

[TO BE PUBLISHED IN PART II, SECTION 3, SUB-SECTION (i) OF THE GAZETTE OF INDIA, EXTRAORDINARY]

GOVERNMENT OF INDIA
MINISTRY OF FINANCE
(Department of Revenue)

Notification No. 16 /2017-Customs

New Delhi, the 20th April, 2017

G.S.R. (E).- In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, being satisfied that it is necessary in the public interest so to do, hereby exempts the goods, falling under Chapter 30 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975), of the description specified in column (2) of the Table below, for supply under Patient Assistance Programmes specified in the corresponding entry in column (3) of the said Table, run by the pharmaceutical companies specified in the corresponding entry in column (4) of the said Table, when imported into India, from the whole of the duty of customs leviable thereon which is specified in the First Schedule to the said Customs Tariff Act, subject to the following conditions, namely:-

- (a) the drugs and medicines are supplied free of cost to the patients under the Patient Assistance Programme of the specified pharmaceutical company;
- (b) the said pharmaceutical company furnishes an undertaking to the Assistant Commissioner of Customs or the Deputy Commissioner of Customs, as the case may be, having jurisdiction, to the effect that-
 - (i) it shall maintain the following records:-
 - (A) name, age, gender, residence and contact details of the patient;
 - (B) copies of valid identity proof and residence proof of the patient and the caregiver, if any, as the case may be;
 - (C) the disease diagnosed and the prescribed dosage of drugs and medicines;
 - (D) the drugs and medicines imported or received and consumed under the said programme;
 - (ii) the goods shall be used for the specified purpose only;
- (c) The said pharmaceutical company also furnishes an undertaking to the Assistant Commissioner of Customs or Deputy Commissioner of Customs, as the case may be, having jurisdiction, to pay, in the event of failure to comply with any of the aforesaid conditions, an amount equal to the duty leviable on such goods but for the exemption contained in this notification, along with the applicable interest thereon.

TABLE

| Sr. No. | Description of drug / medicine | Name of Patient Assistance Programme | Name of pharmaceutical company running Patient Assistance Programme |
|----------------|---|---|--|
| (1) | (2) | (3) | (4) |
| 1. | Xtandi (Enzulatamide) | Xtandi Patient Assistance Programme | Astellas Pharma India Pvt. Ltd. |
| 2. | Dasatinib (Sprycel) | Sprycel Assistance Program | Bristol Myers Squibb India Pvt. Ltd. |
| 3. | Nivolumab (Opdyta) | OASIS | Bristol Myers Squibb India Pvt. Ltd. |
| 4. | Halaven (Eribulin medylate) - Metastatic Breast cancer, Soft Tissue Sarcoma | Hope to Her – 2 to 3 cycles purchased and balanced free upto disease progression | Eisai Pharmaceuticals India Pvt. Ltd. |
| | | HELP - All cycles free for below poverty line patients | Eisai Pharmaceuticals India Pvt. Ltd. |
| 5. | Zonegran (Zonisamide) - for Epilepsy | Livefree - 33% Support to patients for extending duration of treatment as this is a chronic therapy | Eisai Pharmaceuticals India Pvt. Ltd. |
| 6. | Imbruvica | 1+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 7. | Zytiga | 3+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 8. | Velcade 1mg | 3+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 9. | Velcade 3.5 mg | 1+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 10. | Caelax | 1+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 11. | Dacogen | 1+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 12. | Yondelis | 1+1 PAP | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 13. | Simponi | 1 vial free on 1 st | Janssen India, Johnson & |

| Sr. No. | Description of drug / medicine | Name of Patient Assistance Programme | Name of pharmaceutical company running Patient Assistance Programme |
|----------------|---------------------------------------|---|--|
| (1) | (2) | (3) | (4) |
| | | purchase | Johnson Pvt. Ltd. |
| 14. | Remicade | 5+4 on 3 dose therapy, 6+6 on 4 dose therapy | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 15. | Invega all SKUs | 1+1 PAP (Maintenance dosage) | Janssen India, Johnson & Johnson Pvt. Ltd. |
| 16. | Imatinib (Glivec) | Glivec NOA Program/ Glivec International PAP | Novartis India Ltd. |
| 17. | Nilotinib (Tasigna) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 18. | Ruxolitinib (Jakavi) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 19. | Everolimus (Afinitor) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 20. | Ceritinib (Spexib) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 21. | Pazopanib (Votrient) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 22. | Eltrombopag (Revolade) | Win for Patients - Cancer Care | Novartis India Ltd. |
| 23. | Indicaterol (Sequadra) | Win for Patients - COPD | Novartis India Ltd. |
| 24. | Secukinumab (Scapho) | Win for Patients - Skincare | Novartis India Ltd. |
| 25. | Omalizumab (Xolair CSU) | Win for Patients – Skin care | Novartis India Ltd. |
| 26. | Ranibizumab (Accentrix) | Win for Patients - Visioncare | Novartis India Ltd. |
| 27. | RITUXIMAB | SPARSH - The Touch | Dr. Reddy's Laboratories Ltd. |

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