Access to essential medicines is a core element of universal health coverage and therefore a priority for the World Health Organization (WHO). Nutrition-related health products are commonly used in public health and clinical settings to address any form of malnutrition, and particularly to prevent and treat undernutrition or micronutrient deficiencies. These include formulations such as ready-to-use therapeutic foods (RUTFs), therapeutic milks (F-75, F-100), iron-containing multiple-micronutrient powders, and vitamin and mineral supplements. Other medicines or health products used in disease prevention, treatment and management and rehabilitation and palliative care services, may have relevance for nutrition-related conditions and throughout the life-course. Access to and availability of these nutrition-related health products is of high priority, owing to the unabating trends in undernutrition in some parts of the world. Undernourished children, particularly those with severe undernutrition, have a higher risk of death from common childhood illnesses such as diarrhoea, pneumonia and malaria. Nutrition-related factors contribute to about 45% of deaths in children under 5 years of age. In 2017, 2.4% of the children worldwide under 5 years of age were affected by severe wasting, corresponding to a global burden of 16.4 million. The WHO regions most affected were the South-East Asia Region (8.7 million), the African Region (3.4 million) and the Eastern Mediterranean Region (3.2 million). It is indicated that children affected by severe wasting have a higher risk of mortality. The prioritization of, subsequent access to, and availability of, medicines at the country level is often guided by the WHO Model List of Essential Medicines (EML). Including nutrition-related health products in the EML can support the development, review and updating of national lists of essential medical products.

The WHO Department of Nutrition for Health and Development, in collaboration with the Department of Essential Medicines and Health Products, convened a technical consultation in Geneva, Switzerland on 20–21 September 2018, to gather stakeholders’ views on considerations related to, and the feasibility of, including nutrition-related health products in the EML. Stakeholders at the consultation included representatives from governmental agencies, intergovernmental agencies, non-state actors in official relations with WHO, and the private sector.

The objectives of this consultation were to (i) identify common criteria that characterize a nutrition-related health product for potential listing in the EML; (ii) evaluate advantages and disadvantages of listing RUTFs and other nutrition-related health products in the EML, in particular considering manufacturing standards for foods and pharmaceuticals; (iii) identify which dimensions and elements (e.g. availability, access, cost, alternative formulations, quality, country preferences) and trade-offs are considered by stakeholders when assessing RUTFs and other nutrition-related health products for improved access in public health; and (iv) discuss country experiences in the regulatory processes that could help to improve access to nutrition-related health products.

This report summarizes the presentations, some country perspectives and discussions that occurred during the technical consultation and does not contain any official WHO recommendations.

Before the meeting, WHO launched a call for authors covering the proposed objectives. Six papers were selected and presented at the meeting, which also included presentations on other topics of interest and several discussion sessions. Five of the six commissioned papers are published as part of this report.

2 Ready-to-use therapeutic foods (RUTFs) are specifically formulated foods for the treatment of infants and children aged 6 months or older, with severe acute undernutrition, who have appetite and do not have medical complications. These health products are nutrient dense, and contain adequate protein and other essential nutrients such as vitamins and minerals. These foods are soft or crushable and can easily be eaten without any additional preparation. They are consumed without adding water, have a low risk of bacterial contamination, require no refrigeration and have a nutritional composition based on the F-100 therapeutic milk used in hospital settings.
3 The term used in some documents is severe acute malnutrition, although with the WHO broader definition of malnutrition in all its forms, which includes undernutrition (wasting, stunting, underweight), inadequate vitamins or minerals, overweight, obesity, and resulting diet-related noncommunicable diseases, the term undernutrition is used herewith to convey that reference is made to undernutrition only and not to all other types of malnutrition.
The topics covered included the EML and the criteria for selection of medicines included in it; data on the efficacy, safety, feasibility and availability of products; and a mapping of the nutrition-related health products in the 2017 EML and the WHO Model List of Essential Medicines for Children (EMLc), showing efficacy data on vitamins and minerals used in the management of anaemia or as coadjuvants in the treatment of diarrhoea, and as dietary supplements.

Some of the current WHO recommendations that involve nutrition-related health products were discussed. It was made clear that, although the WHO guidelines and other official documents make recommendations for nutrition interventions that include nutrition-related health products, not all recommended nutrition-related health products are currently included in the EML.

The public health sector perspectives on the regulatory aspects of nutrition-related health products included country-specific perspectives from Brazil, Cameroon, India, Mexico, Nigeria, the Plurinational State of Bolivia, South Sudan and Sudan. In Brazil and Mexico, nutrition-related health products are regulated under their current regulatory frameworks, although RUTFs are not currently included in their national lists. The Plurinational State of Bolivia, Nigeria, Sudan and South Sudan already include RUTFs and other nutrition-related health products in their national lists. The Food Safety and Standards Authority of India has specific classifications for nutrition-related health products that are likely to classify RUTFs as foods for special medical purposes. The regulatory framework that defines nutrition-related health products as foods, medicines or for special medical purposes varies across countries.

The role of the Codex Alimentarius, particularly the Codex Committee on Nutrition and Foods for Special Dietary Uses, in relation to the status of the ongoing project to develop a guideline for RUTFs, was discussed in a presentation about international guidelines and standards in the production of foods for special dietary uses and foods for special medical purposes.

The WHO Department of Food Safety and Zoonoses presented on the food safety considerations related to nutrition-related health products. WHO also provided context on therapeutic milks and supplementary foods in the management of acute undernutrition, which outlined severe and moderate acute undernutrition and the specific recommendations. RUTFs are developed as foods that are ready to use without preparation at home, for treatment of infants and children with severe acute undernutrition without medical complications.

An assessment of the perceptions of some stakeholders about the inclusion of RUTFs and other nutrition-related health products in the EML was widely discussed and summarized. It was reported that nutrition-related health products are not consistently classified by various governmental regulatory agencies in WHO Member States. In various countries, RUTFs, for example, are defined as either foods for special dietary uses or medicines. While most stakeholders identified the availability of and access to RUTFs as a challenge in many countries, particularly due to perceived cost, their views varied on whether inclusion in the EML would help or aggravate these challenges. Another assessment weighed the benefits and costs of adding RUTFs and other nutrition-related health products to the EML. The views of stakeholders were divergent and raised concerns on the potential impact that the inclusion might have on local production and alternative formulations, and on uncertainties about how categorization and regulation in the country might impact on access to these products.

2 Therapeutic milks are specially formulated foods used in the treatment of severe acute undernutrition. Therapeutic milks include feeding formulas such as F-75 and F-100, used in the stabilization and rehabilitation phases in hospital settings.
3 Supplementary foods are specially formulated foods in ready-to-eat or milled form that are modified in their energy density, and protein, fat or micronutrient composition, to help meet the nutritional requirements of specific populations. Supplementary foods are not intended to be the only source of nutrients and are different from complementary foods, in that the latter are intended for progressive adaptation of infants aged 6 months and older to the food of the family. Supplementary foods are also different from food supplements, which refer to vitamin and mineral supplements in unit dose forms, such as capsules, tablets, powders or solutions, where national jurisdictions regulate these products as foods. Supplementary foods have been used to rehabilitate people with moderate acute malnutrition and to prevent deterioration of the nutritional status of people most at risk, by meeting their additional needs, focusing particularly on children aged 6–59 months, pregnant women and lactating women. Examples of supplementary foods include fortified blended foods (com–soy blend, wheat–soy blend) and lipid-based nutrient supplements (ready-to-use supplementary foods).
Other presentations covered various aspects of the inclusion of nutrition-related health products in the EML. One covered the process and impact of integration of RUTFs in national essential medicines lists and reported that adding RUTFs to national essential medicines lists and the EML would probably mobilize political commitment to improve treatment of severe acute undernutrition, improve the availability of these products, facilitate their use and reduce costs. A case-study of RUTFs being included in a national essential medicines list was presented; it focused on the public health relevance of including specialized nutrition-related health products in the South Sudan Essential Medicine List and summarized the complex multisectoral process that is being undertaken by the Ministry of Health, aided by WHO and other partners. The inclusion of nutrition-related health products (RUTFs, ready-to-use supplementary food [RUSFs], therapeutic milks F-75 and F-100) in national essential medicines lists supports national prioritization, procurement and distribution, and their use in the existing health-care system. In another case-study from the Plurinational State of Bolivia, the availability of RUTFs for the management of acute undernutrition drew attention to factors such as the existing legal framework, public health insurance, and the implementation of the Programa Multisectorial Desnutrición Cero \(^1\) (Zero Malnutrition Programme), which seem to have facilitated the process of including RUTFs in the national list and ensuring the sustainability of their use.

A panel discussion with manufacturers, intergovernmental agencies and nongovernmental organizations reflected on challenges at the country level in access to nutrition-related health products, with a focus on purchasing and production. It was noted that there are clear challenges with regard to the coexistence of positive and negative considerations for inclusion of RUTFs and other nutrition-related health products in the EML and EMLc.

Overall, the presentations and discussions covered the proposed meeting objectives and some challenges were identified. A definition of common criteria is needed to consider the inclusion of nutrition-related health products in the EML, since stakeholders' perceptions of including RUTFs in the EML vary and are sometimes contradictory. Most of the divergences found in the experts' assessments are explained by the uncertainties about how RUTF products will be classified and regulated at the country level. On the other hand, country case-studies concluded that the inclusion of RUTFs in national essential medicines lists has supported national prioritization, procurement and distribution, as well as their use in the existing health-care system.

This technical consultation and a statement by the WHO Department of Nutrition Health and Development on RUTF\(^2\) constitute part of the analysis requested by the Expert Committee on Selection and Use of Essential Medicines when considering the application for inclusion of RUTFs in the WHO EML for the dietary management of uncomplicated severe acute undernutrition in children under 5 years of age. These activities are in line with WHO functions and efforts to accelerate progress towards achieving the Global Nutrition Targets\(^3\) as well as the WHO triple billion goals\(^4\), in the key areas of guidance; policy; surveillance; and engagement for achieving universal health coverage, addressing health emergencies and promoting healthier populations.

Nutrition-related health products are already included in the EML and EMLc and in various national essential medicines lists. The process of considering the feasibility and practicality of including nutrition-related health products with a food matrix poses a different challenge. The case raised by the application of RUTFs can be used as an index case to develop the needed framework that may be applicable to additional nutrition-related health products in the future, and the feasibility of creating a new list for nutrition-related health products or a new section for nutrition-related health products in the EML.

The presentations and discussions are summarized in this report, which also contains the full-text versions of five of the manuscripts that served as the basis for the consultation.

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