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MNI's feedback to the European Commission consultation on the European Critical Raw Materials Act

The Medical Nutrition Industry International (MNI) welcomes this consultation as an opportunity to highlight the importance of planning for medical nutrition, an essential part of treatment and care.

The consultation mentions the health industries in its introduction, which should not be limited to medical devices or in-vitro diagnostics, but all components of healthcare. As per the European Commissions list of CRMs, ingredients part of medical nutrition are essential to producing a broad range of medicinal products, goods and applications used in healthcare.

MNI's first recommendation is to include in this list, ingredients that are essential to care for people, in addition to the sustainable functioning of the European economy. Malnutrition is a condition where patients are not getting the right nutrition in the right amount to sustain their health or life.

The role of medical nutrition is to help patients address nutritional insufficiencies arising from a disease and/or their treatment, disorder, or condition such as cancer, chronic intestinal failure, frailty in older people. Depending on the situation, medical nutrition is required for short or long term or even for life and it is to be used under medical supervision. **MNI agrees with the analysis of the problem the initiative aims to tackle and supports the 4 policy options.** When defining priorities and objectives for EU actions and determining strategic CRMs based on pre-set criteria, the EU legislators shall consider the absolute need and absence of replacement of the said material: for some components of medical treatment, there are no alternatives and having no access to these CRMs because of insufficient contingency planning often means absence of available treatment and deterioration of patients health.

We welcome President von der Leyen's announcement of the pursuit of supply diversification as we have all been hit by geopolitics instability and the consequences of COVID19 in the provision of essential goods and ingredients.

We suggest focusing on circular economy, as well as encouraging/providing incentives for EU-based resources to support further independence and autonomy. **We recommend the establishment of "strategic reserves" where possible (depending on shelf-life span) of CRMs at EU level to inhibit speculation from international markets and face potential risks of shortages.**

This may concern for instance:

- Sunflower oil (or other oil sources) are often used as a sole source of nutrition; therefore, the type of oil used determines the essential nutrient content (e.g., essential fatty acids). Ingredient substitution is not straightforward as the right nutritional profile needs to be achieved and it is also challenging because of lengthy regulatory approval processes required to make changes to formulations.
- Amino acids are critical sources of protein for patients who cannot tolerate whole proteins and need specialised products.
- Vitamins - A (retinol), D (cholecalciferol), E (a tocopherol), K, B1 (thiamine), B2 (riboflavin), B6 (pyridoxine), Niacin, B12 (cobalamin), Folate, Biotin, C (ascorbic acid)) - and trace elements (Zinc, Copper, Iron, Manganese, Selenium, Chromium, Molybdenum, Iodide, Fluoride), called globally micronutrients, are essential components of medical nutrition products in maintaining good health and treating a disease.

Concerns also lie with other products: Hydrolysed Corn Starch; Lecithin; Maltodextrin; Glucose; Hydroxides, Citrates, Phosphates, Carbonates, Chlorides; Whey & Casein Derivatives; Lactose; Milk Powders

MNI believes it should be mandatory for proper crisis preparedness to improve the EU monitoring, risk management and governance in the field of CRMs and it should involve all actors in the field not only Member States: suppliers, users, manufacturers, prescribers, etc. It is of paramount importance that essential/life-saving ingredients are taken up in the CRMs list and medical nutrition is no exception