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TGA and Pan - has anything changed in five years?

It is rare, in fact almost unheard-of, to gain so revealing a glimpse inside the Therapeutic Goods Administration (TGA) as that provided by the cross examination of its staff in the Selim case, but how concerned should industry be about what their evidence revealed?

Just to recap, allegations included that TGA senior executive Rita Maclachlan had misled her own advisory committee and misrepresented legal advice so as to push through the closure of Pan. It was also alleged that she had been present at a meeting in which one officer said the regulator should "go for the jugular" in relation to Pan.

Over the weekend *The Australian* newspaper reported that TGA officers had shredded notes of a meeting that had advised there was no "imminent risk" posed by Pan products. Imminent risk is a statutory requirement for a medicine recall.

Given these revelations, companies whose commercial fate is in the hands of the regulatory agency have good reason to be alarmed about its past actions, but after all, these events happened over five years ago and the TGA has had a new leadership and a couple of new ministers since then.

So, has it changed?

We don't know and we can't know because the organisation - in comparison to, say, the US Food and Drug Administration - remains a black box with almost no public accountability for its actions beyond what is forced out of it in occasional Senate hearings and intermittent court appearances.

We are forced to fall back on the Selim case and its aftermath for clues to whether the agency has learned anything and whether legitimate expectations that its internal workings match its public stances are at all likely to be met in the future.

After hearing from the TGA staff, Justice Arthur Emmett, urged the parties to talk and asked government barrister David Brogan, "If Mr Selim succeeds, the damages are going to be huge, aren't they? And the reputations of several senior Commonwealth officers are going to be completely destroyed?"

It is not drawing too long a bow to say that this warning led directly to the \$55 million settlement revealed last week since, after it was uttered, the TGA effectively withdrew from the action and agreed to settle.

The statement of less than a page issued on Thursday leaves the reasoning behind the decision to settle open to speculation, so we are entitled to take the position that \$55 million was considered a reasonable price to avoid further damage to the regulator's reputation as well as that of individuals within it. Perhaps, given Justice Emmett's warning and subsequent revelations, it was even considered cheap.

Now the TGA and its minister, Senator Jan McLucas, are trying to consign the Pan matter to the past, ruling out any public enquiry into its broader operations.

Despite the settlement and the judgment brought down against it, the TGA has not conceded any of its specific allegations against Mr Selim.

At no point have the bureaucrats or the politicians stepped up and taken organisational and personal responsibility for what was, at the very least a monumental stuff up and at worst a conspiracy resulting in hundreds of millions of dollars in corporate and personal financial loss including hundreds of jobs once held by ordinary Australians.

All in all, the signs are not good. The take-no-prisoners, business-as-usual response of last week shows the TGA is as insular as ever and that full public accountability is a long way off despite recent commitments to "increased transparency".

No more proof of this is needed than the obvious fact that, try as it might, the regulator cannot turn its back on its behaviour in the Pan case. A wave of further litigation will more than likely engulf it now that its decision-making processes over Pan have been exposed and drag it through the courts for years to come.

None of this, let alone what transpired on Thursday of last week, will rebuild trust in a regulator that must be seen to be "squeaky clean". After all, isn't that what it demands of the industry it regulates?

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