COUNCIL FOR EVIDENCE-BASED PSYCHIATRY

The UK regulator of psychiatric drugs (the MHRA) is entirely funded by the pharmaceutical industry, and employs ex-industry professionals in key leadership positions. Such conflicts of interest could lead to lenient regulation that places commercial interests above patient protection.

> *The [MHRA] has been too close to the industry, a closeness underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff.*
>
> (House of Commons Health Committee Report, 2004)

In September 2013 the MHRA appointed its new Chief Executive. His name is Ian Hudson, and for 12 years prior to his appointment he was an employee of the pharmaceutical company, GlaxoSmithKline. For much of his time at GlaxoSmithKline he was a director at the company. Yet when he was appointed as head of the MHRA, there were no questions raised (in parliament, in the media or elsewhere) about whether an ex-director at GlaxoSmithKline should become chief executive of the very agency responsible for regulating the products of companies like GlaxoSmithKline.

In fact, such questions are rarely raised in the places that count. This is surprising since the composition of the MHRA's current executive committee includes so many ex-industry professionals:

- Ian Hudson (Chief Executive of the MHRA), previously Head of Global Safety at GlaxoSmithKline
- Gerald Heddell (Director of the Inspection, Enforcement & Standards Division), previous posts include European Quality and Compliance Director for GlaxoSmithKline
- Stephen Inglis (Director of National Institute for Biological Standards and Control), previously Research Director of Cantab Pharmaceuticals
- John Parkinson (Director of Clinical Practice Research, Datalink), previously consultant to the pharmaceutical and wider healthcare industries

The MHRA has a conflict of interest policy, but this policy does not militate against the less obvious biases and allegiances that inevitably develop over years of working within a given sector. Such learned tendencies and dispositions to act in ways consistent with company interests can make individuals less impervious to industry lobbying. No existing conflict of interest policy, including the MHRA's, can protect against these subtle yet potent forms of influence. The only protection fit for purpose is to ensure that your regulatory team is not recruited from the very industry whose products it is supposed to regulate.

Alongside the MHRA being governed by ex-industry professionals, the costs it incurs for regulating medicines in the U.K. are, as the MHRA states, entirely 'met by fees from the pharmaceutical industry'.[1] In other words, the regulation of all medical drugs in the U.K. (psychiatric and otherwise) is entirely funded by the very industry whose success or failure depends upon whether its products are approved by organisations like MHRA.

The term used in academia to describe this arrangement is 'regulatory capture'. A regulatory body is 'captured' when it is it financially dependent upon the industry it regulates. This arrangement makes sense to industry, as it would rather be regulated by those financially dependent upon it, than by those fully independent of its influence. The most common and obvious outcome of 'regulatory capture' is that regulation becomes lenient, putting company interests above the interests of those regulation should serve and protect – namely, patients.

Examples of this leniency are easily found. For instance, the MHRA requires only 2 clinical trials to approve a psychiatric drug for public use, even if there exist 4, 5, 6, or more negative trials. In a practice for which there is no clear scientific justification or rationale, the MHRA simply discards the negative trials. This means, in short, that even if 10 negative trials exist, on the basis of only one or two positive trials the drug can still be approved for public use. As the MHRA stated in an email correspondence with a member of CEP in 2012:

> *As a general rule a minimum of two studies is required to prove the efficacy of a drug. A single study will have to demonstrate very compelling results to be considered sufficient alone to demonstrate efficacy.*

Such lenient regulation is exacerbated since industry funding for the MHRA is not guaranteed. In short, regulatory bodies compete among each other to be the regulator that industry prefers, and therefore funds. As the House of Commons Health Committee reported in 2004:

> *[The MHRA] needs to keep a close eye on its market share of regulatory business: increasingly it competes with other European drug regulatory agencies to scrutinise drug licence applications. Like any other regulatory agency, the MHRA walks something of a tightrope, trying to strike a balance between support for the industry and effective medicines control.*

An independent regulatory body would not have to walk this 'tightrope' by keeping its regulation industry-centered and lenient.

A method by which the MHRA protects such leniency is by avoiding full transparency. As the aforementioned Government Health Report stated:

> *The process by which drugs are licensed is far from transparent. There is no public access to the data presented by the pharmaceutical companies nor to the assessments undertaken by the MHRA. There is not enough involvement of patients, the public and the wider scientific community, and the Agency does not listen or communicate well…*
>
> (House of Commons Health Committee Report, 2004)

As Sir Ian Chalmers continues:

> *Denial of access to information held by the [MHRA] puts the interests of pharmaceutical companies ahead of those of patients and prescribers. This is particularly indefensible in the light of evidence that regulatory agencies, supposedly established to protect the public, are acquiescing in biased later publication of the information they hold.*
>
> (Sir Ian Chalmers, quoted ibid: 79)

To conclude with the words of Professor Andrew Herxheimer, Emeritus Fellow, UK Cochrane Centre, Oxford:

> *…when the agency was hived off from the Department of Health…the culture became confirmed that the industry is the client and the client must be looked after: quick service, good service, easy contact, etcetera - so it is a closed community in a sense*
>
> (Dr. Herxheimer, quoted ibid: 78)

CEP calls for a fully independent regulatory body; one that will only use ex-industry professionals for consultancy purposes, but won't appoint them to key leadership positions; one that is also taxpayer funded and so entirely independent of the industry payments upon which the MHRA currently depends.

To contact us or for more information please visit cepuk.org.

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[1] The MHRA states on its website: 'The costs of medicines regulations are met by fees from the pharmaceutical industry'. See: http://www.mhra.gov.uk/SearchHelp/Frequentlyaskedquestions/#l6