

HFMA Bulletin

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Time to review EU Health Claims in light of COVID-19?

Public health, risk assessment and risk communication have never been more challenging than in the wake of the current pandemic; communicating how to protect public health and getting it understood has literally become a matter of life and death. While the search for conventional disease solutions in vaccine form against the new threat of SARS-CoV-2 have been accelerated, health authorities and health professionals globally are scrambling to see if existing active substances can protect or mitigate against this disease.

The emergency has necessitated regulatory relaxations such as the fast-track approval of pharmaceuticals to be used for what were previously unlicensed indications; however, a similar intensity of public health messaging with regards to the importance of nutritional status seems to be lacking – possibly due to long-standing, entrenched regulatory positions. The cost for disease-related malnutrition for health and social care expenditure is more than £13 billion. Improving the identification and treatment of malnutrition (the ‘double burden’ of obesity and malnutrition) is estimated to have the third highest potential to deliver cost savings to the NHS. Unsurprisingly, as evidence mounts, nutrition is also a risk factor in communicable disease, and in the case of COVID-19, severity outcomes. Poor nutrition has been recognized as a major contributor to non-communicable disease and yet society’s solution to this has been focused on cure through medication rather than prevention through nutrition: medical solutions to nutritional problems. In the case of COVID-19, should there be more emphasis on nutrition solutions to medical problems?

For the right historical reasons there have been global restrictions with regard to making

claims on food that they can prevent, treat or cure a human disease. With regard to communicable diseases, the body’s first line of defence is its immune system. There are 12 EU-authorized claims for specific vitamins and minerals that contribute to the normal function of the immune system. Article 14 of EC 1924/2006 (NHCR) saw the first regulatory departure from this position allowing for ‘reduction of disease’ risk claims in the EU, ie claims that the consumption of food or one of its constituents significantly reduces a risk factor in the development of a human disease. To date, only 14 Article 14 Claims have been authorized and, though intuitively the case, none in relation to sub-optimal support of the immune system as a risk factor for disease. In relation to COVID, the emerging picture is not necessarily one around risk reduction through nutrition, but improved health outcomes for subjects with the disease where they have good nutritional status, in particular in respect of Vitamin D – this does not fit neatly into the ‘pigeonhole’ pass/fail approach of the EU legal regime.

The Government response to the emerging evidence on vitamin D and COVID-19 has been muted, while links between vitamin intake (including A and E) and fewer respiratory illnesses continue to be reported. With the ever-growing power of digital communication, the market is well placed to protect consumers in the pandemic through communications that are commensurate with the evidence, however, the current EU regulatory regime stifles such communication unless it has been pre-authorized and fits within the limitations of the regulation. There is a clear ethical dilemma here: should information that could protect consumers during a pandemic be censored?

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