(57)

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 1587] नई दिल्ली, बृहस्पतिवार, अप्रैल 26, 2018/वैशाख 6, 1940
No. 1587] NEW DELHI, THURSDAY, APRIL 26, 2018/VAISAKHA 6, 1940

वित्त मंत्रालय

(राजस्व विभाग)

अधिसूचना

नई दिल्ली, 26 अप्रैल, 2018

का.आ. 1761(अ).—जहां तक केंद्र सरकार निम्नलिखित पदार्थ (प्राकृतिक या संश्लेषित) या प्राकृतिक सामाग्री या ऐसे पदार्थ से बनाए गए लवण या उत्पाद की प्रकृति और उसके प्रभाव तथा इसके दुरुपयोग के बारे में उपलब्ध कराई गयी सूचना और साक्ष्यों के आधार परइस बात से संतुष्ट है और यह आवश्यक समझती है कि निम्नलिखित पदार्थ, या प्राकृतिक सामग्री,या उसके लवण या उसके उत्पादों को स्वापक औषधि और मनः प्रभावी पदार्थ अधिनियम,1985 (1985 का 61) (इसके पश्चात जिसे उक्त अधिनियम के रूप में संदर्भित किया गया है)की अनुसूची में जोड़ा जाना जरूरी है;

अतः अब उक्त अधिनियम की धारा 3 के तहत प्रदत्त शक्तियों का प्रयोग कराते हुये केंद्र सरकार, एतद् द्वारा, उक्त अधिनियम की अनुसूची में विनिर्दिष्ट स्वापक पदार्थों की सूची में और आगे संशोधन करती है,अर्थात्: -

उक्त अधिनियम में, अनुसूची में, क्रम संख्या 110 X और उससे सम्बन्धित प्रविष्टियों के पश्चात निम्नलिखित क्रम संख्या और प्रविष्टियों अंतःस्थापित की जाएगीं, अर्थात्: -

क्रम सं०.	अंतर्राष्ट्रीय गैर-प्रोप्राइटरी नाम	अन्य गैर-प्रोप्राइटरी नाम	रासायनिक नाम
"110Y	ट्रामाडोल	-	-".

[फ़ा० सं०.एन-11012/3/2017-एन सी. II]

विजय कुमार बालयान, अवर सचिव

नोट : स्वापक औषधि एवं मन:प्रभावी पदार्थ अधिनियम, 1985 (1985 का 61) की अनुसूची में पथम बार का.आ. 785 (अ),दिनांक 26 अक्तूबर, 1992 के द्वारा और उसके बाद का.आ. 49 (अ) दिनांक 8 जनवरी, 1993, का.आ. 39(अ) दिनांक 12 जनवरी, 1996, का.आ. 475(अ) दिनांक 11 जून, 2003, सा.का.नि. 621(अ) दिनांक1अगस्त, 2003, सा.का.नि. 1(अ) दिनांक 2 जनवरी, 2004, का.आ. 311 (अ) दिनांक 10 फरवरी, 2011, का.आ. 376 (अ) दिनांक5 फरवरी, 2015,का. सं० 2374(अ), दिनाक 12 जुलाई, 2016 और का. आ. सं० 1383 (अ), दिनांक 2 मई 2017और का.आ. सं०. 821(अ), दिनांक 27 फरवरी, 2018.

MINISTRY OF FINANCE

(DEPARTMENT OF REVENUE)

NOTIFICATION

New Delhi, the 26th April, 2018

S. O. 1761(E).—Whereas the Central Government is satisfied, on the basis of information and evidence which has become available to it, with respect to the nature and effect of and the scope for abuse of the following substance (natural or synthetic) or natural material or any salt or preparation of such substances or materials, and the modification with respect to such substances, and that it is necessary to add the following *substance or natural material or salts* or preparation of such substance or material in the list of psychotropic substances specified in the Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) (hereinafter referred to as the said Act);

Now, therefore, in exercise of the powers conferred by section 3 of the said Act, the Central Government hereby makes the following further *amendments in the list of psychotropic substances* specified in the Schedule to the said Act, namely: -

In the said Act, in the *Schedule, after serial number* 110 X and the entries relating thereto, the following serial number and entries shall be inserted, namely: -

Sl. No.	International non-proprietary names	Other non-proprietary names	Chemical name
"110Y	Tramadol	-	-".

[F. No. N-11012/3/2017-NC. II]

VIJAY KUMAR BALYAN, Under Secy.

Note: The Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) was first amended *vide*number S.O. 785(E) dated 26th October, 1992 and subsequently amended *vide* numbers S.O. 49(E), dated the 8th January, 1993, S.O. 39(E), dated the 12th January, 1996, S.O. 475(E), dated the 11th June, 2003, G.S.R. 621(E), dated the 1st August, 2003, G.S.R. 1(E), dated the 2nd January, 2004, S. O. 311 (E), dated the 10th February, 2011, S. O. 376 (E), dated the 5th February, 2015, S. O. No. 2374 (E), dated the 12th July, 2016, S.O. No. 1383 (E), dated the 2nd May, 2017 and S.O. No. 821(E), dated the 27th February, 2018.

Sl No.	Name of Narcotic Drug and Psychotropic Substance (International non-proprietary name (INN))	Other non-proprietary name	Chemical Name	Small Quantity (in gm.)	Commercial Quantity (in gm./ kg.)
1	2	3	4	5	6
"238 ZH	Tramadol	-	-	5 gm	250 gm".

[F. No. N-11012/3/2017-NC. II]

VIJAY KUMAR BALYAN, Under Secy.

Note.: The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), *vide* number S.O. 1055 (E), dated the 19th October, 2001 and subsequently amended *vide* numbers S.O. 2941 (E), dated the 18th November, 2009, S.O. 1430 (E), dated the 21st June, 2011,S.O. 375 (E) dated the 5th February, 2015, S. O. 2375(E), dated the 12th July, 2016, S.O. 384 (E), dated the 2nd May, 2017 and S.O. 822 (E), dated the 27th February, 2018.

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and Published by the Controller of Publicaoiktions, Delhi-110054.

अधिसूचना

नई दिल्ली, 26 अप्रैल, 2018

का.आ. 1762(अ).—स्वापक औषधि एवं मन:प्रभावी पदार्थ अधिनियम, 1985 (1985 का 61) की धारा 2 के उपखंड(viiक) और (xxiiiक) के तहत प्रदत्त शक्तियों का प्रयोग करते हुए, केन्द्र सरकार, एतदद्वारा, भारत सरकार, वित्त मंत्रालय, राजस्व विभाग की अधिसूचना जिसे का.आ. 1055 (अ),दिनाक 19 अक्तूबर, 2001, के द्वारा भारत के राजपत्र, असाधारण के भाग, II खण्ड-3, उपखण्ड (ii) में प्रकाशित किया गया था, में निम्नलिखित संशोधन करती है, अर्थात :-

उक्त अधिसूचना में सारणी में, क्रम सं. 238ZG और उससे संबंधित प्रविष्टियों के पश्चात निम्नलिखित क्रम संख्याऔर उनसे संबंधित प्रविष्टियों को अंत:स्थापित किया जाएगा, अर्थात :-

क्र.सं.	स्वापक औषधि एवं मन:प्रभावी पदार्थ का नाम (अंतर्राष्ट्रीय गैर-प्रोपराइटरी नाम)	अन्य गैर-प्रोपराइटरी का नाम	रासायनिक नाम	अल्प मात्रा (ग्राम में)	वाणिज्यिक मात्रा (ग्राम में)
1	2	3	4	5	6
"238 ZH	ट्रामाडोल	-	-	5ग्राम	250ग्राम".

[फा.सं. एन-11012/3/2017-एनसी-II]

विजय कुमार बालयान, अवर सचिव

नोट : प्रधान अधिसूचना को का.आ. 1055 (अ), दिनांक 19 अक्तूबर, 2001 के तहत भारत के राजपत्र, असाधारण के भाग, II खण्ड-3, उपखण्ड (ii) में प्रकाशित किया गया था और बाद में इसमें अधिसूचना संख्याका.आ. 2941 (अ),दिनांक 18 नवम्बर, 2009,का.आ. 1430 (अ),दिनांक 21 जून, 2011, का.आ. 375 (अ),दिनांक 5 फरवरी, 2015,का.आ. 2375(अ), दिनांक 12 जुलाई,2016 और का.आ. 384 (अ), दिनांक 2 मई, 2017 और का.आ. 822(अ), दिनांक 27 फरवरी, 2018.के तहत संशोधन किया गया है।

NOTIFICATION

New Delhi, the 26th April, 2018

S. O. 1762(E).—In exercise of the powers conferred by clauses (viia) and (xxiiia) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following further amendments in the notification of the Government of India, Ministry of Finance, Department of Revenue, published in the *Gazette* of India, Extraordinary, Part II, Section 3, Sub-section (ii) *vide* number S.O. 1055 (E), dated the 19th October, 2001, namely: -

In the said notification, in the Table, after serial number 238 ZG and the entries relating thereto, the following serial number and entries shall be inserted, namely: -

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

May 02, 2018

Mr. Dinesh Boudh,
Deputy Secretary (Narcotics Control),
Department of Revenue,
Ministry of Finance,
North Block, New Delhi - 110001

Subject: Notification of Tramadol as a Psychotropic substance - S. O. 1761(E) - regarding.

Dear Sir,

Greetings from Indian Drug Manufacturers' Association.

The Government of India has issued a notification dated April 26th, 2018 - **S. O. 1761(E),** classifying "Tramadol" and it's preparations as a Psychotropic substance and bringing it under the purview of the NDPS Act, 1985 and Rules, thereunder.

Tramadol is an effective pain killer and prescribed extensively by medical practitioners, across the country. Bringing them under the NDPS Act, 1985 without providing reasonable time for Companies manufacturing and exporting Tramadol APIs and preparations, would result in instant violation of the NDPS Act, 1985 resulting in serious implications for Companies, Distributors and Retailers across the country.

For example, Companies who do not manufacture any Psychotropic substances would need to file for new registration with Central Bureau of Narcotics, Gwalior which could take time or there could be APIs or preparations under clearance for export which would amount to violation, as no NOC for export has been obtained from CBN as per Rule 58 and 59 or labeling of Tramadol preparations, already in the supply chain in the domestic market may need to be redone, as labeling requirements for Psychotropic substances under the D&C Act, 1940 need to be complied. The incorrect labeling of Tramadol preparations in the supply chain, currently available with distributors and retailers may be interpreted as a violation of NDPS Act due to this notification, having

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(62)

immediate effect. This in turn would lead to a panic situation leading to non-availability of this pain killer for needy patients.

It is our humble submission that a period of 6 months need to be provided for Companies to comply with provisions of NDPS Rule 65, 67 58 or 59 and the D&C Act with regards to labeling. This time period is required to sensitize all stakeholders about this notification and would also enable the current inventory in the supply chain to be exhausted. We wish to draw your kind notice to the fact, that when RCS Order was amended in 2013 and also when NDPS amendment was done in May 2015, a period of 6 months was given for ensuring proper compliance with the amended order / rules.

We therefore, request that Rule 65 may be amended to include a proviso, stating *"Any new substance which has an established medical or scientific use and included in the list of Psychotropic substances specified in the schedule to the Act would come into effect on the 180th day from the date of such notification"*.

We request your kind consideration and an URGENT amendment to the Rules or an appropriate clarification providing time for necessary compliance.

With best regards,

Yours Sincerely,

D. N. Roy Chowdhury

Deepnath Roy Chowdhury
National President

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