

Press Release

FSMP harmonizes with the provisions of IMS Act to save the life of babies with special medical needs

New Delhi, Feb 26, 2018: Inborn Errors of Metabolism (IEM) is a life threatening special medical condition affecting thousands of infants in the country. One of the main treatments for IEM is specialized diets which fall under the category of Food for Special Medical Purposes (FSMP). Without these specialized diets, children suffering from IEM would not only face cognitive and physical difficulties, but infant would not even survive.

These disorders are increasingly being diagnosed in India due to advances in medical technology and improved facilities for testing. These disorders require special diets or ‘medical foods’. It is important to understand that for Children suffering from such metabolic disorders, these special medical foods are life-saving, as without these diets/ foods the children will stand a little chance to survive.

While being respectful of the IMS Act and its intent, placing FSMPs in the category of IMS Foods poses some genuine challenges e.g., all infant milk substitutes and infant food labels have to carry a statement “mother’s milk is best for your baby” in capital letters. In case of some IEM conditions, an infant cannot digest mother’s milk, hence such a label is medically contraindicated and cannot be affixed. Other issues could also arise e.g. products under the IMS Act can be taken under advice of health workers but this cannot be done for IEM diets, which need to be taken only under medical supervision etc. Hence it would not be feasible to apply the IMS Act into Infant FSMPs.

However, in order to ensure that there is no potential misuse by any food manufacturer or distributor, FSSAI has placed the following statement in the public domain “*while IEM diets are a separate category of Foods for Special Medical Purposes as clarified earlier, the specific provisions of the IMS Act relating to marketing, promotion and sponsorship etc. would henceforth apply to IEM diets also to prevent any potential misuse of this platform to promote normal infant foods or infant milk substitutes as defined under the IMS Act*”. The same can be accessed at <http://diet4life.fssai.gov.in/faqs.html>

Further, to avoid any perceived conflict of interest with IYNCCI, the Steering Committee for IEM comprising of members from Ministry of Health and Family Welfare, Niti Aayog, representatives from the Medical Fraternity such as AIIMS, MAMC, ISIEM etc. and parent support group has decided that as a measure of abundant precaution and in the interest of this meaningful initiative, the IYNCCI/industry representatives would not constitute a part of the committee, and a modified order to this effect has already been issued by FSSAI. Refer to the Order for more details http://diet4life.fssai.gov.in/data/SC_order_revised_22_02_2018.pdf

FSSAI firmly believes that this is a noble cause and as a measure of abundant precaution and to prevent derailment of a meaningful initiative on such grounds, the authority is taking several steps to improve the life expectancy of infants suffering from this medical condition, and expects that both legislations (IMS and FSMP) would be harmonized to the extent feasible and all concerns regarding potential conflict of interest would be addressed.

While these actions are taken as an interim measure, further as a long term measure, the emended proviso in the Regulations of Foods for Infant Nutrition which covers Food for Special Medical Purposes (FSMPs) intended for infants would be reviewed suitably.

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