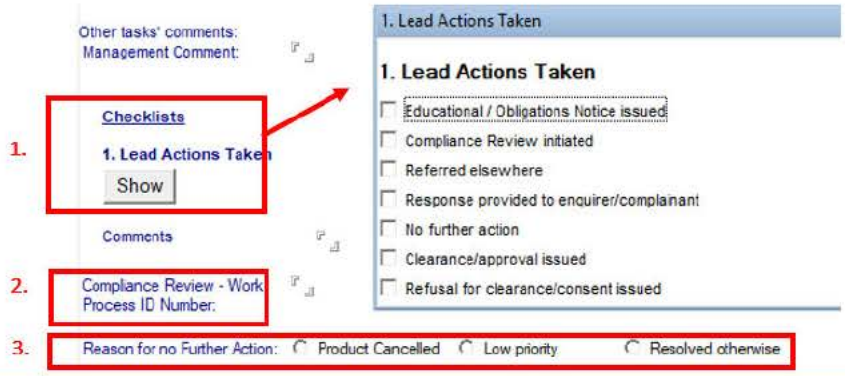
8.5.1 Fill CLP – Finalisation in Work Management

Stage: [Closure: Finalisation]
Responsibility: Work Process Manager

1. Under *CLP – Finalisation* ensure that all task specific fields are filled as per Figure 4 below. Enter the name of the Leads Team Officer in 'Assigned to'. Save and close.

Figure 4. CLP – Finalisation table

Task Specific Fields – Finalisation (Numbers correspond to the field numbers in the guidance table below)



Field usage and guidance summary

Field	Usage	Does this field need to be completed?
1. Lead Actions Taken	Select the appropriate option based on the actions taken to resolve the compliance lead (more than one option can be selected)	Yes
2. Compliance Review- Work	If a priority compliance review was initiated to resolve the detected deficiencies, enter the CRP number of the associated ARTG Work Process	If applicable

	Process ID Number	For all others cases leave blank	
3.	Reason for no Further Action	Based on the actions taken during the lead select the associated reason for no further action	If applicable
4.	Management Comment	Only use if relevant notes should be captured in this field (e.g. providing reasoning for no further action if 'Resolved Otherwise' is selected)	No

8.5.2 Complete CLP – Finalisation in Work Management

Stage: [Closure: Finalisation]
Responsibility: Leads Team

1. Check that all fields within *CLP – Finalisation* are filled correctly as per the task guidance table above.
2. If the compliance lead relates to one product (i.e triggered as an ARTG Work process) record a decision by following the steps depicted in: D19-5519471 LCS - eBS Work Management - Record a Decision on final Task (leaving the field for 'delegate' in blank as this is not a delegate's decision)
3. Save and complete the *CLP- Finalisation* task.

9 Appendix

9.1 Referring to internal areas of the TGA

Example of issue (Note: This is not an exhaustive list)	TGA area	Response expected from referral
The product should be, but is not, registered or listed on the ARTG	Enforcement Coordination Team (ECT) ECT@health.gov.au	Yes, within 5 business days
The product is potentially counterfeit	Enforcement Coordination Team (ECT) ECT@health.gov.au	Yes, within 5 business days
The complaint describes an adverse event	Adverse Event & Medicine Defect (PSAB) adr.reports@health.gov.au	No
The complaint describes adulteration, contamination or a problem thought to have arisen during manufacture, storage or	Adverse Event & Medicine Defect (PSAB) adr.reports@health.gov.au	No

Example of issue (Note: This is not an exhaustive list)	TGA area	Response expected from referral
handling (i.e. a defect of the medicine) Note: defects can include complaints that relate to the integrity of the packaging or quality of a product, including missing expiry date/batch number, capsule integrity and tablet size, amongst others.		
The complaint relates to non-compliance of a manufacturer	Manufacturing & Quality Branch (MQB) GMPCompliance@health.gov.au	No
The complaint relates to advertising material (not including labelling)	Advertising Compliance Unit (ACU) advertising.compliance@tga.gov.au	No
Medicine Interface Assessment	Food-Medicine Interface mailbox food-medincine.interface@health.gov.au	No

9.2 Referring to external areas outside of the TGA

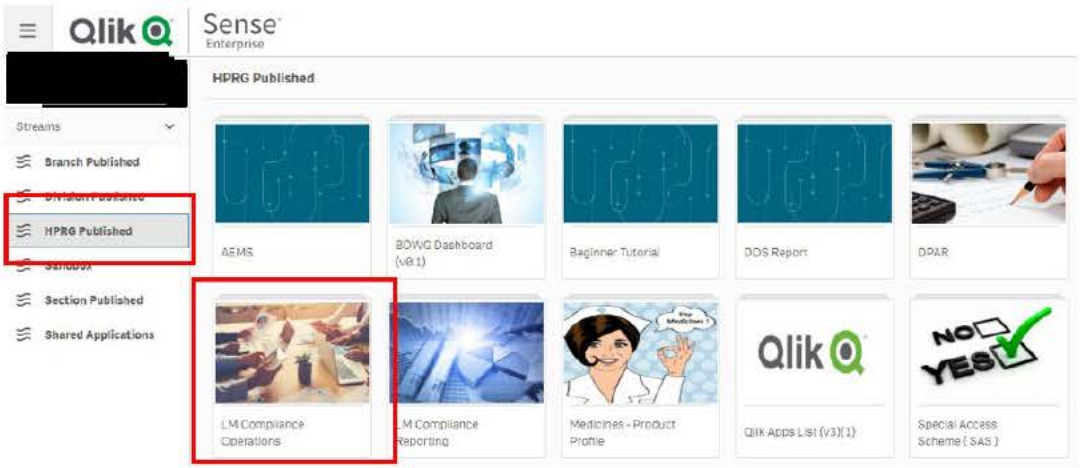
Example of issue (Note: This is not an exhaustive list)	Organisation
The complaint relates to how medicines are stored, housed or sold within a retailer	Contact details of State/Territory medicines & poisons regulation units **ACT** Telephone: 02 5124 9208 Fax: 02 5124 9309 Email: hps@act.gov.au **NSW** Telephone: 02 9391 9944 Fax: 02 9424 5860 Email: pharmserv@doh.health.nsw.gov.au **NT** Telephone: 08 8922 7341 Fax: 08 8922 7200 Email: poisonscontrol@nt.gov.au **QLD** Telephone: 07 3708 5264 Email: mrq@health.qld.gov.au **SA**

Example of issue (Note: This is not an exhaustive list)	Organisation
	Telephone: 08 8204 1944 Email: Health.MTPP@sa.gov.au **TAS** Telephone: 03 6166 0400 Fax: 03 6173 0820 **VIC** Telephone: 1300 364 545 Fax: 1300 360 830 **WA** Telephone: 08 9222 6883 Fax: 08 9222 2463
The complaint relates to 'Australia Made'	Contact ACCC
The complaint relates cosmetics or chemicals	Contact NICNAS
The complaint relates to a healthcare practitioner	Contact AHPRHA

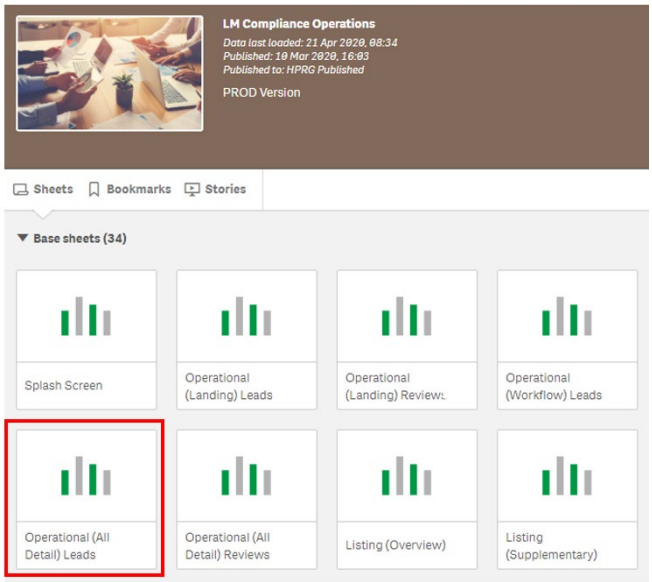
9.3 Guidance for determining similar compliance leads

To help with consistent actioning of similar compliance leads you are able to search and determine relevant compliance leads assessments. The steps to determine this information are:

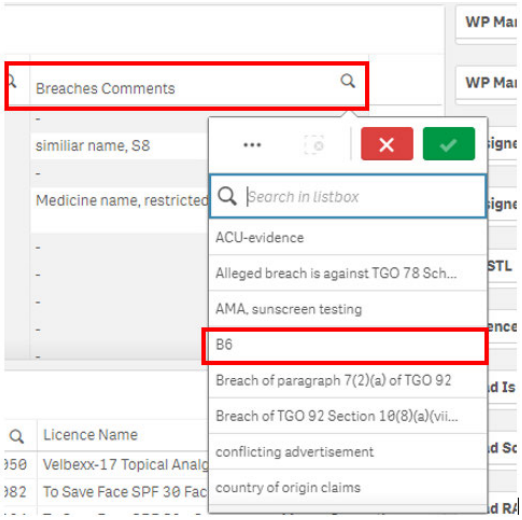
1. From the QLIK Sense Hub access the LM Compliance Operations App.



2. Select the 'Operational (All Detail) leads sheet.



3. Within the field '*Breaches Comment*' you can then search keywords that relate to previous compliance leads assessments and actions. This page will provide an overview of the lead, its open stage, or if closed, the actions taken and breaches found.

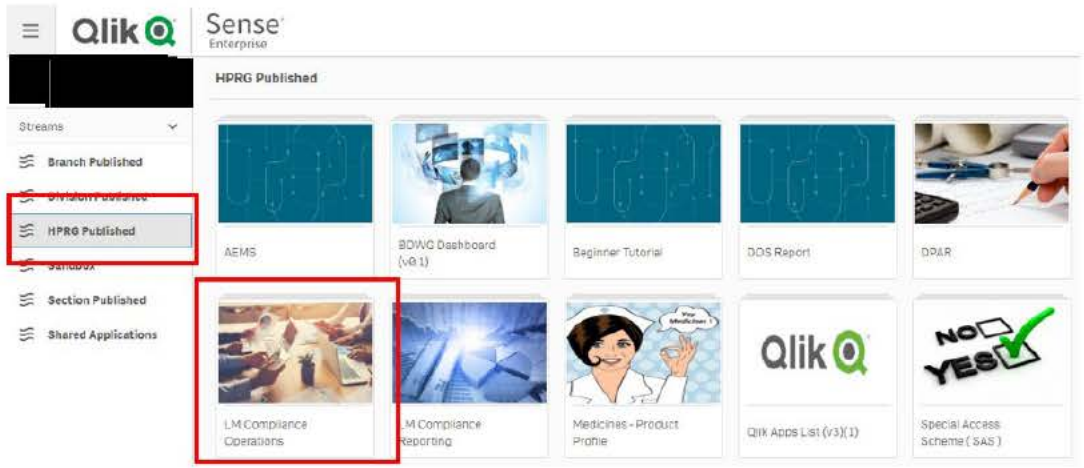


9.4 Guidance for determining medicine & sponsor compliance history

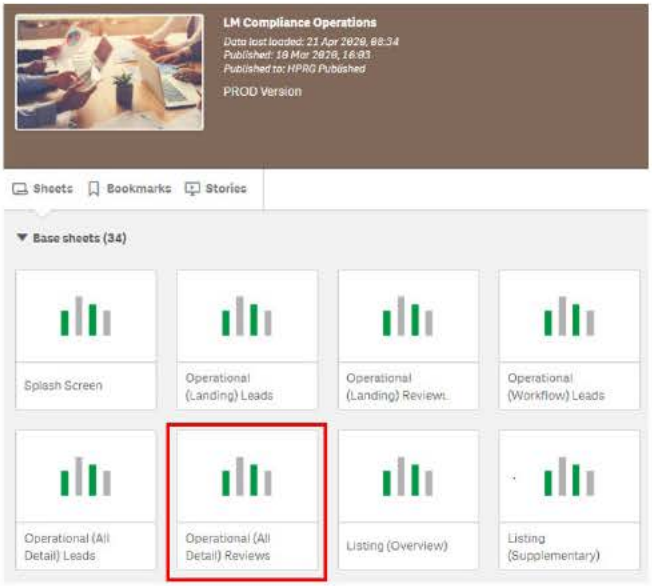
This section aims to provide guidance on how to gather information to determine any relevant sponsor, medicine or issue history to allow the Work Process Manager to determine any relevant context as required throughout completing the RTIC. This information will subsequently be used in determining the correct action and priority for actioning the compliance lead.

9.4.1 Checking if the subject medicine has an open review or a recently completed review

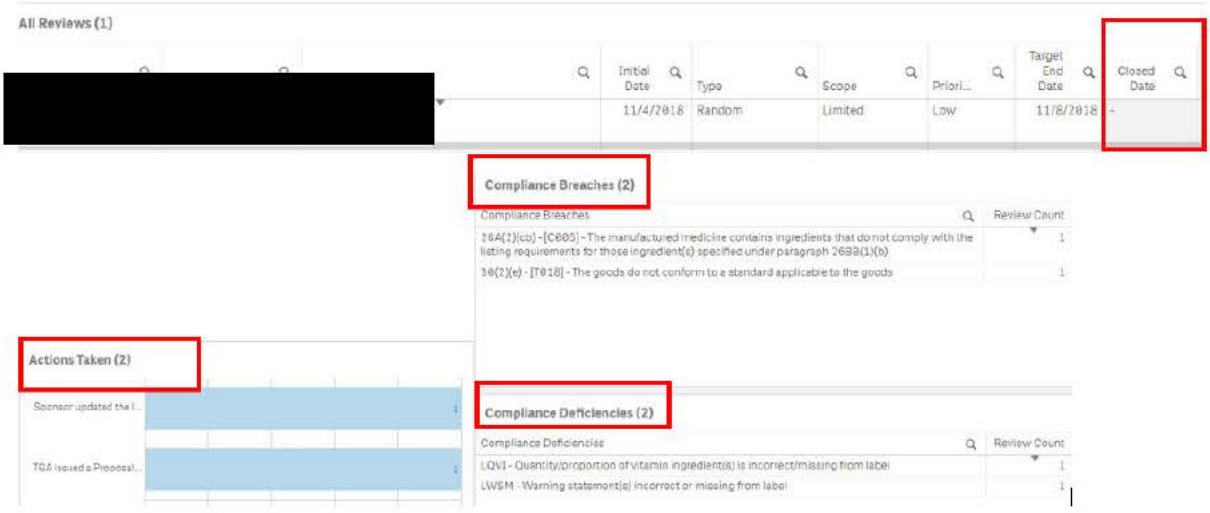
1. From the QLIK Sense Hub access the LM Compliance Operations App



2. Select the 'Operational (All Detail) Reviews sheet.

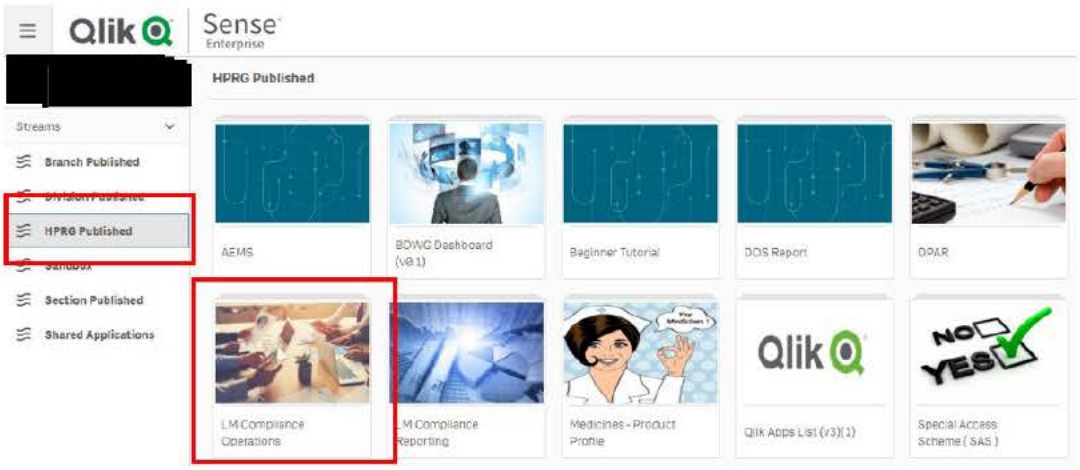


3. Within the field '*AUST L'* you can then search the AUST L and see all open or closed compliance reviews for the medicine. This page will provide an overview of the review, if it is open or closed, the actions taken and breaches determined.

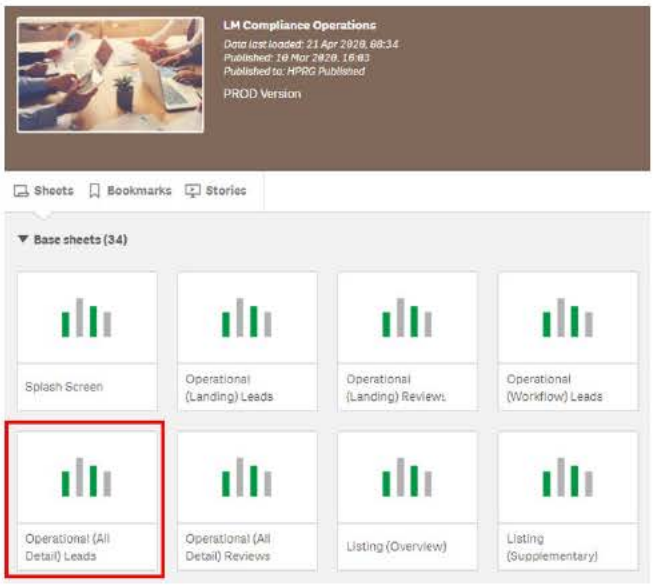


9.4.2 Previous LCS compliance leads for the subject medicine/sponsor

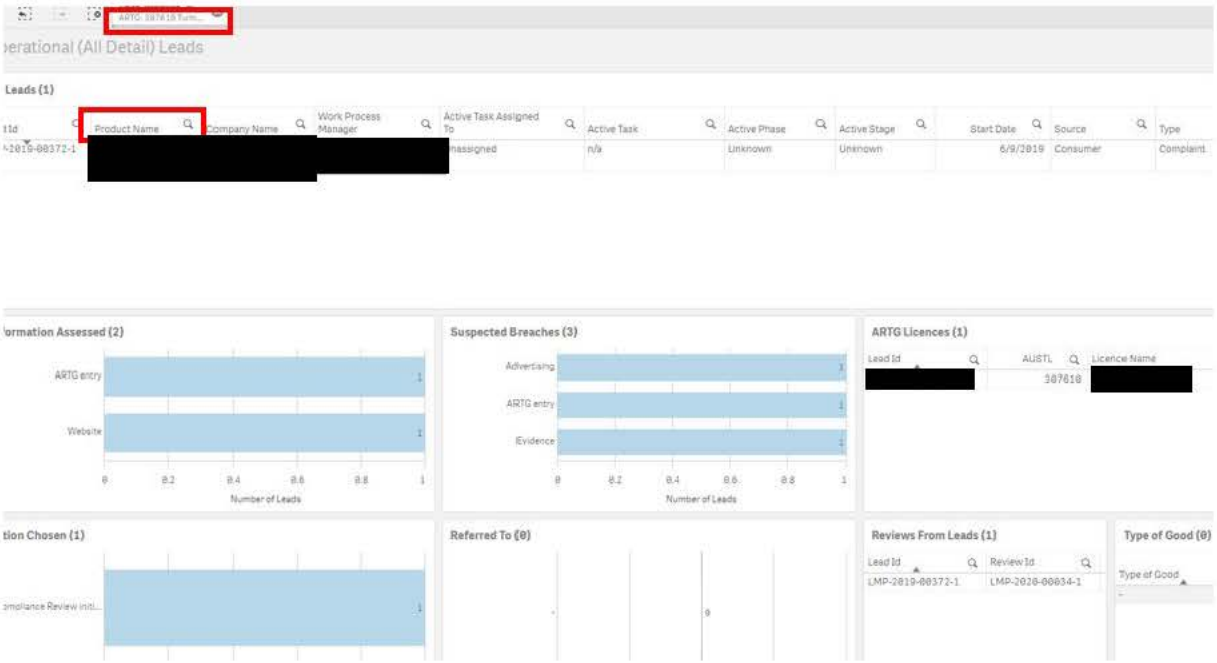
1. From the QLIK Sense Hub access the LM Compliance Operations App



2. Select the 'Operational (All Detail) leads sheet.

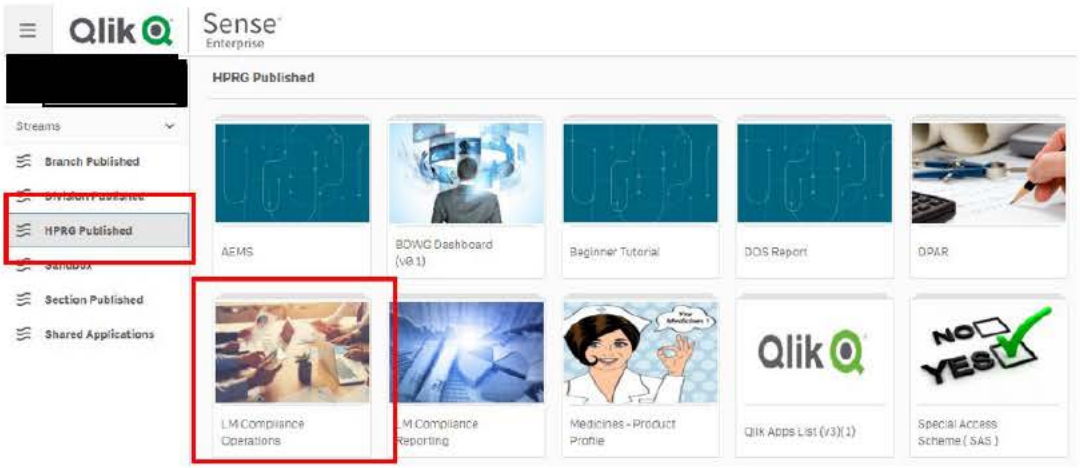


3. Within the field '*Product Name*' search the AUST L or the name of the subject medicine or if searching for sponsor search the associated name within the field '*Company name*'. This action filters for all the open or closed compliance leads for the subject medicine/sponsor (including Aristolochic Acid Assessments and section 14 Assessments). This page will provide an overview of the lead, its open stage, or if closed, the found breaches and actions taken.

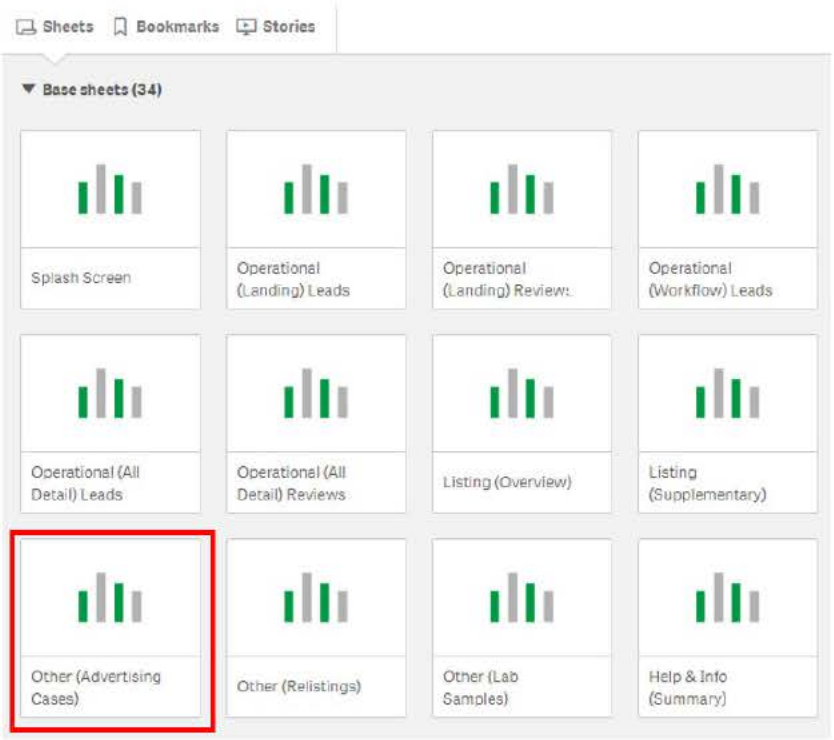


9.4.3 Advertising cases for medicine/sponsor

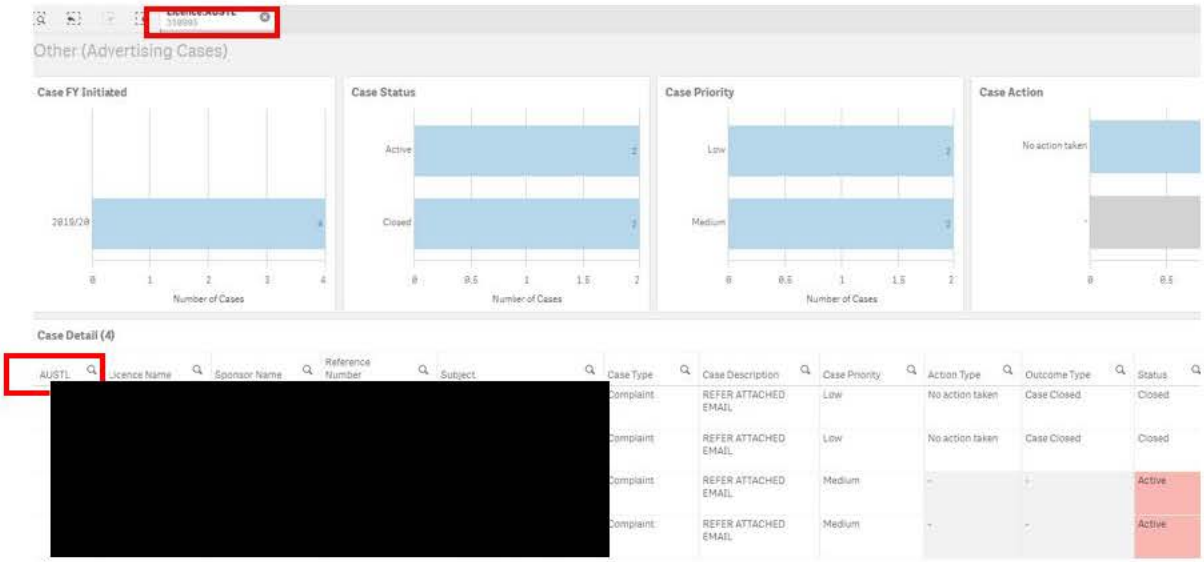
1. From the QLIK Sense Hub access the LM Compliance Operations App



2. Select the 'Other (Advertising Cases) sheet.

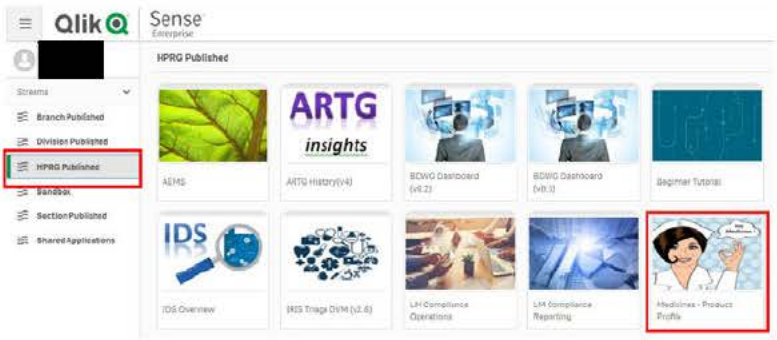


3. Search specific medicines within the field '*AUST L'* to see open or closed advertising cases and associated information. If searching for cases associated with a sponsor within the field '*Sponsor name'* enter the applicable name.

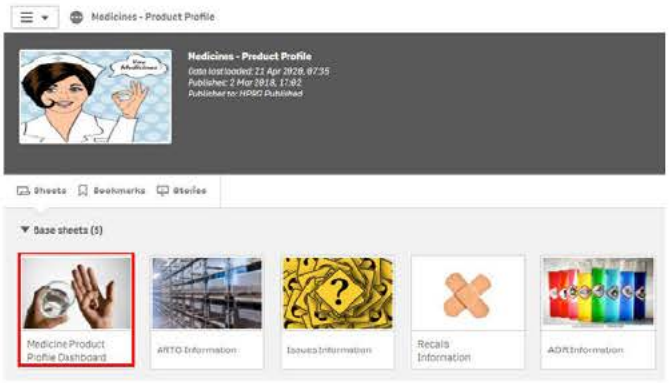


9.4.4 Medicine Issues (Adverse events, defects & recalls)

1. From the QLIK Sense Hub access the Medicines –Product Profile



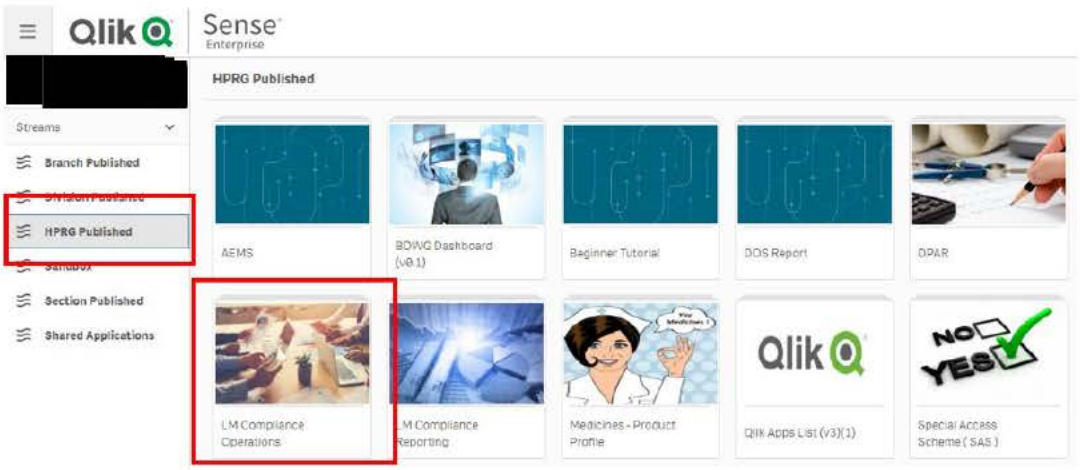
2. Select the 'Medicine Product Profile Dashboard' sheet.



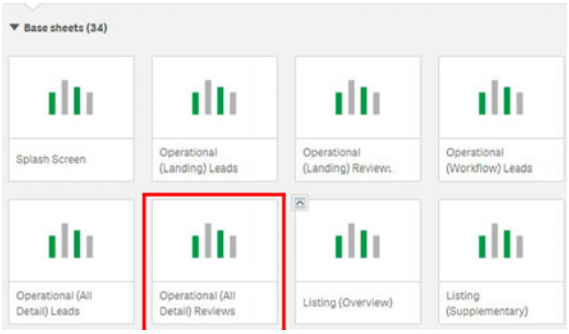
3. Within the field '*Licence ID*' or '*Licence Name*' you can search the AUST L or name of the subject medicine and see any issues like adverse events, defects and/or recalls.

9.4.5 Previous LCS compliance reviews for the subject sponsor

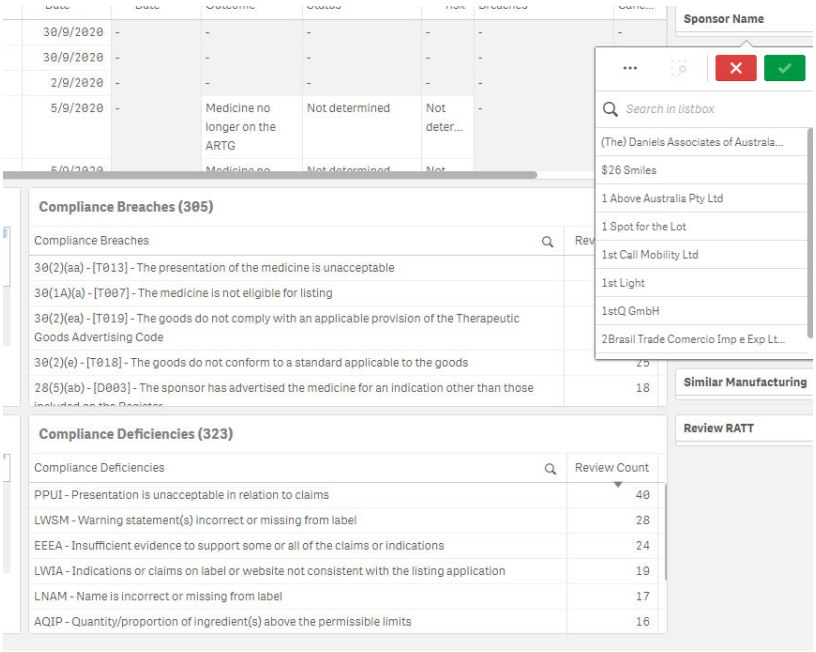
1. From the QLIK Sense Hub access the LM Compliance Operations App



2. Select the 'Operational (All Detail) Reviews sheet.



3. Within the field '*Sponsor*' search the name of the subject sponsor. This action filters for all the open or closed compliance reviews for the subject medicine/sponsor. This page will provide an overview of the reviews, its open stage, or if closed, the found breaches and actions taken.



9.5 Managing Advertising referrals for evidence reviews

Temporarily, please refer to SOP0015.