Load of Generic Products Packages

A Hidden Cost of Generic Savings

A Close look at an implication of pro-generic policies, which creates massive amount of generic products packages, and brings an excruciating yet unvoiced load on distribution infrastructure of Japan.

Research Category

Special Report

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Important Disclaimer:

- All data presented herein are from the sales data from Wholesalers only. This may miss some data points generated through direct sales channels.
- Data points are based on Annual Sales Figures of Year Ending March 2017 (i.e. April 2016 to March 2017), and its previous years data.

Executive Summary

The importance of Generic drugs promotion to curb the mounting challenge of Healthcare Expenditure is well justifiable. They not only reduce the unnecessary expenditure but also help creating resources available for the innovation.

However, several negative outcomes of growing generics penetration also exist for the society. While some of them are already visible, some will exhibit their implications in long run.

The creation of a massive amount of 'packaging variants' by generic companies is one such problem, which is already posing a burden on the Japanese distribution system but do not fetch the attention it deserves.

Whenever an originator product goes off-patent, several generic companies launch their generic versions. Recent trends in Japan suggest that there are ~25-30 companies successfully get into first listing of any major generic product. These products are often available in various formulations, strengths, packaging forms and types of packages. Together all these generic companies create and bring a massive amount of 'packaging variants' into the distribution system to be handled. However, a majority of these 'package variants' create 'negligible' sales and pose a burden to the wholesalers, pharmacies and other healthcare providers to deal with.

This report takes a close look at this less noticed issue of 'creation or massive amount of generic product packages', which bring an enormous burden on distribution infrastructure of Japanese pharmaceutical industry.

- Generic which comprise just ~12% of the total Japan market by value and ~28% by volume, capture a whopping ~58% of the number of packaging variants available in Japan.

- Majority of Generic products generate a very tiny sales and their contribution to 'generic savings' is negligible.

- While a large proportion of GE market is captured by a handful of products only, remaining products contribute equally in terms of introducing products-packages into the system. (*However, we also note that some of the generic companies market their products only in small geographic areas. Hence, such products' sales may look very tiny on national level, but they may have a meaningful presence in local areas*).

- Sales of originators still remain higher than the combined sales of generics products for most of the drugs. However, at the same time the packaging variants from GE capture ~90% of the volume.

- A close analysis of individual products exhibit the gravity of the problem more clearly:

    1. **Bicalutamide** (Casodax) – which is available in ~just one formulation and one strength i.e. a 80MG Tablet – is available in more than 50 types of packaging variants from ~20 companies.

    2. **Donepezil** (Aricept) – 22 out of total 28 GE companies generate <10% of total sales but they create a whopping 260+ number of packaging variants.

    3. **Amlodipine** (Norvasc/Amlodin) - is available in combination with all major ARBs, and all these combinations together create over 900 types of 'packaging variants' in Japan. Amlodipine alone is marketed by ~three dozen generic companies and together they create ~680 types of different packaging variants.

Generic companies are doing well currently, but already under tough surroundings of stiff competition and pricing pressure. These pressure points are bound to increase further in future – and they will bring many of these generic companies under pressure of further cost cutting. These measures will include - shifting manufacturing to low-cost overseas destinations (early signs are already visible), increase in import (a large number of APIs are already imported but trend may extend to importing finished goods), companies will join hands in form of partnering and consolidation, and many of smaller firms will still find it hard to stay in competition and may exit.

So while a cost efficient generic system will continue to exist and prevail – the implications for society would also come in form of

shutting down local businesses, lay-offs and unemployment. Likely implications of weakening the 'essential' industry of nation needed to be studied further.

Background and Rationale

"Just like every good drug comes with some side-effects, there are many aspects of generics proliferation in Japan which are already leading to some 'hidden pains'. However, while a drugs' side effect is well known and well cited in advance, some of the burden created by generics often remain hidden until they become unbearable."

The importance of Generic drugs promotion to curb the mounting challenge of Healthcare Expenditure is well justifiable. They not only reduce the unnecessary expenditure but also help creating resources available for the innovation. The Government led policies have played well in recent years and it is also likely that Government's target to achieve 80% GE penetration will be eventually met sooner or later (new set target is for Sept. 2020).

Just like every good drug comes with some side-effects, there are many aspects of generics proliferation in Japan which are already leading to some 'hidden pains'. However, while a drugs' side effect is well known and well cited in advance, some of the burden created by generics often remain hidden until they become unbearable. It is thus important that policies should also attempt to foresee 'all aspects' of any regulatory initiatives and their implications.

Encise Research Center spots a few avenues which need close investigation over likely long-term socio-economic implications of generics proliferation in Japan.

Generic companies are doing well currently – they are growing and their financial health looks good. However, growing competitions and pricing pressure are bound to bring many of these generic companies under pressure of cost cutting. This pressure will result in form of many measures of cost cutting e.g. shifting own manufacturing to low-cost overseas destinations (early signs are already visible), increase in import (a large amount of APIs are already imported but trend may extend to importing finished goods), companies will join hands in form of partnering and consolidation, and many of the smaller firms will still find it hard to stay in competition and may exit.

So while a cost efficient generic system will continue to exist and prevail – the implications to society would also come in form of shutting down local businesses, lay-offs and unemployment. Likely implications of weakening the 'essential' industry of nation need to be studied further. The example of Germany could be somewhat relevant here – once a ~most reverent destination of pharmaceutical research and delivery has largely lost its domestic ownership (as many of its prestigious local companies were consolidated with global

players in order to withstand competitive pressure). Although the Germany's example is not focused at Generic companies as such, the essence of the message is same.

In this report, however, we look at a rather less noticed issue of 'creation or massive amount of generic product packages', which bring an enormous burden on distribution infrastructure on Japanese pharmaceutical industry.

"Generic which comprise just ~11% of the market by value and ~28% of the market by volume, capture a whopping ~58% of the number of packaging variants available in Japan."

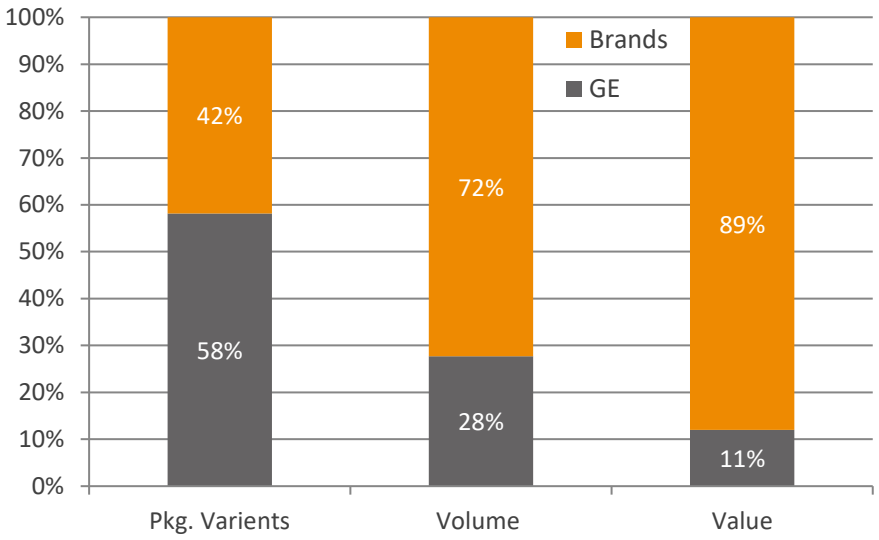
Total Japan Pharma market is ~89% composed of originators products (both brands and long-listed products) by value, however this ratio is gradually decreasing and YoY change in FY 2016 alone was ~-1%.

The composition of originators products drops to ~72% on volume basis, and over ~28% of the market is composed by generic products. (**Note:** generics penetration by volume is ~67% while only long-listed drugs are taken into consideration.)

The ratios drop significantly further when 'number of packaging variant' are taken into consideration – generic which comprise just ~11% of the market by value and ~28% of the market by volume - capture a whopping ~58% of the number of packaging variants available in Japan.

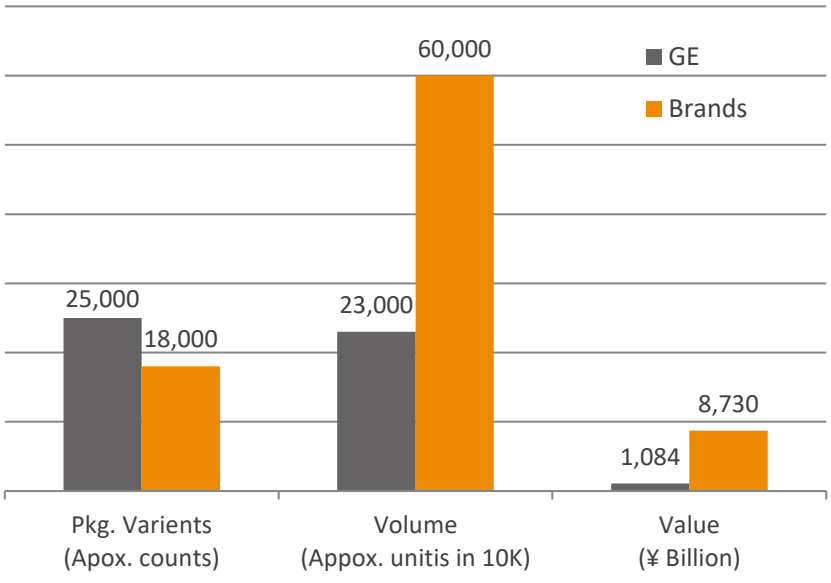
This brings a significant burden on storage, logistics, handling and distribution function mainly for pharmaceutical wholesalers and to some extent to the chemists. Figure 1 and 2.

Figure 1.
GE vs. Brands: Market-Share Comparison (FY 2016)



Source: Encise Inc.

Figure 2.
GE vs. Brands: Market-Share Comparison on Actual Figures (FY 2016)



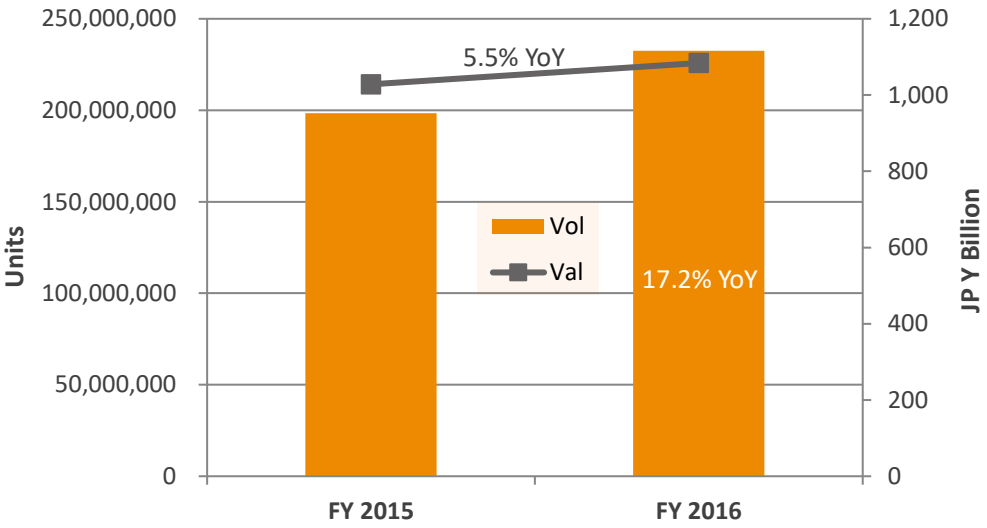
Source: Encise Inc.

A Close Look at the Generic Market from availability of 'Packaging Variants' point of view:

The total Japan GE market was ~¥1.1 Trillion in 2016. Backed by favorable government reforms, it grew by ~5.5% YoY on value basis; however the volume growth for the same period was over three times to ~17.2% YoY. The contrast in volume to value growth was mainly due to stringent pricing regulations for GE drugs (Figure 3).

"Generic volume growth significantly overweight generic value growth - due to stringent pricing amidst otherwise pro-generic government initiatives."

Figure 3.
Japan GE Market YoY Change in Value & Volume (FY 2016)



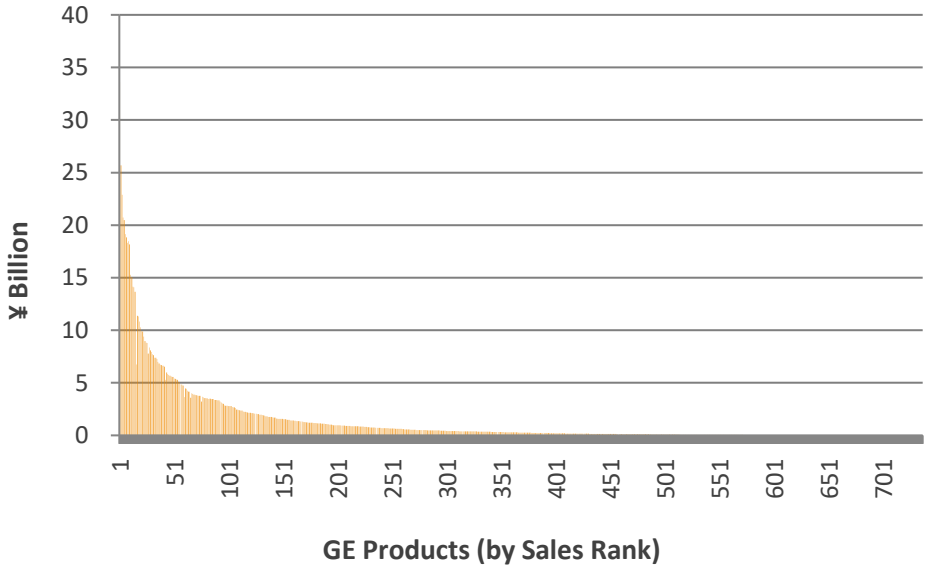
Source: Encise Inc.

There are over 700 types of total independent GE products available in Japan by composition (active ingredients only; not counting their different formulations and strengths available).

Of these 700+ independent GE products available, only ~dozen of them generate over ¥10Billion of sales, and ~five dozen of them have annual sales of over ¥5Billion. Rest of the 650+ products (over 90% of all) together generates less than ¥50 Billion of revenue (Figure 4).

"Majority of Generic products generate a very tiny sales and their contribution to 'generic savings' is negligible."

Figure 4.
Japan GE Market: Sales of All GE Products (FY 2016)



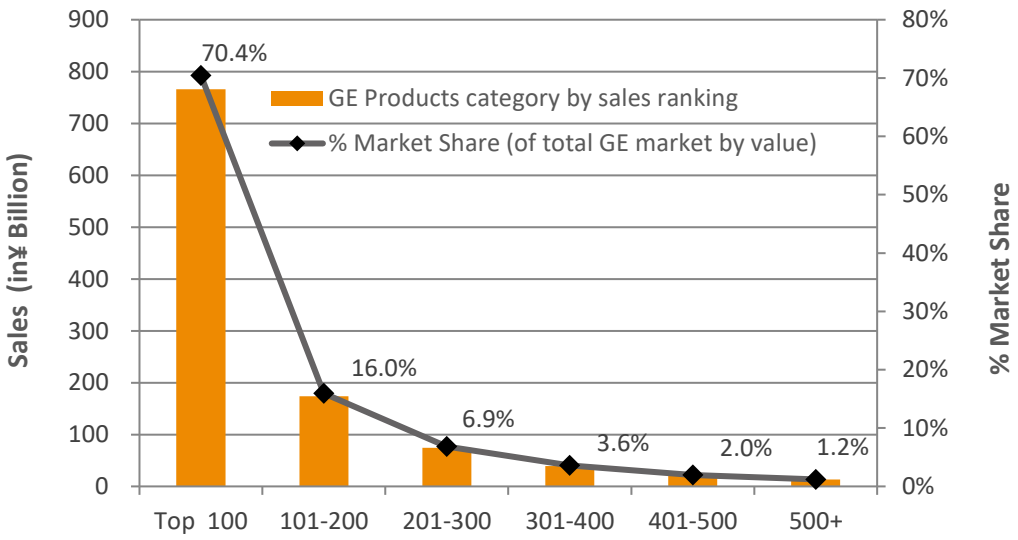
Source: Encise Inc.

Figure 5 is not be very surprising, leading products always form a bigger pie of the market and it stands true for originators drugs and for other markets as well. However, the issue here is not the sales but the number of packaging variants created by these GE products which have very tiny sales.

It has become a norm in recent in years in Japan that whenever a major products goes off patent, ~25-30 companies launch GE versions at the same time. The contrast in their sales and creation of 'packaging variants' leads to several issues, which we see in details into case studies section.

"While a large GE market share is captured by a handful of products only, remaining products contribute equally in terms of introducing products-packages into the system."

Figure 5.
Sales of GE Products by 'Sales Category' (FY 2016)



Source: Encise Inc.

A Close look at the Top-100 GE products

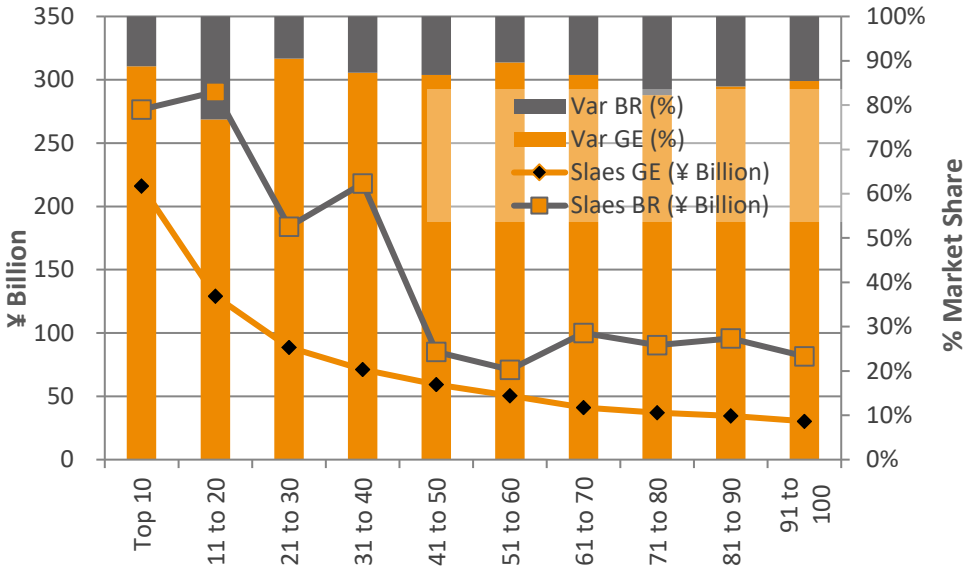
Figure 6 take a close look at further breakdown of top-100 GE products with respect to their sales and packaging variants created by them and their corresponding originator products.

Sales of originators (Sales BR) remain higher than GE (Sales GE) in all sub-groups. However, at the same time the packaging variants from GE capture ~90% of the volume in most sub-groups.

This explains the severity of the ground situation.

''Sales of originators (Sales BR) remain higher than GE (Sales GE) in all sub-groups. However, at the same time the packaging variants from GE capture ~90% of the volume in most sub-groups."

Figure 6.
Japan GE Market : Sales of All GE Products (FY 2016)



Source: Encise Inc.

In this section, we take a close look at the issue of 'packaging variants' by comparing a few individual products for their Originators to GE versions.

"Bicalutamide – which is available in ~just one formulation and one strength i.e. a 80MG Tablet – is available in >50 types of packaging variants."

Case Study 1: Bicalutamide - Packaging Variants Created by one of the Simplest Formulation (by availability of forms and strengths)

These days, more and more GE companies are entering to target specialty fields including anti-cancer drugs. The so called 'difficult to make' specialty products are most attractive targets to the generic companies in particular.

In recent years, Japan has seen many GE companies entering anti-cancer field as well. **Casodax** (**Bicalutamide**, preliminarily indicated for prostate cancer) for instance was once considered as 'difficult to make' attractive target for generic companies. However, a total of 15 generic companies were successfully listed as 'first to launch' at the time of first NHI listing for Bicalutamide generics.

The product is available in just one form i.e. 80 MG table. However, even this simplest product (by means of formulation and strength variation) results into generating to a total 52 different package variants by all companies (including 6 from the originator).

The sales of originator is still above 50% by value and it along with five major GE companies (with a total of 12 packaging variants) covers over 90% or the total Bicalutamide sales.

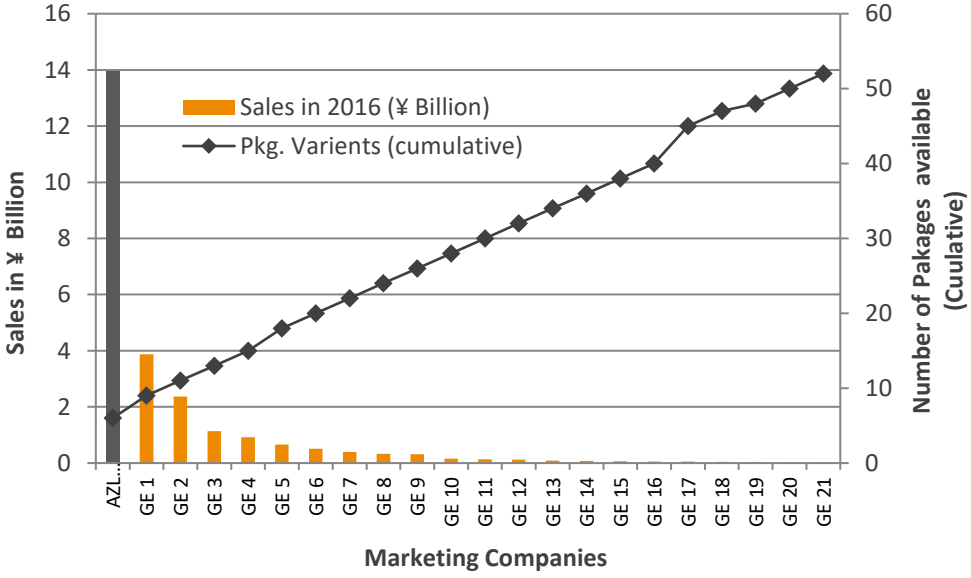
On the other hand remaining 16 GE companies together generate less than 10% of the sales but they create 34 Packaging variants to be managed by the wholesalers, pharmacies and other healthcare providers.

Table 1
Bicalutamide at Glance

Molecule Name	Originator	Generics
Number of Manufacturers	1	20
Number of Marketers	1	21
Number of Dosages Forms available	2	1
Number of Strengths available	1	1
Number of Package Sizes available	4	4
Volume Sales in 2015 (000' Units)	281	393
Volume Sales in 2016 (000' Units)	244	405
Value Sales in 2015 (¥ Billion)	18	14
Value Sales in 2016 (¥ Billion)	14	11
Number of Packaging Variants Available	**6**	**46**

Source: Encise Inc.

Fugure 7
Bicalutamide at Glance



Source: Encise Inc.

Case Study 2: Donepezil - Situation for easy-to-make, small-molecule, major brands

Being market leader into anti-Alzheimer's space, with lucrative and growing sales at the time of patient expiry, and relatively easy-to-make small molecule, as expected ~30 GE companies has launched GE versions of Aricept. Aricept is available in four different formulations from Originator Eisai as well as from GE companies.

"In case of Donepezil – 22 out of total 28 GE companies generate <10% of total sales but they create a whopping 260+ number of packaging variants."

Originator Eisai still holds over 60% of the value market share. Originator, along with next top six generic companies' together capture over 90% of the entire market. Reaming less than 10% of the sales is generated by 22 GE companies who together create whopping 262 packaging variants.

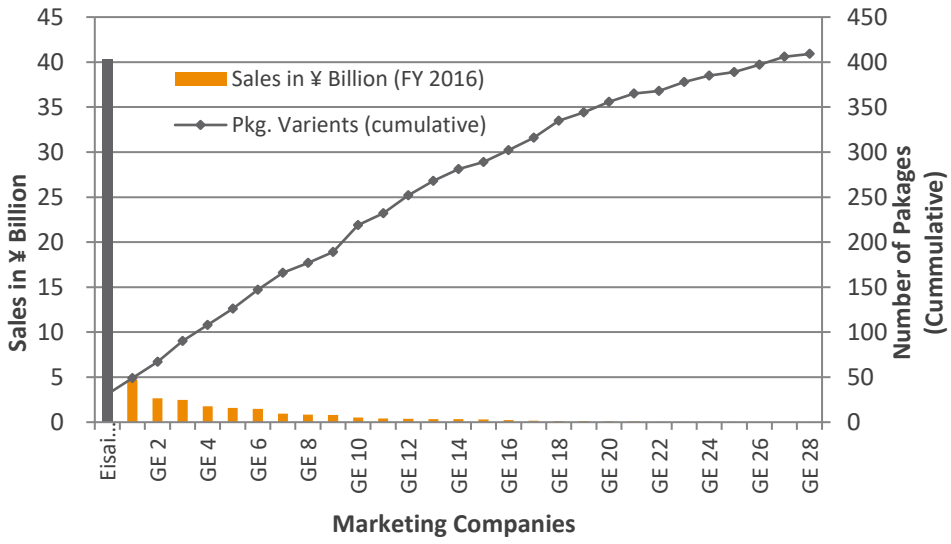
Sales from marketing companies of donepezil and the communitive number of packaging variants created by them exhibits the gravity of the problem - Figure 8.

Table 2
Donepezil at Glance

Molecule Name	Originator	Generics
Number of Manufacturers	1	28
Number of Marketers	1	28
Number of Dosages Forms available	4	4
Number of Strengths available	5	7
Package Unit of Measure	3	4
Number of Package Sizes available	8	7
Volume Sales in 2015 (000' Units)	1,714	1,316
Volume Sales in 2016 (000' Units)	1,416	1,557
Value Sales in 2015 (¥ Billion)	55	23
Value Sales in 2016 (¥ Billion)	40	20
Number of Packaging Variants Available	**31**	**378**

Source: Encise Inc.

Figure 8
Donepezil at Glance



Source: Encise Inc.

Case Study 3: Amlodipine - The King of GE-Packaging Variants

"Amlodipine besylate is available in combination with all major ARBs, and all these combinations together create over 900 types of 'packaging variants' in Japan. Amlodipine alone is marketed by ~three dozen generic companies and together they create ~680 different packaging variants."

One of the most successful products of all times was naturally long awaited target for generic companies. Amlodipine besylate is available in combination with all major ARBs, and all these combinations together create over 900 types of 'packaging variants' in Japan. In this analysis however we take only Amlodipine besylate into consideration for the sake of clarity.

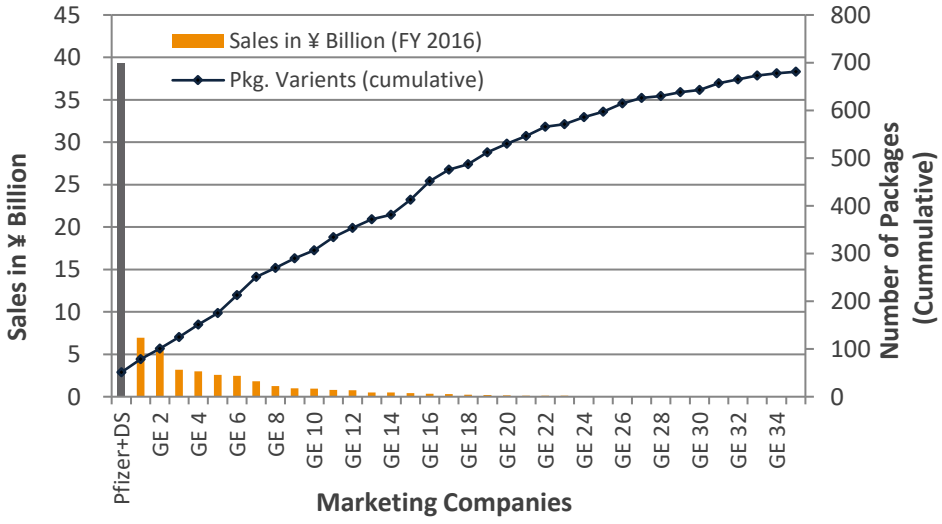
Amlodipine is marketed by about three dozen generic companies in Japan and they create a massive ~680 different packaging variants. Despite many years of generics entry and availability of a large number of generic players, the originator, Pfizer still holds ~1/3rd of the value share. The top 10 companies generate ~90% of the market share by creating ~270 different packaging variants (<40% of total) and reaming ~25 companies generate ~10% of sales but they bring ~410 packaging variants into the system (>60% of total). Altogether, amlodipine besylate only from all companies create a massive ~680 types of packaging variants! (Figure 8).

Table 3
Amlodipine at Glance

Molecule Name	Originator	Generics
Number of Manufacturers	2	35
Number of Marketers	2	35
Number of Dosages Forms available	1	2
Number of Strengths available	3	6
Package Unit of Measure	1	2
Number of Package Sizes available	4	11
Volume Sales in 2015 (000' Units)	3,477	4,437
Volume Sales in 2016 (000' Units)	3,186	5,001
Value Sales in 2015 (¥ Billion)	52	37
Value Sales in 2016 (¥ Billion)	39	34
Number of Packaging Variants Available	**51**	**630**

Source: Encise Inc.

Figure 8
Amlodipine: The King of GE Packaging Variants



Note: Combined sales from Pfizer and Dainippon Sumitomo is takes as originator's sales

Source: Encise Inc.

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