conferenceseries.com

3rd World Summit on HEALTH NUTRITION

January 06, 2022 | Webinar

Evolution and Regulation of Intravenous Nutrient Therapy (IVNT) in the United Kingdom (UK) for the Promotion of Health and Well-Being

Morkel Jacques Otto

Harvard Medical School, United Kingdom

Statutory regulation of the administration of market authorised (licensed) medicines (prescription only medicines - POMs) in the UK fall under a number of agencies including the Medicines and Healthcare products Regulatory Agency (MHRA) [1], Care Quality Commission (CQC) [2] and the Advertising Standards Agency (ASA) [3]. Intention to prosecute a practitioner by any of the aforementioned agencies may result in the notification of the applicable professional statutory body e.g., the General Medical Council (GMC) [4], General Dental Council (GDC) [5], Nursing and Midwifery Council (NMC) [6], General Pharmaceutical Council (GPhC) [7], College of Paramedics [8] and the Chartered Society of Physiotherapy [9].The MHRA is responsible for the regulation of (1) medical claims made by practitioners, (2) advertising of medicines [10] and the (3) issuing of market authorisation of medicines (licensed medicines - POMs) and unlicensed medicines ("specials"). Several injectable nutrients including vitamins, amnio acids and minerals are labelled as medicinal products (POMs) and have MHRA market authorisations. Medical claims made for medical indications are only permitted for POMs and "Specials". It also regulates medicinal product advertising [4] and medical claims made by healthcare professionals. Prosecution powers may include a fine and or jail term and the possibility of being struck off from a relevant statutory professional body's register. The importation and wholesale supply of unlicensed medicines ("specials"), regardless of their route of administration, requires a license granted by the MHRA. Only authorised prescribers e.g., doctors, dentists, nurse independent prescribers, pharmacist independent prescribers, paramedic independent prescribers and physiotherapy independent prescribers are permitted to prescribe market authorised medicines (POMs) and unlicensed medicines.Imported medicines that are market authorised (licensed) approved in other jurisdictions outside the of UK e.g., the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), Canada, Australia, South Africa, India and many others require a MHRA approved market authorisation for licensed medicines and a "specials" import license for unlicensed medicines. Importation from any jurisdiction outside the UK is illegal.The MHRA's equivalent of other medicine regulatory jurisdictions in general view injected (sub-cutaneous, intramuscular and intravenous) agents as medicines that require market authorisations. However, in contrast, the UK MHRA do not regard an agent as a medicine if the agent is administered for health and well-being and no medicinal claims are made about the agent regardless of what the mode of administration is, e.g., intravenous, intramuscular, sub-cutaneous, transdermal, per rectum, inhalational, oral, sublingual and intranasal.Therefore, intramuscular or intravenous agents are not viewed by the MHRA as medicinal products provided that no medical claims are made, and they are by default are non-regulated (non-Pom) and not requiring market authorisations. The Care Quality Commission (CQC) regulates medical treatments performed by registered healthcare professionals using medicinal products and product advertising. Practitioners advertising and prescribing POMs must be CQC registered. Prosecution powers include a fine and or a jail term and the possibility of being struck off from a relevant statutory professional body's register.

Conclusion: Empiric administration of high concentration intravenous nutrients (IVNT) for health and well-being promotion and for the prevention of ill-health, is mainly based on anecdotal evidence and does not rely on specific nutrient blood tests prior to infusion. Despite IVNT's very good safety track record in the UK and very rarely associated with allergic reactions (mostly due to preservatives) and extremely rarely anaphylactoid reactions, extra caution is advised when administering intravenous iron and Vitamin B1 as a single agent. Annual Cardio-pulmonary Resuscitation (CPR) training and in-date shelf-life emergency drugs adrenaline and injectable corticosteroids (antihistamines optional) are mandatory minimum safety requirements.

Biography

Morkel Jacques Otto is from Harvard Medical School Post Graduate Education Safety, Quality, Informatics and Leadership (SCQIL) 1-year program (2020-2021) Capstone research project.