Table 1. Recommended enforcement actions and priority for action by equivalent Non-Compliance Risk and lead context

This risk based activity model outlines the enforcement actions we may take based on the categorisation allocated to a lead. This is a guide only as the decision to use a particular action is taken on a case by case basis. These actions may be taken alone or in combination to achieve outcomes in the most timely and efficient manner.

ACTIVITY				
Context \ **Risk**	**Equivalent Non-Compliance Risk‡**			
	Low Minor deficiencies only	**Medium** ≥ 1 efficacy deficiency (no safety deficiencies)	**High** ≥ 1 safety deficiency	**Critical** ≥ 1 safety deficiency[1]
Combination of: • Concern about **Lead Background*** (★★★★ – ★); • **Lead credibility/ source†**; • **Lead quality^** **Low** ↓ **High**	Education notice Obligations notice	Obligations notice	Initiate compliance review	Initiation of compliance review Quarantine Notice
	Education notice Obligations notice	Obligations notice	Initiate compliance review	Proposal to cancel[2,3] Referral for recall consideration[4], Infringement notice[1]
	Obligations notice	Initiate compliance review	Proposal to cancel with discretion[2] Proposal to quarantine Referral for recall consideration	Referral for recall consideration[4] Immediate cancellation[5], Infringement notice[1]
	Initiate compliance review Infringement notice	Initiate compliance review	Proposal to cancel[2,3] Referral for recall consideration[4] Infringement notice[1]	Referral for recall consideration[4] Immediate cancellation[5] Infringement notice[1]

PRIORITISATION SCHEME		
Priority for action	**Colour code**	**Target time for action (working days)**
Low		≤ 60
Medium		≤ 20
High		≤ 10
Critical		≤ 2

** See **Table 2** for details of how the Lead Background is determined, taking into account sponsor and medicine lead frequency and the compliance history of the sponsor.*

‡ Due to alleged/potential deficiencies (breaches of legislated requirements) that are the subject of the lead.

*† Referrals of **advertising cases** for evaluation of evidence for indications/claims are attributed a higher priority for a compliance review (evaluation of evidence)—prioritisation by the LCS will be in consideration of the advertising prioritisation model (medium or high).*

^ Sufficiency of information to be able to determine that a breach is likely to have occurred.

[1] Where adverse impacts on consumer safety are likely or imminent will be actioned independently of the sponsor's compliance profile, which will be considered to determine if an infringement notice is appropriate.

[2] Assumes sufficient information is available to be confident of a breach without requesting information from the sponsor. Discretion means sponsor receives Proposal to Cancel notice and is then provided successive opportunities to correct deficiencies, where possible, in response to the Proposal to Cancel notice to bring their product into compliance without the TGA proceeding to cancel the medicine from the ARTG.

[3] Sponsor receives Proposal to Cancel notice and has opportunity to respond/refute TGA assessment and immediately correct the deficiencies. However, if deficiencies are not rectified, LCS will proceed to enforcement action (cancellation) without further notification to the sponsor.

[4] Referral in collaboration with Adverse Events and Medicines Defects Section.

[5] Product is cancelled without prior notice, but only if the criteria specified under section 30(1) or 30(1A) of the Therapeutic Goods Act (1989) have been met.

Table 2. Guide to calculation of Lead Background

The Lead Background (★★★★ to ★) takes into account (a) the sponsor's compliance history[a] from past compliance reviews, (b) the frequency of leads overall for the sponsor (adjusted for number of listed medicines they have on the ARTG, and (c) the number of past leads for the medicine that is the subject of the current lead within the preceding 3 years. The numbers presented in each category are provided as a guide to enable consistency between decisions. It is important to note that delegate discretion will be exercised when making a decision about the history of a particular sponsor or medicine.

		Sponsor Compliance History (based on past compliance reviews)[a]			
		Good	**Fair**	**Moderate**	**Poor**
Sponsor lead frequency[†]	**Low (4th quartile)**	★★★★	≤ 2 medicine leads: ★★★★ 3-4 medicine leads: ★★★ ≥ 5 medicine leads: ★★	≤ 2 medicine leads: ★★★ 3 medicine leads: ★★ ≥ 4 medicine leads: ★	≤ 2 medicine leads: ★★ ≥ 3 medicine leads: ★
	Medium (2nd - 3rd quartiles)	≤ 2 medicine leads: ★★★★ 3-4 medicine leads: ★★★ ≥ 5 medicine leads: ★★	≤ 1 medicine leads: ★★★★ 2 medicine leads: ★★★ ≥ 3 medicine leads: ★★	≤ 1 medicine leads: ★★★ 2 medicine leads: ★★ ≥ 3 medicine leads: ★	≤ 1 medicine leads: ★★ ≥ 2 medicine leads: ★
	High (1st quartile)	≤ 2 medicine leads: ★★★ ≥ 3 medicine leads: ★★	≤ 2 medicine leads: ★★★ 3 medicine leads: ★★ ≥ 4 medicine leads: ★	≤ 1 medicine leads: ★★ ≥ 2 medicine leads: ★	★

a, Sponsor compliance history is explained in the RPC paper on the 'Enforcement model for listed medicines compliance reviews' that will be considered by the Committee at the same meeting

†, Frequency of substantive (non-spurious) leads relative to total number of listed medicines by the sponsor, adjusted so that sponsors with a small number products are not disproportionately represented by a few leads (the median number of listed medicines by sponsor is 2). This indicates whether the sponsor's products are disproportionately complained about or referred to LCS, or whether their products are on par with their peers. LCS proposes to use sponsor rank as the adjustment factor, but this is still in development.

Note: 'medicine leads' means past leads within the last 3 years about the same medicine that is the subject of the current lead.

Note: if the medicine that is the subject of the lead has been subject to a compliance review in the past, the Non-Compliance Risk for that review will be taken into account to adjust the Lead Background up or down accordingly from the table above. For example, if a high number of past leads about the medicine suggests a Lead Background of 'Fair', but the medicine was recently reviewed by us as being compliant, then the profile may be down-graded to 'Good'.