



Drug Information Bulletin

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Indian Pharmaceutical Association

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Editorial

Retaining the brand name same even after changing the active constituent with other therapeutic category is a common practice in India. For an example- that there are five products like- Itraconazole Capsule, Esomoprazole Gastro-Resistant Tablets IP, Albendazole Tablets IP, Metronidazole Oral Suspension BP and Pantoprazole for Injection 40 mg under a particular “Brand name”. There are several examples of such products. This is well debated because it is creating confusion amongst all stake holders. Sometimes it creates severe health problems due to dispensing error also.

Several memorandums have been sent to the concerned authorities for quick solution of the problem to protect the health of the people. This issue has been discussed in several meetings of DCC during 2008 to 2011 where DCC unanimously resolved that “the change of formulation composition without changing the brand name is not only misleading but may also result in undesirable pharmacological effects as the consumer would take the formulation assuming that it has the earlier composition. DCC further recommended that such type of practice needs to be discouraged and the state drugs controllers should ensure that the same brand name should not be permitted to retain by the manufacturers, if the composition of the API (s) in the new formulation changed “and as a result DCGI has requested Drugs Controllers of all states and UTs to take steps in this matter.

Health activists are surprised to note that DCGI took 8 years to convey the decision of DCC on such an important issue. More over experts believe that it is difficult to implement this direction as there is no suitable legislative provision at this moment and require suitable amendment of the Drugs and Cosmetics Act & Rules.

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Editor

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Prices of 9 non scheduled anticancer drugs reduced up to 87 percent in India

Recently NPPA caps prices of 9 non scheduled anticancer drugs by up to 87 percent on publishing an additional list in continuation of office Memorandum No. 8(64)/2019DP/Div.II dated 08.03.2019, 11.03.2019 and 19.03.2019. The list is as follows:

Sl. No.	Drug	Strength and Dosage form	Brand Name	Pack size	Old MRP	Revised MRP
1	Erlotinib	100 mg tablet	Erlotaz	10	6600	1840
2	Erlotinib	150 mg tablets	Erlotaz	10	8800	2400
3	Pemetrexed	100 mg Injection	Pemxcel	1	7700	800
4	Pemetrexed	500 mg Injection	Pemxcel	1	22000	2880
5	Epirubicin	10 mg Injection	Epichlor	1	561	276.8
6	Epirubicin	50 mg Injection	Epichlor	1	2662	960
7	Leuprotide acetate	3.75 mg Injection	Leuprogen Depot	1	3990	2650
8	Everolimus	0.25 mg tablet	Lanolimus 0.25 mg	10	726	406
9	Everolimus	0.5 mg tablet	Lanolimus 0.5 mg	10	1452	739

Mean availability of anti-neoplastic essential medicines was 38% in private-sector retail pharmacies, 43% in public hospital pharmacies and 71% in private hospital pharmacies: A study

As per the article published in BMJ, the view of the author is-

Since patient's caregivers can avail prescribed medicines from any pharmacy outlet in the survey anchor/hospital area (either hospital or several retail pharmacies), we also evaluated mean availability by survey anchor.

On average, across survey anchor areas (hospital and private-sector retail pharmacies combined), the mean availability of anti-neoplastic EMs and non-cancer medicines was 70% and 100%, respectively. For cancer medicines, the availability remains below WHO's target of 80%.

The median price for all surveyed cancer was 0.71 times the MSH international reference price. However, the estimated cost of chemotherapy medicines needed for treating a 30 kg child with standard-risk leukaemia was INR 27 850 (US\$442) and INR 17500 (US\$278) for Hodgkin's lymphoma, requiring 88 and 55 days' wages, respectively, for the lowest paid government worker. In other

words, medicines seem to be unaffordable in local context.

Only a few (n = 3) of the surveyed medicines were available in the government discount-pharmacy outlets (Jan Aushadhi scheme), but these Jan Aushadhi prices were half of what a consumer will pay in private retail pharmacies. We urge the government to include more medicines in the scheme and take measures to improve popularity of these pharmacies - to help reduce out-of-pocket medicines cost.

Note that these results from New Delhi (India's capital region) represent the best-case scenario and we expect the access to be relatively poor in other Indian states - especially those with lower socioeconomic status and poor-functioning health systems.

For details:

<https://gh.bmj.com/content/4/2/e001379>

New Drug: Guselkumab for plaque psoriasis

Approved indication: plaque psoriasis

Tremfya (Janssen-Cilag)

prefilled syringe containing 100 mg/mL solution

Interleukins are signalling molecules involved in the regulation of the immune system. Changes in interleukins can upset this regulation and cause immune-mediated diseases. Increases in

interleukins 17 and 23 can lead to the abnormal proliferation of keratinocytes seen in psoriatic skin. These interleukins have therefore become the targets for treatment when systemic therapy is needed for moderate to severe psoriasis. Interleukin 17 is a target for the monoclonal antibodies ixekizumab and secukinumab, while interleukin 23 is the target of tildrakizumab and ustekinumab.

Guselkumab is another monoclonal antibody. It binds to a subunit of interleukin 23. This prevents the interleukin from binding to its receptor so cell proliferation should be reduced.

The antibody has to be given by subcutaneous injection. A maximum concentration is reached 5.5 days later and with the recommended regimen a steady state is reached at 20 weeks. The antibody is probably catabolised and has a half-life of about 18 days.

The main efficacy studies of guselkumab included two double-blind, placebo-controlled phase III trials in patients with moderate to severe psoriasis ([Table](#)).^{1,2} Guselkumab 100 mg was injected at weeks 0, 4 and then every 8 weeks. Adalimumab, a tumour necrosis factor inhibitor, was given as an active comparator. The primary outcomes were improvements in the Investigator Global Assessment and the Psoriasis Area and Severity Index (PASI). Although the trials lasted for 48 weeks, the primary end points were assessed at 16 weeks.

In the first trial (VOYAGE 1) 329 patients were randomised to receive guselkumab, 334 adalimumab and 174 placebo. After 16 weeks of treatment with guselkumab the psoriasis had cleared or was minimal in 85.1% of the patients and 73.3% had achieved at least a 90% reduction in the PASI score (PASI 90). The corresponding figures were significantly lower for adalimumab (65.9% and 49.7%) and placebo (6.9% and 2.9%). Patients in the placebo group were then switched to guselkumab and by 48 weeks they had achieved similar responses to those seen in patients who took guselkumab for the whole trial. The advantage over adalimumab was also maintained at 48 weeks.¹

The second trial (VOYAGE 2) had a similar design with 496 patients randomised to guselkumab, 248

to adalimumab and 248 to placebo, switching to guselkumab after 16 weeks. In addition, at 28 weeks patients who responded to guselkumab were re-randomised to continue it or switch to placebo. Those switched to placebo could be re-treated if the psoriasis relapsed. After 16 weeks the psoriasis was minimal or had cleared in 84.1% of the guselkumab group, 67.7% of the adalimumab group and 8.5% of the placebo group. The respective results for PASI 90 were 70%, 46.8% and 2.4%. These responses were sustained in patients who continued taking guselkumab throughout the trial. For those switched to placebo it took about 15 weeks for the benefit (PASI 90) to be lost. At 48 weeks 36.8% of these patients still had a PASI 90 response compared with 88.6% of those who continued treatment with guselkumab.²

In VOYAGE 2, 112 patients who did not respond to adalimumab were switched to guselkumab at week 28. By week 48, 66% of these patients had achieved a PASI 90 response.²

Another trial (NAVIGATE) looked at patients who did not respond to ustekinumab. After 16 weeks of treatment with ustekinumab 133 patients with an inadequate response were randomised to continue ustekinumab while 135 switched to guselkumab. The end point of the trial was the number of visits at which the investigators assessed the psoriasis as cleared or minimal. Between 28 and 40 weeks this outcome had been achieved at a mean of 1.5 visits with guselkumab and 0.7 visits with ustekinumab. The proportions of patients with minimal or cleared psoriasis at week 52 were 36.3% with guselkumab and 17.3% with continued ustekinumab.³

Infections were the most frequent adverse events in the clinical trials.¹⁻³ These were mainly upper respiratory tract infections. Injection-site reactions were also common. Some patients develop antibodies to guselkumab and serious hypersensitivity reactions have occurred. In view of the risk of reactivation, patients should be screened for tuberculosis before starting guselkumab. Live vaccines should not be used during treatment or for 12 weeks afterwards. Guselkumab has not been studied in human pregnancy or lactation. Whether guselkumab

significantly increases the risk of malignancy is uncertain.

Biological therapies can be considered when a patient with moderate to severe plaque psoriasis requires systemic therapy or phototherapy. The trials show that guselkumab has greater efficacy than placebo and adalimumab.^{1,2} It can also be considered for patients who do not respond to ustekinumab.³ As the effects of guselkumab wear off after the drug is stopped, treatment may need to be continued for a longer duration than in the trials. This will require additional monitoring of its safety.

References

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2. Reich K, Armstrong AW, Foley P, Song M, Wasfi Y, Randazzo B, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the

treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. J Am Acad Dermatol 2017;76:418-31.

3. Langley RG, Tsai TF, Flavin S, Song M, Randazzo B, Wasfi Y, et al. Efficacy and safety of guselkumab in patients with psoriasis who have an inadequate response to ustekinumab: results of the randomized, double-blind, phase III NAVIGATE trial. Br J Dermatol 2018;178:114-23.
Ref. Australian Prescriber

NHS England will pay for SMA drug Spinraza

The National Health Service England and Biogen have entered an access agreement to fund Biogen's spinal muscular atrophy drug Spinraza for a limited period to evaluate its efficacy. Details regarding the amount to be paid for the drug, which costs \$750,000 for the first year and \$375,000 per year thereafter in the US, weren't disclosed by NHS England.

Ref. [Reuters](#)

Forthcoming Events
Awareness Programme on
Adolescent and Adult Vaccination

Organized by:
IPA- Bengal Branch in association
with Apollo Hospital

Date: 1st June 2019
Time: 6.00 pm
Venue: IPA Auditorium

79th FIP World Congress of Pharmacy and Pharmaceutical

22 - 26 September 2019,
Abu Dhabi, United Arab Emirates

Theme:

New horizons for pharmacy – Navigating
winds of change

For details:

<https://abudhabi2019.congress.pharmacy/registrati>
[on-forms/](#) *g winds of change*
horizons for pharmacy

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