Pfizer Was Judged to Have Misled the Public Over the Covid Vaccine But Faces a Derisory Fine. The System is Broken

Description

When Albert Bourla, the CEO of Pfizer, agreed to be interviewed by the BBC in December 2021, he probably saw it as an opportunity for a bit of free advertising and PR for his company and its Covid vaccine. And so it turned out, apparently. An undemanding set of questions from the docile Fergus Walsh gave Dr. Bourla the chance to opine unchallenged on all things Covid and Covid vaccination, and no doubt communicate a few of his company's key marketing messages.

However, UsforThem, an organisation which campaigns for the needs and rights of children, saw things differently. Its researchers noticed that during his interview Dr. Bourla had made statements about Covid and the use of Covid vaccines in children that were misleading, unbalanced and not capable of substantiation. They took these concerns to the U.K. regulatory body, the Prescription Medicines Code of Practice Authority (the PMCPA), and a recent article in the *Telegraph* reports that the PMCPA agreed with them.

It is scandalous that it took the PMCPA a year to deal with this case. Meanwhile, Bourla and his colleagues have continued to make vast profits on the back of their COVID-19 vaccines, aided no doubt by these misleading statements. The PMCPA is the U.K. pharmaceutical industry's very own 'self-regulatory' body. Self-regulation is a valuable privilege delegated to this industry by the MHRA, whose statutory responsibility it is to ensure that everyone, not just the pharmaceutical industry, complies with the laws which regulate the promotion of medicines. Failure to comply can, but very rarely does, result in criminal charges.

Those of you shocked by the revelation that the MHRA is 86% funded by the pharmaceutical industry, prepare yourselves: because the PMCPA is 100% funded by the pharmaceutical industry. It also reports to the board of its industry body, the Association of the British Pharmaceutical Industry (the ABPI). This Board is mostly comprised of senior management of U.K. pharmaceutical companies. In fact, at the time this complaint about Pfizer was made, the President of the ABPI Board was also head of Pfizer in the U.K., and the current ABPI Vice-President is the Pfizer U.K. Country President. The PMCPA actually describes itself as “a division of the ABPI”. So, no potential conflicts of interest there then.

Thus, UsforThem will probably have achieved this significant judgment in the teeth of determined opposition. The PMCPA’s own records demonstrate that it is not uncommon for complainants, as in this case, to wait a year or even longer for a final decision. Prevarication, inefficiency and delay appear to have been weaponised by the pharmaceutical industry over the past few years to enable complaints about misbehaviour to be kicked down the road far enough for the impacts of any resulting adverse judgments to be diluted and to allow sales and profits from misleading advertising and unethical promotion to be maximised.

And now that Bourla and Pfizer have eventually been found guilty of misleading the U.K. public about their Covid vaccine, what penalties or sanctions are they facing? Well, fortunately for them, nothing too serious: it is not possible to know exactly the extent of their offences, as the report of this case has not yet been published. However, the breaches of which they have apparently been found guilty – misleading the public, making unsubstantiated claims and failing to present information in a balanced way – could conceivably be covered by just three clauses of their industry’s Code of Practice. The current level of fine (or as the PMCPA prefers to call it ‘administrative charge’) for a single breach of one clause currently stands at £3,500 (or £12,000 if the breach is upheld at appeal). So, for this particular case, three individual clause breaches could mean that Pfizer is now facing a bill for a sum as little as £36,000. Had it not decided to appeal, that bill might only have been as low as £10,500. When viewed alongside the eye-watering profits Pfizer stands to make from its Covid vaccines, and no doubt the resulting generous bonuses banked by Bourla (even when just considered over the 12 months it has taken for the PMCPA to arrive at a decision for this case), these ‘penalties’ are of course derisory, both as punishments and also disincentives to similar behaviour in the future.

The failure of penalties meted out by the PMCPA to incentivise better behaviour is clearly demonstrated by the fact that over the past three years the PMCPA has judged Pfizer to have misled the public about its COVID-19 vaccines on no fewer than four previous occasions – including three occasions on which it was judged to have “failed to maintain high standards” and two occasions on which it was additionally judged to have “brought discredit on the pharmaceutical industry”. And it’s not just Pfizer who has been caught out misbehaving in this way. AstraZeneca too has been found guilty by the PMCPA of misleading the public about the safety and efficacy of its COVID-19 vaccine. It is clear that these penalties not only fail to encourage companies to learn from their own errors, but from the errors of others too.

These days it must surely appear to many people that the entire regulatory system for oversight of pharmaceutical industry activities in the U.K. is slipping out of democratic control and that as a result it is failing to act in their interests. This has become more evident over the past three years, during which concerns have been raised about the rushed approvals of the Covid vaccines without adequate

scrutiny and transparency. Similar concerns have also been raised about the post-marketing safety surveillance of these vaccines. To this list must surely now be added worries about how the behaviour of the pharmaceutical industry is regulated when it comes to its communication and interactions with the general public, clinicians, politicians, the media and journalists.

In order to restore public confidence in our entire pharmaceutical regulatory system, I believe that there are now three things which need to done.

First, the era of self-regulation of the U.K. pharmaceutical industry by the PMCPA and the ABPI must come to an end. It is now time that pharmaceutical companies were no longer allowed to mark their own homework. Inefficiency and delay can no longer be allowed to be used as a shield for malpractice. A new, properly resourced and truly independent body is needed to carry out this role. Such a body could possibly be financed at arms length by the MHRA from a levy on U.K. pharma companies based on, for example, their annual U.K. turnover. There are those who say that the MHRA should actually take this role back for itself. However, there is now such a level of concern and suspicion amongst the public about the competence, transparency and independence of the MHRA that I believe that trust can only be rebuilt by the establishment of a completely new system of oversight.

In addition, the penalties and sanctions resulting from breaches of the regulations must be made more severe. The current derisory ‘administrative charges’ can in no way act as satisfactory punishments for serious breaches of the regulations, particularly those which represent egregious betrayals of public trust. Neither do they currently act as any kind of disincentive for any future similar misbehaviour.

Secondly, a public inquiry is needed to investigate the process which the MHRA has used, and continues to use, for approving COVID-19 vaccines. This should consider all aspects of the approval process, including how approval was expedited using Regulation 174 and Conditional Marketing Authorisations, the drivers for expedition, approval of line-extensions, age-stratification of approvals and any potential conflicts of interest. There is currently a petition asking the Government to launch such an inquiry which can be found and signed here. At the time of writing the number of signatories stands at just over 13,300.

Thirdly, the last time there was any parliamentary scrutiny of activities of the pharmaceutical industry in the U.K. was a select committee investigation which reported in 2005. That report made a number of important observations and recommendations, some of which were implemented, many of which were not. Almost two decades later the world has changed a great deal and it is now again time for a parliamentary select committee to take another look at this issue – particularly in the light of the recent national response to COVID-19.

I will leave the final word to those parliamentarians of 2005, whose concerns seem possibly even more relevant today than they did then:

> Our overarching conclusion is that the U.K. pharmaceutical industry is in many ways outstanding: it conducts excellent research, produces products which make a vital contribution to the health of the nation and is of great economic importance; however for want of critical scrutiny by, and lack of deference and accountability to, the public and public bodies, the industry lacks the discipline and quality control that it needs but cannot itself

provide.

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