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It is tragic that we now have a respected body, the Medicines and Healthcare products Regulatory Agency (MHRA), granting a licence for a product for which there is not only no evidence of efficacy but good evidence against any efficacy.1 I have some sympathy with the MHRA in the face of a European Directive which has to be obeyed but which is almost totally irrational. However, I think that because “efficacy” appears in the directive and there is evidence against efficacy, it could have resisted granting a licence.

This fiasco takes us back to the days before drug regulation was introduced, partly to prevent the hazards of snake oil-type remedies. While this product may have no benefit, it probably has no direct harm either. But it may have major indirect harms—not only in individual patients who may not benefit from other effective remedies but also in a general sense by undermining the rational basis for medicine.

Notes

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Footnotes

- Competing interests: SJE is a former employee of the UK Medicines Control Agency (now MHRA) and a member of the Pharmacovigilance Working Party of the CHMP at the European Medicines Agency.

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