

TRAINING MANUAL FOR
TREATMENT ADVOCATES

HEPATITIS C VIRUS
& COINFECTION
WITH HIV

SECTION 10: FIGHTING FOR NEW HCV DRUGS IN THE ERA OF PANGENOTYPIC GENERICS

- Nobody should be treated with older, more toxic medicines now that we have safe and highly effective direct-acting antivirals.
Treatment advocates must fight for affordable, widely available DAAs for everyone infected with hepatitis C!
- DAAs attack different parts of the hepatitis C virus, making it impossible for the virus to reproduce. There are different classes of DAAs, each targeting a specific part of the HCV life cycle.
- Certain DAA regimens are used with RBV (but for a shorter time) —especially in people with cirrhosis.
- Sometimes prescription drug makers will sell older medications at a lower price, making them more accessible than newer and safer treatments in middle-income countries.

- Some of these older medications work only for people with a certain HCV genotype, and they are less effective and have worse side effects than newer treatments.
- This older, cheaper treatment may wind up costing more for people with HCV and health care systems because:
 - People may need to switch their ARVs to avoid prescription drug interactions with DAAs, but certain HIV drugs may not be available everywhere;
 - Several tests are needed, to monitor safety and see whether treatment is working;
 - Multiple medical visits are needed, which could result in losing people to follow up and unnecessary costs to the healthcare system;
 - While DAAs have few side effects, they do still occur for some people, making it difficult for some people to complete treatment; and
 - Treatment duration depends on whether or not someone has an early response.
 - This uncertainty makes it difficult for people who are considering HCV treatment, and for health care providers, who need to put aside sufficient time to provide care.

Tailoring advocacy efforts for DAAs

- HCV treatment advocates have learned lessons from the HIV/AIDS movement and have been pushing for faster, wider, more affordable access to generic DAAs.
- It is important to learn about the local and national epidemics where you are so that you can advocate for the best possible HCV treatments.
 - HCV DAAs can be used with OST, but some cannot be used with certain ARVs—these may be the ones that are available in your country
 - Some DAAs work only against a single genotype; while others work against multiple genotypes or all genotypes. Some regimens are simple—fixed-dose combinations—that require less monitoring during treatment.

Tailoring advocacy efforts for DAAs

- Some countries may not have access to the newer pangenotypic regimens due to intellectual property barriers.
- Originator companies (also referred to as the patent holders) can:
 - Offer ***voluntary licenses***, or an arrangement to permit generic companies to produce or market a medicine in return for royalty payments
 - Choose to exclude countries from their voluntary licenses, so they cannot produce or market the medicines at lower costs
- Only DAAs available through voluntary licensing are daclatasvir and those by Gilead (SOF/LED, SOF/VEL and SOF/VEL/VOX). **Several dozen middle-income** countries have been left out of the license by Gilead.
 - Therefore, countries face enormous prices for SOF/LED, SOF/VEL, and SOF/VEL/VOX.

Tailoring advocacy efforts for DAAs

- National drug regulatory authorities must approve the medicines when they are registered in the country.
- Originator companies often delay registration in countries, and under-resourced regulatory agencies and local clinical trial requirements can delay the time it takes to approve a medicine.
- Advocates can work to speed up registration in their country and push regulatory authorities to approve medicine faster.

Tailoring advocacy efforts for DAAs

- Generic competition often reduces prices dramatically. Ways to expand access to generics:
 - Patent oppositions on certain DAAs or active pharmaceutical ingredients used to produce them
 - Awareness building and pressuring governments to make use of international intellectual property provisions, such as issuing a **compulsory license** on a DAA.
 - A compulsory license enables a government to procure an affordable generic version of a medicine for use in the national health program.
 - Procuring generic DAAs for personal use
 - Hepatitis C buyers' clubs, using vast networks of patients, liver doctors, and activists, and a quality assured supply chain have been created around the world, which enable generics to be imported (under personal importation provisions) at a significantly reduced price than the list price in high-income countries

ADVOCACY EXERCISE

Discussion Questions:

1. What do we know about HCV in our area?
2. What do we need to know about new HCV drugs?
3. Why do you think it is important to get access to DAA treatment?
4. What is the price of DAAs in your country? Do you know the prices in other countries in the region?

Action Steps:

1. How can we create or improve access to the high-quality, generic DAAs that are right for us?
2. Are generic HCV treatments available through buyers' clubs in your country?