IPA Quality Forum – Launch of best practice document

Investigation of Market complaints

5th INDIA PHARMACEUTICAL FORUM 2020

IPA
Innovation, Quality and Global Reach

IPA Sub-group on Handling of Market Complaints

Context and objective(s)

- **Promoting thought leadership** is among top 3 focus areas of IPA Quality Forum
- Handling of market complaints was identified as **one of 8 areas for developing and sharing best practices** across companies
- **Effort was initiated in 2017** with 6 representatives from member companies of IPA Quality Forum

Team members

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Document created by the subgroup in order to develop and share a harmonized set of ‘best-practices’ with the broader pharma community; 4 key imperatives

‘Need of the hour’ for quality and compliance	▪ **Product complaint handling system is second most cited 483**, with 326 EIR observations, which was 3% of overall EIR observations[1]
Standardized set of best practices needed across companies	▪ While, guidance documents from various regulatory agencies are available online, the interpretation and implementation of each (through the QMS) was **largely at the discretion of respective companies**
Latest thinking across agencies need to be understood	▪ Several best-practices have been made available by agencies over the years; this effort was taken up to **represent agencies’ most current thinking on this topic**[2]
Need for adopting a risk-based approach across companies	▪ **Help pharma community choose a risk based approach towards addressing market complaints**, through a harmonized best-practice document for handling market complaints

SOURCE: 1 USFDA's 2016 enforcement statistics; 2 https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

This best-practice document is a culmination of efforts from multiple sources

Benchmarking of best practices across organizations

Available guidance from various regulatory authorities

Review by independent external expert(s)

Over last 2 years, the team has got together through multiple calls, in person meetings, and emails

The document covers best practices across the ‘life-cycle’ of a market complaint; i.e. from receipt to closure of complaints

Receipt of complaint

- Defines process to be followed once complaint is received

Categorization of complaint

- Categorisation of complaints in critical, major or minor

Regulatory notification

- Process to raise Alert notification or field action report

Investigation

- Historical review of product
- Health Hazard Evaluation
- Risk assessment

Receipt & handling of samples

- Process for receipt and handling of samples

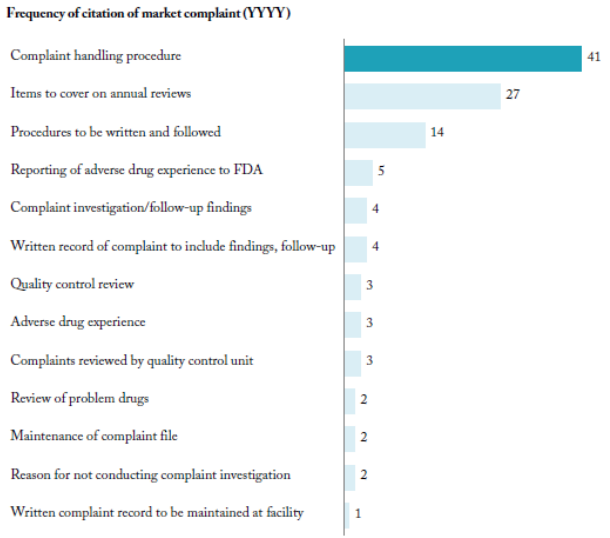
Closure of complaints

- Process to close the complaint

The best practice document additionally provides process for trending of complaints, management review, record keeping and quality metrics data

The document also shares 4 sets of read-to-deploy templates

1. Trending of market complaints
2. Risk assessment
3. Query template
4. Dosage form wise investigation checklist



Type of complaint	Severity	BMR	BPR	Analysis as per approved RSM/PMOP	Physical Inspection of complaint/ Reserve Sample	Analysis of complaint/ Reserve sample	Check weighter	Stability Data	Method/ Process	Was a root cause of change past ?	In-process checks	Procurement of raw material	Calibration/ PMP	Complaint log	Qualification	Equipment log book	Operating instructions	Annual Product Quality Review	Incident	Change to procedure	Training
Bitter taste of tablet	Low	✓	✓	✓	✓			✓	✓		✓	✓		✓	✓	✓		✓	✓	✓	✓
Smell defect of product	Medium	✓	✓	✓	✓			✓	✓		✓	✓		✓	✓			✓	✓	✓	✓
Broken capsule	Medium	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓	✓			✓	✓	✓	✓
Black spots on tablet	Medium	✓	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Coating peel off	Medium	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Product not dissolving	High	✓		✓	✓	✓		✓	✓		✓	✓		✓				✓	✓	✓	✓
Difficult to swallow	Low	✓			✓			✓	✓		✓				✓			✓	✓	✓	✓
Lack of effect	Medium	✓	✓	✓		✓		✓	✓		✓	✓			✓			✓	✓	✓	✓

Date of receipt	
Mode of complaint receipt	Mail/-Courier-/-Fax-/-Telephonic-/-Other (Specify:_____)
Market	
Complainant information	
Greeting/salutation	
Name of complainant	
Occupation/relation to the patient	
Company	
Address	
Telephone	
Email	
Complaint related ro	Packaging-/-Quality-/-ADE/Other (Specify:_____)
Response Letter requested by Complainant	Yes-/-No-/-NA
Did the complainant request monetary reimbursement?	Yes-/-No
Any additional information	
Product information	
Brand name	
Generic name	
Dosage form	Tablet/Capsule/Dry Powder Injection/Dry Powder Suspension/Drops/ Inhaler/Cream/Spray/Liquid Injection, Other (Specify:_____)
Controlled substances product	Yes-/-No
Strength	
Pack type	
Batch No	
Expiry Date	
Manufacturing site	
NDC Number	
Storage condition	