

Attachment 2 – Prioritisation and handling model for listed medicine compliance leads

Application of the model – Examples

The following examples illustrate the use of the model on incoming leads. All the described steps follow the proposed categorisation and prioritisation described in tables 1 and 2 of Attachment 1. Triage of incoming leads generally occur within 1-3 working days.

Aspects for lead-assessment	Example 1	Example 2	Example 3
Lead description	Referral from Regulatory Affairs agent claiming that multivitamin product for pregnancy exceed the permitted amount of folic acid	Complaint from consumer claiming that a product for reducing appearance of varicose veins does not work as promised on the label/website	Referral from the Advertising Unit for an evidence evaluation- referred as 'medium priority'
Equivalent Risk due to alleged/potential breaches	High – Contains an ingredient in an amount that exceeds the permissible limit for listed medicines	Medium - Efficacy claims are unsupported, misleading, but consumer safety is not expected to be adversely affected	Medium - rated in accordance with Advertising Unit internal rating
Lead Background*	★★★★	★★★★★	n/a
Sponsor compliance history	Moderate. Two other products reviewed within the last 2 years. Two 'C' and three 'B' deficiencies identified.	Good. One other product reviewed within the last 3 years. No deficiencies were identified	n/a
Sponsor rank-adjusted lead frequency	Low (4 th quartile). One lead received 2 months ago in relation to a different issue, it was rated 'C'	No past leads	n/a
Medicine leads	None	None	n/a
Priority for resolution	High	Low	Medium
Enforcement action	Initiated compliance review	Obligations Notice	Initiated compliance review
Action time	≤ 10 working days	40 working days	20 working days

*See Attachment 1 for guidance on the criteria to determine the Lead Background