



No. 14-1/2022-PEC  
Government of Pakistan  
Ministry of National Health Services, Regulations and Coordination  
(Drug Regulatory Authority of Pakistan)  
Park Road, Islamabad  
\*\*\*\*\*

Islamabad, 06<sup>th</sup> August, 2025

### **NOTIFICATION**

Subject: - **REVISED POLICY FOR REGISTRATION AND ENLISTMENT OF FORMULATIONS CONTAINING VITAMINS AND MINERALS**

This directive is issued in supersession of the previous Vitamin Policy notified vide letter No. F.291-DRB/2019 (PE&R) dated 14<sup>th</sup> January, 2020.

2. The DRAP's Policy Board, in its 56<sup>th</sup> meeting held on 12<sup>th</sup> September, 2024, while considering the vitamin policy to align the categorization of vitamin and mineral products with international standards, has approved a revised policy. Accordingly, it has been decided that formulations containing ingredients above the Tolerable Upper Intake Level (UL) will now be registered as drugs, based on their status with Reference Regulatory Authorities. All other formulations, with ingredients at or below the Tolerable Upper Intake Level (UL), may be enlisted by the Health & OTC (non-drug) Division under their respective rules, regardless of their brand names as per Annexure-I.

3 Accordingly, above decision of Policy Board is hereby circulated for information and compliance by relevant stakeholders.

  
(Hafiz M. Ali Tayyab)

Additional Director (PE&R)/  
Secretary, Registration Board

### **Distribution: -**

1. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
2. Executive Director, Pharma Bureau, Karachi.
3. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
4. Director, MIS Division, with the request to upload on DRAP website.

### **Copy for information to: -**

1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. Director, Biological Evaluation & Research, DRAP, Islamabad.
3. PS to Chief Executive Officer, DRAP Islamabad.
4. Office File.

(Extract taken from 56<sup>th</sup> meeting of Policy Board)**International Comparisons:**(Source Vitamin and Mineral Safety published by Council for Responsible Nutrition, 3<sup>rd</sup> Edition, 2014)

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN), US Institute of Medicine (IOM), European Commission on Safety of Food (ECSCF) or European Food Safety Authority (EFSA), UK Expert group on Vitamins Minerals (EVM) and Japan Consumer Affairs Agency (JCAA).

Nutrient Vitamins and Minerals	CRN UL (amount/ day)	US IOM UL (amount/ day)	EC SCF/EFSA UL (amount/ day)	UK SVM SUL or GL (amount/ day)	Japan (Amount per Unit)
Vitamin A	10,000 IU (3,000 µg RAE)	10,000 IU	10,000 IU	5,000 IU	2,000 IU
Beta Carotene	25mg non- smokers, smokers should not use.	Not determined	Not determined	7 mg supplements, smokers should not use.	-
Vitamin D	250 µg (10,000 IU)	100 µg (4,000 IU)	100 µg (4,000 IU)	250 µg (1,000 IU)	2,000 IU
Vitamin E	1,000mg (1600IU)	1,000mg (1600IU)	300mg	540mg	150mg
Vitamin K	10mg	Not determined	Not determined	1mg	150µg
Vitamin C	2,000mg	2,000 mg	Not determined	1,000mg	1,000 mg
Vitamin B1 (Thiamine)	100mg	Not determined	Not determined	100mg	25mg
Vitamin B2 (Riboflavin)	200mg	Not determined	Not determined	40mg supplement 43 mg total (GL)	12mg
Nicotinic acid	500mg	35mg	10mg	17mg	-
Nicotinamide	1500mg	35mg	900mg	500mg supplement 560 mg total (GL)	60mg
Pyridoxine	100mg	100mg	25mg	10mg	10mg
Folic Acid	1,000µg	1,000µg	1,000 µg	1,000 µg	200µg
Vitamin B12	3,000 µg	Not determined	Not determined	2,000 µg	60µg
Biotin	2,500 µg	Not determined	Not determined	900 µg	500µg
Pantothenic Acid	1,000mg	Not determined	Not determined	200mg supplement 210mg total (GL)	30mg

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN) European Food Authority (EFSA), UK Expert group on Vitamins and Minerals (EVM), European Commission on Safety of Food (ECSCF), US Institute of Medicine (IOM) and Japan Consumer Affairs Agency (JCAA).

Nutrient Vitamins and Minerals	CRN UL (amount/ day)	US IOM UL (amount/ day)	EC SCF/EFSA UL (amount/ day)	UK SVM SUL or GL (amount/ day)	Japan (Amount per Unit)
Calcium	1,500mg	2,500mg	2,500mg	1,500mg	600mg
Phosphorous	1,500mg	4,000mg	Not determined	250 mg supplement 2400 mg total (GL)	-
Magnesium	400mg	350mg	250mg	400mg supplement (GL)	300mg
Potassium	1,500mg ( 500mg thrice)	Not determined	Not determined	3,700 mg supplement (GL)	2,800 mg
Boron	6mg	20mg	10mg	9.6mg (SUL)	-
Chromium	1,000mcg	1,000mcg	Not determined	10 mg (10,000 µg) total (GL)	-
Copper	9mg	10mg	5mg	10 mg total (SUL)	6mg
Fluoride	No ULS (UL=6 mg)	10	7mg	Not determined	-
Iodine	500µg	1,100µg	600µg	500 µg supplement 930µg total (GL)	-
Iron	60mg (full stomach)	45mg (empty stomach)	Not determined	17mg supplement (GL)	10 mg
Manganese	10mg	11mg	Not determined	4 mg supplement 12.2mg total (GL)	300mg
Molybdenum	350µg	2,000µg	600µg	230µg food (GL)	-
Selenium	200 µg	400 µg	300 µg	350 µg Supplement 450 µg total (SUL)	-
Zinc	30mg	40mg	25mg	25 mg supplement 42 mg total (SUL)	15 mg

CRN: Council for Responsible Nutrition

ECSCF: European Commission on Safety of Food

GL: Guidance Level (may apply to total or supplemental intake)

UK EVM: UK Expert group on Vitamins and Minerals (EVM)

US IOM: United States Institute of Medicine

EFSA UL European Food Authority (EFSA)

SUL: Safe Upper Tolerable Limit

UL: Tolerable upper intake level