Community activists, doctors, researchers, representatives for learned societies, and regulators, concerned about the quality of life of people living with hepatitis C (HCV) and HIV, hereby declare the following:

We welcome individual and public health benefits from interferon-free, direct-acting antiviral (DAA) regimens. DAA drugs have the potential to eradicate hepatitis C. Now that HCV treatment has become highly effective, safe, tolerable and easy to deliver, the primary focus of our work is ensuring that new high standard treatments is accessible and affordable in all countries: and urgently to people in need.

High DAA pricing has made it impossible to provide HCV treatment and plan universal access throughout WHO Europe national health systems. The current prices proposed for DAAs are neither ethical nor justifiable and force limited access, or no access to new HCV treatments. Drug prices should be more closely linked to costs: especially after development costs and reasonable reward for innovation have been met. Even in countries where DAAs are available, they are being rationed: only the sickest people are being treated.

Drug prices should be affordable: we strongly ask the pharmaceutical companies to adopt a pricing policy based on the “high volume, low price” model, which allows national or regional treatment plans granting universal access to cure while still ensuring manufacturing and development costs recoup and reasonable reward for innovation. If drug prices prevent universal access, Governments have the right and the duty to use TRIPS flexibilities, including compulsory licensing, in order to protect the health of their citizens.

We request:

A plan for action The development of, and community representation in, a European Union (EU)-wide Strategic Action Plan on HIV, Viral Hepatitis, Tuberculosis and STIs that will mobilise, support and augment national agencies and systems.

Support from industry Pharmaceutical companies must support compassionate use and other for free access programmes; these must be immediately scaled-up to provide unrestricted access to optimal DAA regimens to people in clinical need. These compassionate use to molecules and combinations without market authorisation, need to be in place until the companies apply for national approval and also until the agreements with national health authorities are in place.

Better standard of care Interferon and first generation protease inhibitors must be eliminated from the standard of care for hepatitis C. Development and use of ribavirin-free regimens should be prioritised and expedited.

Guidelines for clinical care, not reimbursement or rationing Guidelines for HCV screening, diagnosis and management must focus on clinical and public health benefits of treatment, rather than providing a framework for treatment rationing.

Updated guidelines HCV treatment guidelines must be updated to include optimal regimens upon their approval.

Continued treatment development and optimisation Community engagement in the development and optimisation of HCV treatments and formulations must continue. Companies should accelerate development of optimal regimens for paediatric use. Inclusion of people from all marginalised populations in DAA clinical studies including feasibility of new models of treatment delivery must be a high priority.

Real world research Late phase DAA clinical studies should be conducted in real-life populations, including people who inject drugs. Studies of older HCV treatment report similar adherence and treatment outcomes among people who inject drugs and non-users. Without an evidence base to support treatment in the highest-prevalence population, treatment will continue to be unjustifiably withheld from drug-users.

Prisons Governments and health and justice authorities need to provide access to the right to voluntary testing, best prevention and treatment for hepatitis C in prisons.

National community representation The community must be represented and participate on the boards of national competent authorities in Europe, whose remit it is to determine pricing and indications.

Governments must play a role Governments across WHO Europe – along with pharmaceutical industry – must prioritise access to the best, most effective HCV treatments at an affordable price through their public health systems in view of elimination in 15 years.
The EU must play a role

The EU must ensure affordable access to the best most effective HCV DAAs in all member state countries and not impede access to WHO Europe nations outside the EU enforcing trade agreement that harm access to health.

Treatment is available where it is needed most

A new strategy must be implemented to provide widespread access to optimal DAA regimens in middle-income countries where the majority of people with HCV live.

Transparent registration timelines

Total transparency and regular updates with timelines for DAA registration and licensing is essential. This includes transparency in regulatory and pricing negotiation between stakeholders.

Simple, affordable diagnostic tests

The development of affordable, rapid, reliable and accurate point of care HCV diagnostics – that can be used in all settings – must be prioritised and expedited.

Ukraine

Ukraine is facing terrible problems including a huge health crisis, namely on HIV, hepatitis and TB where prevalence and incidence are among the highest in Europe. Ukraine needs voluntary licensing agreements with no royalties. Like Eastern Europe, Central Asia and South Caucasus countries such as Belarus, Moldova and Georgia, the Ukraine also needs substantial health aid by the EU and US to save the national health system.

Notes:

The European AIDS Treatment Group, having been involved in hepatitis C advocacy for over 7 years, holds an international workshop on viral hepatitis, bringing together multiple stakeholders to discuss the continuing efforts to eradicate hepatitis C. The seventh international workshop on viral hepatitis, held in Sitges, Barcelona, Spain - aka “Sitges VII” focused on access to treatment and care for people living with hepatitis C, whether living with hepatitis C alone or living with HIV co-infection. Community delegates and their allies met with representatives of pharmaceutical industry between Friday 3rd through Sunday 5th of October 2014. The Sitges VII Declaration was outlined by consensus during the meeting by members of the community of people living with hepatitis C and their allies, and further developed following a wider internal EATG consultation.