PAAB Tags 2022

QUARTERLY REVIEW

Confidence in confidentiality

As a reminder, client tags trigger internal audits for validation by PAAB's Director of Pre-clearance Services, Yin Man. Any tags pertaining to Yin are validated by the Commissioner and removed from the report provided to Yin. **No Reviewer, Senior Reviewer or Director is EVER aware of tags generated by clients**. You can be confident in the confidentiality of the tagging system. For additional reassurance, the tagging system, tag assessments, and documented actions taken will periodically be reviewed by an external auditor.

What does PAAB use the tags for?

- Staff and system performance metrics
- To identify trends and training opportunities
- To stay inform on what is going well (best practices) and areas for improvement

If you'd like to learn more about the client tagging system, check out the Client Tagging System Advisory. You'll also find links to useful videos on tagging a review and tagging phone calls.

A quarterly review of the eFiles tag report

Total number of submissions

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2787	2904	2598	2586

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
5	6	18	15

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Therapeutic area distribution

QUARTER 1		QUARTER 2		QUARTER 3		QUARTER 4	
2	Respiratory	1	Respiratory	4	Respiratory	7	Oncology
1	Oncology	1	Oncology	4	Infection & Infestation	3	Infection & Infestation
1	Hematology (ITP)	1	Biologic/Immuno modulator	3	Dermatology	1	Diabetes
1	Neurology (ADHD)	1	Blood/Anemia/Coagulation	3	Pulmonary	1	Pulmonary (COPD)
		1	Urology	2	Cardiovascular	1	Cardiovascular
		1	Diabetes	1	Neurology (Migraine)	1	Neurology (ADHD)
				1	Oncology	1	Dermatology

Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2	4	6	6

Validated tag breakdown

QUARTER 1		QUARTER 2		QUARTER 3		QUARTER 4	
2	Particularly helpful discussion or action	2	Particularly helpful discussion or action	4	New issues were raised late in the review process	4	New issues were raised late in the review process
		2	Inconsistencies with historic approvals for the same brand	1	Inconsistencies with historic approvals for the same brand	1	Inconsistencies with historic approvals for the same brand
				1	Issue with level of expertise	1	Particularly helpful discussion or action

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<mark>NEW:</mark> Q4 PAAB action taken:

Reviewers were reminded at the reviewer meeting, to provide comments on layouts as early as possible even if the English copy has not been approved as placement within a piece or the need to change the visual treatment of copy, might impact how the sponsor chooses to structure the piece.

The issue of mobile has evolved over time. Reviewers were reminded to provide the rationale for why we are now asking for information which was not requested in the past so that the client does not perceive it as inconsistent and understands the need for new information. For example, QR code link functionality and the need for a mobile review (see [Advisory on APS Breakpoints and QR Code Links](#))

Most common reason tags could not be validated:

PAAB submission guidance state that eFile numbers should be provided when there is copy being leveraged from previously approved pieces. When this is not done and comments arise, this does not qualify as "inconsistency" as there are many reasons that copy could be challenged, including that it was previously challenged and additional information was provided to finalize the copy, or the previous submission was a different context. In scenarios where copy was previously discussed prior to approval, it is actually highly consistent that this copy would be challenged again if the context from the previous discussions is not shared. Please try to ensure that backfiles are always quoted when leveraging copy from previous pieces.

The **most common reason** for tags being deemed "invalid" is a **lack of information** to adequately set the context for validation. It's important to ensure that you provide a detailed description in the "comments" section. The greater the detail provided, the better the ability of the auditor to validate the tag and develop process improvements, training or take other actions to reduce the likelihood of the issue arising again in the future.

Q3 PAAB action taken:

The November 15 reviewer meeting addressed the impact of late-stage comments on clients, ways to reduce and minimize their occurrence (e.g., provide feedback on early stage layouts if submitted; ask clarifying questions early on) and ways to accommodate oversights. Reviewers also discussed French reviews (addressing only issues that change the meaning of the message).

Reviewers were reminded of the importance of checking backfiles for previously approved copy and to be articulate about the rationale for challenging copy which has been previously approved (e.g., marketplace change, PM update, context is different).

The issue of the reviewer's understanding of application in a scenario was raised and addressed with the reviewer. The misunderstanding was clarified for application to future reviews.

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Most common reason tags could not be validated:

Tagging a file prior to a call, that the call was unclear, does not align with the intent of the tag. Labelling something unclear should only occur after the interaction has transpired. Additionally, please ensure to provide context as to what was unclear on the call (or in the letter) to assist in validation and facilitate the appropriate training.

Tag for confrontational interaction was flagged, however, there was no indication in the written communications of confrontation and there were no calls to assess. When selecting this ticket, please remember to fill out the comment box. This helps the Director of Preclearance with context and interpretation to validate the tag and choose appropriate action.

Q2 PAAB action taken:

There were 6 tags total in Q2. Two cases of "Inconsistencies with historic approvals" were seen. In both scenarios, the reviewer acknowledged the oversight and advised that corrections will occur moving forward. While oversights are regretful, we do look to rectify them once identified. We will continue to monitor to ensure that no trends develop.

Is there more information you would like to know and see in the next quarterly update? Let us know on the [Forum](#).