[TO BE INTRODUCED IN THE NATIONAL ASSEMBLY OF PAKISTAN]

A

BILL

further to amend the Drug Regulatory Authority of Pakistan Act, 2012

WHEREAS it is expedient further to amend the Drug Regulatory Authority of Pakistan Act, 2012 (No. XXI of 2012), for the purposes hereinafter appearing;

It is hereby enacted as follows:

1. **Short title and commencement.**- (1) This Act may be called the Drug Regulatory Authority of Pakistan (Amendment) Act, 2017.

(2) It shall apply to the Islamabad Capital Territory.

2. **Amendment in section 2 of Act XXI of 2012.**- In the Drug Regulatory Authority of Pakistan Act, 2012 (No. XXI of 2012), hereinafter referred to as the said Act, in section 2, after paragraph (xxxvi), before the full stop at the end, following shall be added, namely:-

"and also include the following:-

(a) Milk-based formulas prepared from cow milk with added vegetable oils, vitamins, minerals, and iron. Theses formulas are prescribed for most healthy full-term infants
(b) Soy-based formulas made from soy protein with added vegetable oils (for fat calories) and corn syrup and/or sucrose (for carbohydrate). These formulas are prescribed for infants who cannot tolerate the lactose in most milk-based formulas or who are allergic to the whole protein in cow milk and milk-based formulas;
(c) Special formulas are prescribed for low birth weight (LBW) infants, low sodium formulas for infants that need to restrict salt intake, and "predigested" protein formulas for infants who cannot tolerate or are allergic to the whole proteins (casein and whey) in cow milk and milk-based formulas.

3. **Amendment in Schedule II of Act XXI of 2012.**- In the said Act, in schedule II, in part A, in paragraph (1), in sub-paragraph (i), after para (iii), the following new para shall be added, namely:

"(iv) in case of selling a formula milk for an infant only after getting a copy of a certificate containing any one or more than one conditions according to the acceptable medical reasons for the use of formula milk developed by WHO and UNICEF duly signed by a recognized medical doctor."

STATEMENT OF OBJECTS AND REASONS

Positive effect of breastfeeding on the health of infants and mothers are observed in all settings. Nevertheless, a small number of health conditions of the infant or the mother may justify recommending that she does not breastfeed temporarily or permanently. These conditions can be ascertained only by a registered medical practitioner and should be based upon WHO and UNICEF recommended conditions for giving a formula milk to an infant. Health professionals opined that in some health conditions the use of formula milk is suitable; however, in formal health conditions baby formula should be avoided in better interest of the child and mother.

Commercial infant formula is made in accordance with the Codex Alimentarius Standards – this means minimum standards of nutrient composition must be met. There are many different brands of commercial infant formula. However, both proteins and fats found in them are inferior to that in human milk, it is less easily digested and protective factors are absent. The nutritional composition is the same as branded commercial formula. The only difference is in the way in which it is marketed and distributed. It is also labeled more simply.

Infant/baby formula milk manufacturing is a multi-billion dollar industry and the quantum of their trade is increasing rapidly. No one can deny the fact that sale of one tin or packet of baby formula milk deprives a child to the most suitable food, the breast milk. Additionally, the government should take notice of the manufacturers of infant/baby formula milk who are using unethical tactics and influencing the health practitioners, merely to enhance the sale of their products and maximize their profit on the cost of the health of innocent children.

Currently our country is spending some $40 million annually on the import of formula milk only, which is the highest amount spent by any country in the world on this particular commodity. There are some 160 varieties of infant formula milk available in the markets. Drug Regulatory Authority of Pakistan should strictly monitor and regulate the import and local manufacturing of formula milk. In addition to that the sale of formula milk must be restricted and conditioned with the provision on prescription of a registered medical practitioner so that the detrimental effects associated with the use of different formula milk brands may be minimized up to the maximum.

The Bill has been designed to achieve the aforementioned purpose.

Sd/-
Ms. Nafeesa Inayatullah Khan Khattak
Member-in-charge