

Regulatory complaints and compliance activities: investigation and prioritisation process

Regulatory Compliance Framework

All complaints are carefully prioritised. We value all information we receive about cases of potential non-compliance and regularly adjust our strategies for prioritisation in response to new information or trends.

The approach we take to monitoring and enforcing compliance is detailed in our [Regulatory Compliance Framework](#). All complaints are considered in accordance with this Framework.

Our monitoring and compliance programs receive a large number of reports of possible non-compliance with regulatory requirements from many sources.

All reports, including complaints by the general public or competitors, about a therapeutic good, are recorded and considered, but due to the large number of complaints it is not possible to investigate all of them individually but they are stored for future reference if the need arises.

We take a risk-based approach to prioritise complaints, and the actions we take are appropriate to the likely risk associated with the non-compliance.

Prioritisation criteria

The following criteria are indicative of the factors that guide prioritisation of investigations of potential compliance issues, including complaints.

We prioritise issues that may:

- Have adverse health consequences for consumers as a result of public access to dangerous or inappropriate goods.
- Affect TGA's reputation among key stakeholders leading to a loss of confidence in our regulatory processes and subsequently a loss of confidence in available therapeutic goods.

We may not follow up on complaints, including complaints about a competitor's product, if these criteria are not met.

We are less likely to pursue matters that are one-off events, unless there are public health consequences and/or non-compliance is a deliberate and a blatant breach of the law.

An initial decision not to further investigate a complaint may be revisited at a later time if circumstances change.

We have no jurisdiction over food, cosmetics or the practices of healthcare professionals and so we do not investigate any of these complaints. Complaints about

- food are within the regulatory jurisdiction of the states and territories;
- cosmetics are a matter for the NICNAS and/or the ACCC; and
- healthcare professionals should be directed to the relevant [professional board](#).

Information on the conduct of compliance activities and complaints

To ensure privacy principles are followed and to respect natural justice requirements, we do not routinely provide complainants with details of our prioritisation decisions or advise them of the progress of our investigations. We do not release the names of complainants in response to inquiries, including in response to requests under the Freedom of Information Act.

However, information on the outcomes of some of our compliance activities is available in the [Compliance Actions](#) section of the TGA's website.

The TGA has also developed a large amount of educational material for consumers, healthcare providers, industry and students covering all aspects of TGA's regulatory processes. This information can be found on the TGA website at:

<http://www.tga.gov.au/educational-materials>

Details relating to TGA's customer service standards can be found at:

<http://www.tga.gov.au/tga-customer-service-standards>