Twinvir and Generic Harvoni from Bangladesh

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The vexed question of what generic drug treatment to use for treating Hepatitis C genotype 1 has been on many peoples minds over the past 6 months.

Whilst research shows that Gilead's Harvoni (Sofosbuvir plus Ledipasvir) is the most effective against this Hep C genotype Harvoni only wins this position by a couple of percentage points with other drug combos such as Sofosbuvir + Daclatasvir and Sofosburvir + Simeprevir close behind Harvoni in cure rates.

The big difference has been that Sof+Dac and Sof+Sim have been available in generic form for nearly 6 months whereas Sof+Led (Harvoni) has not been available except as an API.

So a lot of people have chosen to use the Sof+ Daclatasvir or Sof+Simeprevir to treat their G1 infection.

To add to this mix the anticipated release of Indian generic Harvoni, due in December 2015, has appeared threatened from several directions and this has caused some worry amongst people how had decided to wait for generic Harvoni.

Then suddenly there was news of a generic Harvoni available out of Bangladesh. This product, Twinvir, was being manufactured by a well known manufacturer named Incepta. Incepta has a good reputation making and selling generic drugs to Africa.

The question on everyone's lips was "How reliable is this drug?"

Last week a sample of Twinvir was brought to Australia for testing by Dr James Freeman of FixHepC. Using a mass spectrometer the Twinvir sample was compared with a genuine, branded sample of Gilead's Harvoni.

The results was that both samples were identical.

This was good news and certainly insurance against the Indian generic Harvoni being blocked however there were still problems.

Dealing with India can be tricky, even very difficult, for the inexperienced. Bangladesh is India on steroids, it is chaos.

So getting reliable supply lines set up is a challenge to say the least. Then getting effective and reliable shipping systems in place is another challenge. Because of Bangladesh's currency laws even paying for the Twinvir is difficult.

However my friends in India are now in the process of solving these problems and have flown to Bangladesh recently for this purpose.

At this point in time they expect to have reliable supply lines and shipping systems in place by the first week in November for Twinvir and also a generic version of Daclatasvir.

How is Twinvir made?

Bangladesh does not have the capability to actually make the active ingredients, the APIs, used in Harvoni so these are imported in bulk from China, I believe from Mesochem.

Once Incepta has the APIs it is simply a matter of mixing the APIs with an appropriate filler and running

that mix through a tableting machine. A simple process indeed a process that is totally automated using machinery that is common to all pharmaceutical manufacturers around the world.
We already know that Mesochem’s APIs are perfect copies of the branded APIs.
Costs
We still do not know what the exact cost of a 12 week treatment of Twinvir, delivered, will be but expect it to be around the US$1,500 mark

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