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Efficacy of generic Direct Acting Antiviral Treatment for Hepatitis C, imported into Russia and Eastern Europe.

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Introduction:

Prices of branded Direct Acting Antivirals for Hepatitis C (HCV) are very high in Russia and most of Eastern Europe. Sofosbuvir is now registered in Russia but is not available through the government treatment programmes.

A 12-week course of original SOF is offered privately for around $9,500, which is unaffordable for most people. An increasing number of people in this region are treating their HCV infection with generic drugs produced in India, China or Egypt and legally imported.
This analysis assessed the efficacy of these generic DAAs.

Methods:

Generic versions of sofosbuvir (SOF), ledipasvir (LDV) and daclatasvir (DCV) were sourced from generic suppliers in India and Egypt, costing $700 to $900 per treatment course.
The choice of DAAs and length of treatment were determined based on baseline HCV Genotype and stage of fibrosis. Online patient Facebook groups such as the Gepatitka group provided patient support.

Patients taking generic DAAs were evaluated pre-treatment, at week 4 (RVR), at the end of treatment (EOT, typically week 12) and then for SVR 4, 12, and 24.
This analysis includes available data from 213 patients being monitored in hospitals, private doctors and AIDS clinics in Russia, Belarus, Ukraine, Spain, Colombia, Israel and Estonia.

Results:

213 patients were treated; 156 received SOF/DCV, 47 SOF/LDV, and 10 received SOF/RBV. The median length of treatment was 12 weeks.
The SOF, LDV and DCV were mainly from Indian generic companies (see Table 2).
Overall, the patients were 56% male with a mean age of 36.4 years; 41% were Genotype 1 and mean baseline HCV RNA was 6.37 $\log_{10}$ IU/mL.
Rapid virological response (RVR) was observed in 85% (141/165) of the patients (see Table 1 for results by treatment). Based on currently available data, 100% (81/81) reached HCV RNA<LLOQ at the end of treatment (EOT) and 100% (85/85) at SVR 4.

Conclusions:

In this programme, treatment with legally imported generic DAAs achieved high rates of SVR in Russia and Eastern Europe.

The price of a 12 week treatment starts from $435 for SOF/RBV and £495 for SOF/DCV via this treatment access programme, versus over $15,000 if bought commercially.

Mass treatment with generic DAAs is a feasible and economical alternative route of accessing curative DAAs, where the high-prices for branded DAA's prevent access to treatment.

Acknowledgements:

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Table 1: Baseline Characteristics

Patients	SOF/RBV N=10	SOF/DCV N=156	SOF/LDV N=47
% Male	60 %	56 %	53 %
% Cirrhosis	0 %	11 %	13 %
% GT 1	20 %	25 %	100 %
% GT 3	70 %	69 %	0 %
+ RBV	100 %	20 %	23 %

Figure 1: Patients by genotype

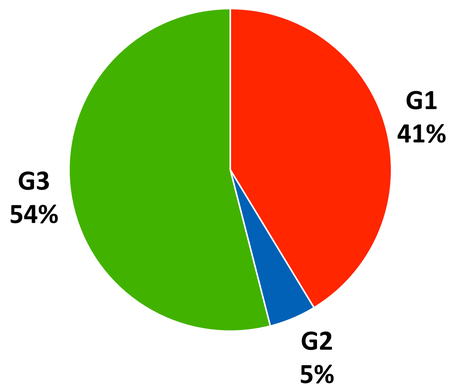

Figure 2: Fibrosis scores of patients

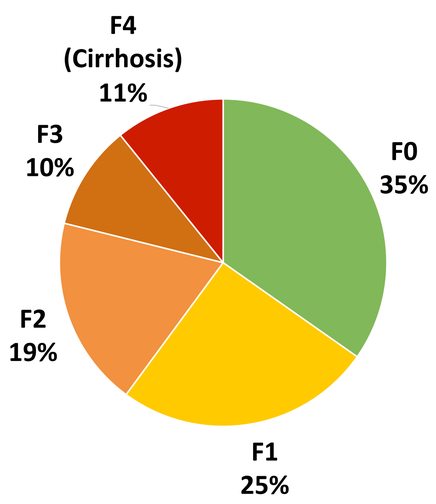

Table 2: Generic manufacturers used

Company	SOF	DCV	LDV
Hetero	119/213 (56%)	87/156 (56%)	31/47 (62%)
Natco	29/213 (14%)	11/156 (7%)	8/47 (16%)
Mylan	16/213 (8%)	2/156 (1%)	0/47 (0%)
Zydus	14/213 (7%)	17/156 (11%)	2/47 (4%)
Strides A.	10/213 (5%)	0/156 (0%)	0/47 (0%)
Marcyrl	7/213 (3%)	5/156 (3%)	1/47 (2%)
Chinese API	0/213 (0%)	25/156 (16%)	1/47 (2%)
Other	12/213 (6%)	8/156 (5%)	4/47 (8%)
No data	6/213(3%)	1/156 (1%)	3/47 (6%)

Figure 3: Generic treatments taken by patients

Pharmed Healthcare | Hetero | Natco | Zydus

Table 3: HCV RNA <25 IU/mL at RVR, EOT and SVR

Patients	SOF/RBV N=10	SOF/DCV N=156	SOF/LDV N=47
RVR	7/8 (88%)	100/120 (83%)	34/37 (92%)
EOT	4/4 (100%)	62/62 (100%)	15/15 (100%)
SVR 4	3/3 (100%)	58/58 (100%)	25/25 (100%)
SVR 12	2/2 (100%)	42/43 (98%)	16/16 (100%)

Figure 4: RVR responses by genotype

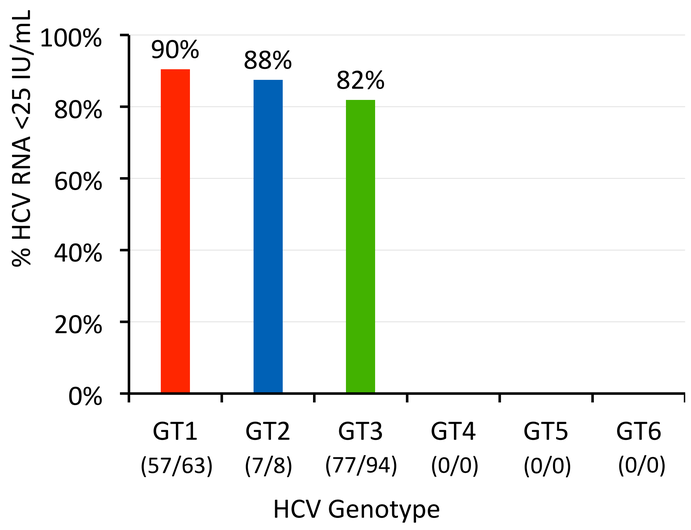

Figure 5: SVR4 responses by genotype

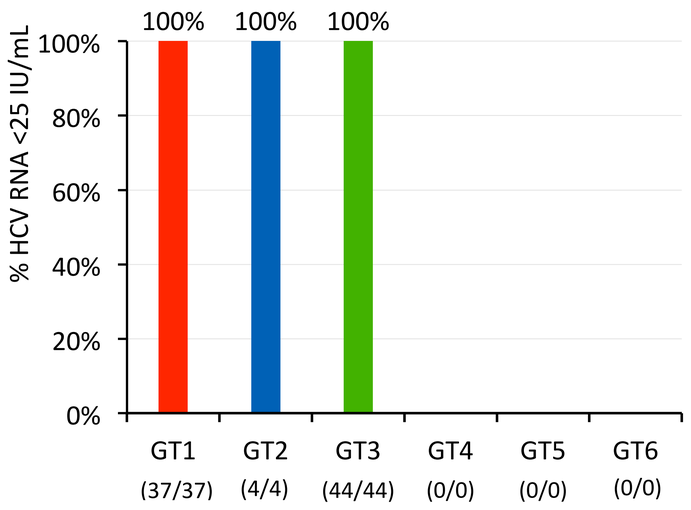

Figure 6: SVR12 responses by genotype

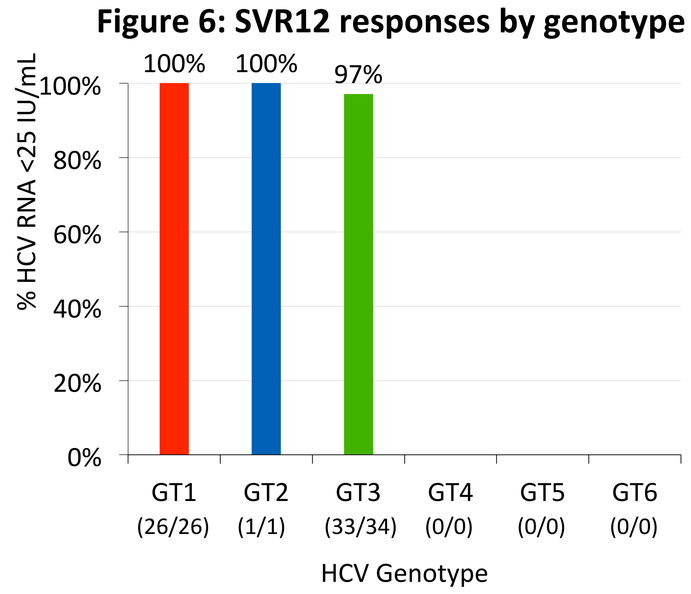

Figure 7: Locations of patients; ITPC EECA, Gepatitka community