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“Cholesterol con”

Leading doctors oppose NICE guidance to roll out new cholesterol lowering drug on the NHS

Leading doctors, including academics, physicians and general practitioners have written to the chair of NICE and the Secretary of State for health Sajid Javid calling for immediate withdrawal of approving a new cholesterol lowering drug, Inclisiran.

The signatories include Consultant Cardiologist and Chairman of The Public Health Collaboration, Dr Aseem Malhotra, the past president of the Royal College of Physicians Sir Richard Thompson, the Chairman of BAPIO, Dr JS Bamrah CBE, Dr Campbell Murdoch, Royal College of General Practitioners Clinical Adviser and Professor Sherif Sultan, President of the International Society of Vascular Surgeons.

In a scathing letter they highlight six main concerns for why this drug should not be approved until further data is made available that reveals the drug actually prevents heart attacks, strokes or death in patients with heart disease or familial hypercholesterolaemia. These concerns are that inclisiran is an investigational drug in the UK, that there is a lack of transparency in the NICE decision making process, that there is no long term data on effectiveness or safety, the decision is based on a surrogate marker (LDL-C) , there is no evidence of cardiovascular benefit with Inclisiran lowering LDL-C and finally that NICE approval of the drug will result in loss of professional confidence in the organisation.

“We are concerned about your draft final guidance recommending the novel anti-cholesterol drug inclisiran (Leqvio and made by Novartis) for people with primary hypercholesterolaemia or mixed dyslipidaemia who have already had a cardiovascular event such as a heart attack or stroke.

We would ask for this decision to be over-turned immediately until there is enough data to support any hard outcome benefit of Inclisiran, namely the prevention of heart attacks, strokes or death” they write

“The decision for NICE follows an agreement on a population-level commercial deal between NHS England and NHS Improvement and Novartis which will make inclisiran available with a discount to its list price.

The full details to the pricing agreement have been kept confidential and not available for independent scrutiny. This lack of transparency should be of concern to the British public, prescribing doctors and taxpayers who fund NICE” they continue

“We propose that more long-term data on safety and efficacy is accumulated before recommending Inclisiran, even as an adjunct to statin therapy.”

The authors also point out “there is conflicting evidence that LDL-C is a causal factor in heart disease. A 2020 recent study published in the BMJ by Danish researchers, for example, demonstrated that LDL-C the lowest risk of all-cause mortality was found at an LDL-C concentration of 3.6 mmol/L (140 mg/dL).

In comparison the **highest** association with all-cause mortality was actually at LDL-C levels of less than 1.8mmol (70mg/dL).

Notably, NICE recommendations suggest that people with LDL-C concentrations persistently 2.6 mmol/l or more, despite maximum tolerated lipid-lowering therapy, should be on Inclisiran. This has no independent scientific basis”

“Furthermore, an independent peer reviewed systematic review of drug trials carried out by three cardiologists in 2020 published in BMJ Evidence Based Medicine revealed that there was no clear relationship with reduction in LDL in both high risk and low risk patients in reducing cardiovascular events”

“The lack of transparency in the decision-making process may undermine professional and public confidence in NICE and its decision-making processes. This could be critically damaging to professional confidence in the delivery of evidence-based healthcare in the UK.

In light of our concerns, we urge you to withdraw the current guidance on Inclisiran for people with primary hypercholesterolaemia or mixed dyslipidaemia who have already had a cardiovascular event such as a heart attack or stroke until further important clinical data with clear cardiovascular benefits are made available” the authors conclude.

Dr Aseem Malhotra FRCP, Consultant Cardiologist, Professor of Evidence Based Medicine and Chairman of the Public Health Collaboration said,

“What we witnessed take place in the news a few weeks ago was in my view nothing short of a brilliant PR stunt carried out by the pharmaceutical industry supported by scientists with personal or institutional financial ties to manufacturers of the drug with no counter view on the science or media exposure of their flagrant conflicts of interest. Media headlines suggested that 30,000 lives could be saved over 10 years from this drug when current evidence reveals not a single life would be saved nor a single heart attack or stroke prevented. If NICE approve this drug it will be a victory of marketing over science, and not what’s in the best interest of patients, the public or the NHS. The totality of evidence reveals that lowering LDL-cholesterol has no clear relationship with preventing heart attacks, strokes or death and the lower is certainly not better with an association with very low levels of LDL-C with increased mortality. This unscientific obsession with lowering LDL-C as a primary focus in preventing and managing heart disease needs to stop. This decades long mass experiment has failed. It’s time to stop falling for the great cholesterol con”

Sir Richard Thompson, Past President of the Royal College of Physicians and personal physician to her majesty the Queen from 1993-2005 said,

“Once again, the levels of the surrogate marker, serum cholesterol, are being dangerously extrapolated by Pharma to the development of clinical disease, but they may not be an independent marker of vascular disease. The effects of inclisiran on disease must therefore be evaluated before this drug is widely prescribed”

Dr Campbell Murdoch, General Practitioner and Royal College of General Practitioners Clinical Adviser said

“LDL-cholesterol is needed for the human body to survive. Drugs should not be used to treat it as a waste product. The role of healthcare professionals is to support people’s health. Lowering LDL-C with an injection is not, in itself, a health benefit”

Dr Malcolm Kendrick, General Practitioner and author said,

“NICE, in a secret deal with the drug giant with Novartis have approved a cholesterol lowering medication called, inclisiran, that could cost the NHS billions over the next ten years. Yet, there is no evidence that it provides any benefit. In the words of NICE itself ‘There is also no long term evidence yet on inclisiran’s effect on cardiovascular outcomes.’ In fact, the evidence from early studies strongly suggests that Inclisiran does not work. We call upon NICE to reverse this decision, that overturns all the key principles of Evidence Based Medicine which they are supposed to use to make their decisions”

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For all media and press enquiries please contact Dr Aseem Malhotra

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Notes for journalists: The Public Health Collaboration is a registered charity whose membership is made up of healthcare professionals, patients and members of the public. The charity campaigns on informing and implementing healthy decisions for better public through tackling medical and health misinformation. The charity takes no corporate sponsorship and is funded by the public for the public. For more information, please visit <https://phcuk.org/>