LETTERS

APPRAISAL OF DRUGS FOR TYPE 2 DIABETES

Basing approval of drugs for type 2 diabetes on real world outcomes

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Naci and colleagues rightly point out that although drugs are often approved on the basis of glucose lowering efficacy, we really need agents that reduce important outcomes such as symptomatic microvascular disease and cardiovascular events.¹ The authors suggest that real world evidence of clinical effectiveness should be required from the drug industry, using routine healthcare data to monitor outcomes.

At the University of Surrey we have entered into partnership with Eli Lilly to provide some of these essential outcomes data using primary care records. Our preliminary analysis further highlights the need to extend studies into the real world. In practice people treated with glucagon-like peptide-1 (GLP1) agonists and sodium-glucose co-transporter-2 (SGLT2) inhibitors have a significantly higher body mass index than those in clinical trials (GLP1 agonists: 37.5 in practice, 31.8 in aggregated trials; $P<0.001$; SGLT2 inhibitors: 34.7 in practice, 30.6 in trials; $P<0.001$). Trial populations are not representative of the people treated with these new drugs, and the effectiveness in practice may be less certain.

If this investigation into real world outcomes is to be funded by the drug industry, stringent precautions must be taken to

minimise the biases identified in industry funded research.² Non-trial research should be registered in a similar way to clinical trials, with demands for high quality research protocols to be recorded before data extraction and analysis.

We agree that drug outcomes data must include outcomes relevant to patients. Only well constructed studies in the real world will confirm the effectiveness of new and existing drugs.

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Full response at: www.bmj.com/content/351/bmj.h5260/rr-0.

- 1 Naci H, Lehman R, Wouters OJ, et al. Rethinking the appraisal and approval of drugs for type 2 diabetes. *BMJ* 2015;351:h5260. (9 October.)
- 2 Lexchin J, Bero LA, Djulbegovic B, et al. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003;326:1167-70.

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