# Community Pharmacy Supply Of Hepatitis C Treatments

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1. Introduction To Hepatitis C Infection

Chronic hepatitis C constitutes a major global health concern as it is a leading cause of chronic liver disease, cirrhosis and hepatocellular carcinoma. The goal of therapy is to prevent these complications through viral eradication.

The hepatitis C virus (HCV) was first identified in 1989 and HCV infection has become a major health problem worldwide. Approximately 0.8% of the Scottish population is thought to be chronically infected with HCV (around 37,500 individuals). The prevalence of infection varies between population groups ranging from 50% in injecting drug users (IDU) to less than 0.04% among new blood donors.

Up to 80% of patients infected with HCV become chronically infected and most of these patients will show evidence of chronic hepatitis.

Hepatitis C is usually slowly progressive over a period of many years. Five to fifteen per cent of patients with chronic hepatitis may progress to liver cirrhosis over 20 years. Four to nine per cent of patients with cirrhosis will develop liver failure; and two to five per cent of patients with cirrhosis will develop primary hepatocellular carcinoma.

In the UK the two major routes of transmission of HCV have been sharing of drug injecting equipment by IDU and transfusion of infected blood or blood products. Virus inactivation treatment of blood products began in 1987 and since 1991 blood donations have been screened for hepatitis C, eliminating blood products as a source of HCV infection.

HCV is characterised by genotypes and subgroups with prevalence varying depending on the geographical location. Currently, throughout the world, there are 11 recognised hepatitis C genotypes. The most common genotypes in Scotland are genotype 1, 2 and 3. HCV genotype 1 and particularly subgroup b, does not respond to therapy as well as genotypes 2 and 3.

Within a region, a specific genotype may also be associated with a specific mode of transmission, such as genotype 3 among persons in Scotland who abuse intravenous drugs.

2. Treating Hepatitis C

Treatment of chronic HCV infection has two goals. The first is to clear the infection, achieving sustained eradication of HCV (i.e. sustained virologic response [SVR]), which is defined as the persistent absence of HCV RNA in serum 3 months or more after completing antiviral treatment. The second goal is to prevent progression to cirrhosis,
hepatocellular carcinoma (HCC), and decompensated liver disease requiring liver transplantation.

Response rates to treatment are dictated by genotype, treatment history and patient specifics such as age, gender and other infections present, e.g. hepatitis B virus or HIV. The stage of liver disease is also an important predictor of viral response. Traditionally, those with advanced fibrosis or cirrhosis achieve lower treatment response rates. Antiviral therapy for chronic hepatitis C should be determined on a case-by-case basis. However, treatment is generally recommended for patients who meet the following criteria:

- Age greater than 18 years.
- Positive HCV antibody and serum HCV RNA test results.
- Willingness to be treated and to adhere to treatment requirements.
- No contraindications for treatment.

The treatment of hepatitis C has evolved over the years. Until recently, HCV infection could be effectively treated with combination drug therapy (peginterferon alfa, ribavirin and directly acting antivirals) with SVR rates in 50-80% of patients. Since 2014, there have been several new oral direct acting antivirals (DAAs) licensed that are expected to provide SVR rates of greater than 90% with improved tolerability and reduced durations of treatment. Further treatments are in development and expected to be licensed in 2015 and 2016. DAAs are medications targeted at inhibiting viral proteins involved in the HCV life cycle. They target specific non-structural proteins of the virus and results in disruption of viral replication and infection. There are four classes of DAAs, which are defined by their mechanism of action and therapeutic target. The four classes are non-structural proteins 3/4A (NS3/4A) protease inhibitors (PIs), NS5B nucleoside polymerase inhibitors (NPIs), NS5B non-nucleoside polymerase inhibitors (NNPIs) and NS5A inhibitors.

2.1. Peginterferon alfa-2b (ViraferonPeg®)

Peginterferon alfa-2b consists of IFN alfa-2b attached to a single 12-kd PEG chain. It is excreted by the kidneys. Peginterferon alfa-2b has sustained absorption, a slower rate of clearance, and a longer half-life than unmodified interferon, which permits more convenient once-weekly dosing and significantly improves quality of life for patients.

The adult dose is 1.5 micrograms/kg by subcutaneous injection once weekly.

Adverse effects include the following:

- Haematological complications (i.e. neutropenia, thrombocytopenia).
- Neuropsychiatric complications (i.e. memory and concentration disturbances, visual disturbances, headaches, depression, irritability).
- Flu-like symptoms.
- Metabolic complications (i.e. hypothyroidism, hyperthyroidism, low-grade fever).
• Gastrointestinal complications (i.e. nausea, vomiting, weight loss).
• Dermatologic complications (i.e. alopecia).
• Pulmonary complications (i.e. interstitial pneumonitis).

2.2. Peginterferon alfa-2a (Pegasys®)

Peginterferon alfa-2a consists of IFN alfa-2a attached to a 40-kd branched PEG molecule. Peginterferon alfa-2a has sustained absorption, a slower rate of clearance, and a longer half-life than unmodified interferon, which permits more convenient once-weekly dosing and significantly improves quality of life for patients.

The adult dosage is 180 micrograms by subcutaneous injection once weekly.

Adverse effects include the following:

• Haematological complications (i.e. neutropenia, thrombocytopenia).
• Neuropsychiatric complications (i.e. memory and concentration disturbances, visual disturbances, headaches, depression, irritability).
• Flu-like symptoms.
• Metabolic complications (i.e. hypothyroidism, hyperthyroidism, low-grade fever).
• Gastrointestinal complications (i.e. nausea, vomiting, weight loss).
• Dermatologic complications (i.e. alopecia).
• Pulmonary complications (i.e. interstitial pneumonitis).

2.3. Ribavirin (Rebetol®, Copegus®)

Ribavirin is an antiviral nucleoside analogue. Given alone, ribavirin has little effect on the course of hepatitis C. Given with Peginterferon, it significantly augments the rate of sustained virologic response.

The dose of ribavirin is based on patient body weight, viral genotype, renal function and the peginterferon product that is used in combination. The daily dose varies between 800-1400mg daily. Ribavirin is administered orally in two divided doses with food (morning and evening). Due to the teratogenic potential of ribavirin, the tablets or capsules should not be broken, crushed or opened. Women of childbearing potential or their male partners must use two effective forms of contraception during the treatment and for a period of time after the treatment.

Adverse effects of ribavirin include the following:

• Haematologic complications (i.e. haemolytic anemia).
• Reproductive complications (i.e. birth defects).
• Metabolic complications (i.e. gout).
2.4. **Simeprevir (Olysio®)**

Simeprevir is a NS3/4A protease inhibitor. It is considered as a second generation HCV protease inhibitor because of the enhanced binding affinity and specificity to NS3/4A when compared with the first-generation protease inhibitors with linear structure.

Simeprevir is a NS3/4A protease inhibitor, thus preventing viral maturation through inhibition of protein synthesis.

### 2.4.1. Prescribing information

Simeprevir is indicated for treatment of genotype 1 and 4 chronic hepatitis C infection as a component of a combination antiviral regimen. Simeprevir efficacy in combination with peginterferon alfa and ribavirin is substantially reduced in patients infected with hepatitis C genotype 1a with the NS3 Q80K polymorphism at baseline.

In all patients, treatment with simeprevir should be initiated in combination with peginterferon alfa and ribavirin.

- Simeprevir 150mg once daily in combination with peginterferon alfa and ribavirin for 12 weeks then followed by an additional 12 -36 weeks of peginterferon alfa and ribavirin.

Simeprevir must not be used as monotherapy; if peginterferon alfa or ribavirin is discontinued for any reason, simeprevir must also be discontinued. To prevent treatment failure, the dose of simeprevir must not be reduced or interrupted.

Patients will have their virological response checked at week 4, 12 and 24 of treatment. Based on this result patients will either continue or stop treatment.

### 2.4.2. Administration

Patients should be instructed to swallow the capsule with food. If a dose of simeprevir is missed, and the patient notices within 12 hours of the usual dosing time, the patient should take the missed dose with food as soon as possible and then take the next dose at the regularly scheduled time. If a dose of simeprevir is missed by more than 12 hours after the usual dosing time, the patient should not take the missed dose and should resume dosing with food at the regularly scheduled time.

### 2.4.3. Adverse effects

Simeprevir appears to be safe with relatively few adverse side effects. The most common adverse effects reported are nausea, rash, pruritus, dyspnoea, blood bilirubin increase and photosensitivity reactions.

Photosensitivity reactions have been observed with simeprevir in combination with peginterferon alfa and ribavirin, including serious reactions which resulted in
hospitalisation. Photosensitivity reactions occurred most frequently in the first 4 weeks of treatment but can occur at any time during treatment. Photosensitivity may present as an exaggerated sunburn reaction, usually affecting areas exposed to light (typically the face, “V” area of the neck, extensor surfaces of the forearms, and dorsa of the hands). Manifestations may include burning, erythema, exudation, blistering, and oedema. Patients should be instructed to use sun protective measures, limit sun exposure during and avoid tanning devices during treatment with simeprevir.

2.4.4. Interaction with other medicinal products

Co-administration of simeprevir with substances that moderately or strongly induce or inhibit cytochrome P450 3A (CYP3A4) is not recommended as this may lead to significantly lower or higher exposure of simeprevir, respectively. Co-administration of simeprevir with medicinal products that are substrates for OATP1B1 and P-gp transport may result in increased plasma concentrations of such medicinal products.


2.4.5. Pregnancy and concomitant use with ribavirin

When simeprevir is used in combination with peginterferon alfa and ribavirin, women of childbearing potential or their male partners must use two effective forms of contraception during the treatment and for a period of time after the treatment as recommended in the Summary of Product Characteristics for ribavirin.

2.5. Sofosbuvir (Sovaldi®)

Sofosbuvir is an HCV-specific uridine nucleotide prodrug that blocks replication of HCV by inhibiting the HCV NS5B polymerase and terminating the generation of HCV RNA chains.

2.5.1. Prescribing Information

Sofosbuvir is indicated for treatment of chronic hepatitis C infection as a component of a combination antiviral regimen. The treatment regimen and duration are dependent on both viral genotype and patient population

- Genotype 1 or 4:

Sofosbuvir 400mg once daily plus ribavirin and peginterferon alfa for 12 weeks; may consider sofosbuvir plus ribavirin for 24 weeks in genotype 1 patients ineligible to receive peg-interferon-based regimen.

- Genotype 2

Sofosbuvir 400mg once daily plus ribavirin for 12 weeks.
• Genotype 3

Sofosbuvir 400mg daily plus peginterferon alfa and ribavirin for 12 weeks, may consider sofosbuvir plus ribavirin for 24 weeks in patients ineligible to receive peg-interferon-based regime.

Sofosbuvir must not be used as monotherapy, if peginterferon alfa or ribavirin is discontinued for any reason, sofosbuvir must also be discontinued.

2.5.2. Administration

The film-coated tablet is for oral use. Patients should be instructed to swallow the tablet whole. The film-coated tablet should not be chewed or crushed, due to the bitter taste of the active substance. The tablet should be taken with food if possible although efficacy on an empty stomach is not affected to any clinically significant extent (as per Sovaldi SPC, Gilead March 2015).

Patients should be instructed that if vomiting occurs within 2 hours of dosing an additional tablet should be taken. If vomiting occurs more than 2 hours after dosing, no further dose is needed. These recommendations are based on the absorption kinetics suggesting that the majority of the dose is absorbed within 2 hours after dosing.

If a dose is missed and it is within 18 hours of the normal time, patients should be instructed to take the tablet as soon as possible and then patients should take the next dose at the usual time. If it is after 18 hours then patients should be instructed to wait and take the next dose at the usual time. Patients should not be instructed to take a double dose.

2.5.3. Adverse effects

Sofosbuvir has mainly been studied in combination with ribavirin, with or without peginterferon alfa. In this context, no adverse drug reactions specific to sofosbuvir have been identified. The most common adverse drug reactions were fatigue, headache, nausea and insomnia.

2.5.4. Effects on ability to drive and use machines

Sofosbuvir has moderate influence on the ability to drive and use machines. Patients should be informed that fatigue and disturbance in attention, dizziness and blurred vision have been reported during treatment with sofosbuvir in combination with peginterferon alfa and ribavirin.

2.5.5. Interaction with other medicinal products

Sofosbuvir is a substrate of both drug transporters P-gp and BCRP, therefore medicinal products which are potent inducers of these pathways have the potential to effect sofosbuvir metabolism and reduce its therapeutic effect. Although interactions have not
been directly studied, co-administration with the analeptic modafinil, with certain anticonvulsants (e.g. carbamazepine, phenytoin, phenobarbital, oxcarbazepine), with some antimycobacterials (e.g. rifabutin, rifampin, rifapentine) or with St John's Wort, all potent inducers of P-gp, is expected to decrease the concentration of sofosbuvir leading to reduced therapeutic effect. Sofosbuvir should not be used with such products.

Consult [www.hep-druginteractions.org](http://www.hep-druginteractions.org) and Sovaldi® Summary of Product Characteristics for further information for safety of concomitant meds.

2.5.6. Pregnancy and concomitant use with ribavirin

When Sofosbuvir is used in combination with ribavirin or peginterferon alfa/ribavirin, women of childbearing potential or their male partners must use two effective forms of contraception during the treatment and for a period of time after the treatment as recommended in the Summary of Product Characteristics for ribavirin.

2.6. Sofosbuvir and Ledipasvir (Harvoni®)

Harvoni® is a fixed dose oral combination treatment combining sofosbuvir 400mg and ledipasvir 90mg.

Ledipasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. Sofosbuvir is an HCV-specific uridine nucleotide prodrug that blocks replication of HCV by inhibiting the HCV NS5B polymerase and terminating the generation of HCV RNA chains.

2.6.1. Prescribing Information

Harvoni® is indicated for treatment of chronic hepatitis C infection as monotherapy or with ribavirin. The treatment regimen and duration are dependent on both viral genotype and patient population.

- **Genotype 1 or 4 treatment naïve:**
  
  Harvoni® ONE tablet daily for 8 – 12 weeks. Ribavirin may be added if presence of cirrhosis or poor prognostic factors.

- **Genotype 1 or 4 treatment experienced:**
  
  Harvoni® ONE tablet daily with ribavirin for 12 weeks.

- **Genotype 3:**
  
  Harvoni® ONE tablet daily with ribavirin for 12 – 24 weeks. Ribavirin may be added if presence of cirrhosis or poor prognostic factors.
2.6.2. Administration

The film coated tablet is for oral use. Patients should be instructed to swallow the tablet whole with or without food. Due to the bitter taste, it is recommended that the film-coated tablet is not chewed or crushed.

Patients should be instructed that if vomiting occurs within 5 hours of dosing an additional tablet should be taken. If vomiting occurs more than 5 hours after dosing, no further dose is needed. If a dose is missed and it is within 18 hours of the normal time, patients should be instructed to take the tablet as soon as possible and then patients should take the next dose at the usual time. If it is after 18 hours then patients should be instructed to wait and take the next dose at the usual time. Patients should be instructed not to take a double dose.

2.6.3. Adverse effects

In clinical studies, fatigue and headache were more common in patients treated with ledipasvir/sofosbuvir compared to placebo. When ledipasvir/sofosbuvir was studied with ribavirin, the most frequent adverse drug reactions to ledipasvir/sofosbuvir and ribavirin combination therapy were consistent with the known safety profile of ribavirin, without increasing the frequency or severity of the expected adverse drug reactions.

2.6.4. Interaction with other medicinal products

Ledipasvir and sofosbuvir are substrates of drug transporter P-gp and BCRP. Medicinal products that are potent P-gp inducers (e.g. rifampicin, St. John's Wort, carbamazepine and phenytoin) may decrease ledipasvir and sofosbuvir plasma concentrations leading to reduced therapeutic effect of ledipasvir/sofosbuvir and should not be used with Harvoni®.

Co-administration of omeprazole with ledipasvir/sofosbuvir can decrease the concentration of ledipasvir due to gastric acid suppression. It is recommended that proton pump inhibitors or H2 receptor-antagonists should not be taken before ledipasvir/sofosbuvir. They should be administered at the same time as ledipasvir/sofosbuvir. Antacids should not be taken with 4 hours of Harvoni. See the Summary of Product Characteristics for Harvoni® for further information. Consult www.hep-druginteractions.org and Harvoni® Summary of Product Characteristics for further information for safety of concomitant meds.

2.6.5. Pregnancy and concomitant use with ribavirin

When ledipasvir/sofosbuvir is used in combination with ribavirin, extreme care must be taken to avoid pregnancy in female patients and in female partners of male patients. Women of childbearing potential or their male partners must use two effective form of contraception during treatment and for a period of time after the treatment has concluded as recommended in the Summary of Product Characteristics for ribavirin.
3. Supply Of Hepatitis C Medication In NHSG

NHSG has a commitment to deliver on the Scottish Government’s policy initiative “Shifting the Balance of Care”. The policy guidelines require improvements to health and social care services that improve the health and well-being of the population. In particular, changes are required so that the work of secondary care and primary care becomes more integrated and that care becomes located around community-based services. The development of new medicines, like those for HCV, has meant that many treatments have become available that transform previously fatal or debilitating diseases into conditions that a patient may manage successfully for many years. Realising the investment in the patient’s health requires that health services commit to normalising the patient’s experience of care as much as possible, through integration with standard primary-care services. To achieve these aims for patients with HCV in Grampian the hospital Hepatology team will identify patients that they consider may be suitable to receive their HCV medicines in primary care.

Following a diagnosis of chronic hepatitis C, all patients will attend an assessment review with a member of the hospital Hepatology team. At this review the patient will undergo any necessary investigations and appropriate baseline monitoring. The individual treatment options available will be discussed along with health promotion and counselling regarding training on the administration of medication and monitoring requirements. An assessment of the patient for suitability of supplying medication from primary care will also be made and the patient will be requested to nominate a community pharmacy of their choice.

The patient may be discussed at the Hepatology multidisciplinary team (MDT) meeting to assess the most appropriate DAA to achieve clearance of the hepatitis C virus if they are out with the NHSG HCV treatment guidelines. If the most appropriate treatment regimen contains ribavirin and or pegylated Interferon alfa, this will be dispensed by the pharmacy department at ARI and the patient will collect monthly supplies while attending routine review appointments with the Hepatology team. The DAA will be dispensed by the patients nominated community pharmacy.

3.1. Community Pharmacy dispensing of Hepatitis C medication

The Hospital Pharmacy Team will contact the patients nominated community pharmacy to discuss the planned future supply arrangements and confirm that the community pharmacist is in agreement to dispense the medication. Patient specific information, treatment duration, requirement for supervision and installment dispensing and guidance to enable the community pharmacist to provide pharmaceutical care to the patient will be discussed. The Hospital Pharmacy Team will email the community pharmacy a completed patient transfer form (Appendix 1) and procurement information.

The Hepatology team will prescribe the hepatitis C medications on a HBP5 prescription on a monthly basis. The initial prescription will be posted a minimum of 14 days prior to initiation of treatment to allow the community pharmacy adequate time to obtain supplies of the medication. Subsequent prescriptions will be posted monthly to the community
pharmacy to ensure continuous treatment of the patient. DAAs are high cost items and contractors can receive an initial advanced payment to support procurement costs. The Hepatology team will contact the community pharmacy if the patient’s treatment is to discontinue early or if there is to be a break in treatment.

The community pharmacist will retain a dispensing record and maintain a running stock balance of the medication. The community pharmacist will provide appropriate pharmaceutical care to the patient and contact a member of the Hepatology team if they identify any relevant clinical issues or have any concerns regarding compliance. The community pharmacist will complete and email a monthly compliance reporting form (Appendix 2) to the Hepatology Pharmacy Team at the end of each monthly prescription.

The NHS Grampian Pharmaceutical Care of Patients Receiving Treatment for Hepatitis C Service Specification contains detailed information regarding the service outline and necessary involvement from the community pharmacy and hospital pharmacy team.

3.2. Responsibilities

The Hospital Hepatology Team Will:

- Assess suitability for patient to initiate treatment.
- Assess suitability for the patient to receive their medication from a community pharmacy.
- Assess the need for instalment dispensing or supervision of administration of medication at community pharmacy.
- Inform the patient’s GP that treatment is being initiated.
- Discuss health promotion including the importance of abstaining from alcohol /illicit drugs and counselling on treatment.
- Provide the patient with information related to potential adverse effects of treatment and when to contact the Hospital Hepatology Team.
- Ensure that the patient is aware of the need to comply with treatment and attend review appointments.
- Ensure that the patient knows what to do if they miss a dose or vomit after taking a dose.
- Ensure that the patient is aware that any newly prescribed or OTC medicines may interact with their medications and this should be discussed with the Hospital Hepatology Team prior to starting any new medicines.
- Ensure the patient is aware that women of childbearing potential or their male partners must use two effective forms of contraception during treatment and for a period of time after the treatment has concluded.
- Provide the patient with information detailing the required monitoring schedule and review appointments in verbal and written form.
- Train the patient/carer on the administration of treatment.
- Review the patient at the out-patient clinic to monitor compliance, response to treatment and adverse effects.
• Ensure relevant clinical information is communicated to the patients nominated community pharmacist including transfer form and a copy of the patients monitoring and review schedule at the out-patient clinic.
• Generate monthly prescriptions for treatment and send to the patient’s nominated community pharmacy.
• Ensure dose modifications are communicated to the community pharmacy, including discontinuation of therapy.
• At any stage of treatment, advise the community pharmacy of concerns regarding monitoring or potential adverse effects of treatment.
• Report any adverse drug reactions to the Committee on Safety of Medicines.

The Community Pharmacist Will:

• Provide appropriate pharmaceutical care to patients prescribed treatment for HCV.
• Complete the appropriate patient care record (PCR) for the patient detailing the agreed course/s of action, counselling and advice needs and any requirements for follow up or referral.
• Ensure that the patient is aware of the need to comply with treatment and attend review appointments.
• Ensure that the patient knows what to do if they miss a dose or vomit after taking a dose.
• Contact the patient’s named Hepatology specialist nurse in the Hospital Hepatology team if the patient fails to turn up for their initial prescription following notification by the specialist service.
• Dispense treatment to patients who have nominated them as their community pharmacy in a timely manner.
• Ensure the patient has been issued with relevant patient information leaflets.
• Retain a dispensing record, record any missed doses and maintain a running stock balance of the medication for each patient.
• Contact the Hospital Hepatology Team if the patient does not collect their medicines on a regular basis and report missed doses. If the patient fails to collect or present for daily supervision on two consecutives days please urgently contact the patient’s named Hepatology nurse.
• Complete, and e-mail, a compliance reporting form to the Hepatology Pharmacy Team on the last installment day of each monthly prescription.
• Contact the patients named Hepatology nurse if any concerns regarding the patient.
• Contact the patients named Hepatology nurse if the patient expresses any concerns that the community pharmacy is unable to address or the pharmacist identifies any reason why the next supply should not be made.
• Contact the Hepatology Pharmacy Team if no further HBP5 prescription has been received in the post and the next due date of supply is imminent.
• Contact the Hepatology Pharmacy Team if there is a potential supply issue with the medicine.
The Patient Will:

• Nominate a community pharmacy of their choice to receive their prescription and issue their medication.
• Agree to comply with treatment and attend for routine out-patient review and blood monitoring.
• Report any adverse drug reactions to the community pharmacist and/or Hospital Hepatology Team.
• Agree to inform community pharmacist and /or Hospital Hepatology Team of any OTC or new medications prescribed to ensure that there are no interactions.

3.3. Procurement

Harvoni® and sofosbuvir are supplied by Alcura UK Ltd in their role as a medicine wholesaler. The community pharmacy will order the medicine from Alcura UK Ltd by completing and faxing the attached order form (Appendix 3). The prescription number will require to be added to the order form prior to faxing the order.

Simeprevir is supplied directly from Janssen-Cilag Ltd. The community pharmacy will order the medicine directly from Janssen-Cilag Ltd by contacting their customer services.

4. Hepatology Team Contact Details

4.1. Hepatology specialist nurses

• For urgent information telephone information ;
  - Shona Allan 01224 551398
  - Lorna Bailey 01224 554931
  - Louise Cobb 01224 559624
  - Pauline Dundas 01224 559632
  - Emma Grieve 01224 559630
  - Rachel Thomson 01224 559623

• For non-urgent email information: 
  grampian.livernurses@nhs.net

4.2. Hepatology Pharmacy Team

• For urgent information telephone information:
  Lynne Crighton 01224 559348

• For non-urgent email information: 
  grampian.hepatologypharmacyteam@nhs.net
## Appendix 1 – Patient Transfer Form

<table>
<thead>
<tr>
<th>Patient name</th>
<th>CHI number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient address</td>
<td>Relevant past medical history &amp; medications</td>
</tr>
<tr>
<td>Patient contact telephone number(s)</td>
<td>HCV Genotype</td>
</tr>
<tr>
<td>Patient e-mail address</td>
<td>Cirrhosis Y/N</td>
</tr>
<tr>
<td>Nominated community pharmacy</td>
<td>Treatment experienced or naïve</td>
</tr>
<tr>
<td>Pharmacy e-mail address</td>
<td>Patients General Practitioner</td>
</tr>
<tr>
<td>Treatment choice, regimen &amp; duration</td>
<td>Administration/supply:</td>
</tr>
<tr>
<td>Date treatment to commence</td>
<td>Weekly dispensed only</td>
</tr>
<tr>
<td></td>
<td>Daily consume on premises</td>
</tr>
<tr>
<td></td>
<td>Other please specify</td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
<tr>
<td>Transfer form completed by (Print name)</td>
<td>Date sent to pharmacy:</td>
</tr>
<tr>
<td>Patient consent</td>
<td></td>
</tr>
</tbody>
</table>

I ____________________________ consent to receiving my supplies of medication from my nominated community pharmacy as specified above and for the transfer of clinical information necessary to the management of my care.

Patient Signature _____________________________ Date _______________________

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NHS GRAMPIAN - Community Pharmacy Supply Of Hepatitis C Treatments - Pharmaceutical Care Information Pack
NHS Grampian Hepatology Team - April 2015
### Appendix 2 – Compliance Reporting Form

#### NHS Grampian
Community Pharmacy Patient Compliance Reporting Form for Hepatitis C Therapy

<table>
<thead>
<tr>
<th>Community Pharmacy Details (Stamp may be used)</th>
<th>Patient details:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHI______________</td>
</tr>
<tr>
<td></td>
<td>Date treatment commenced: __________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Treatment month number</th>
</tr>
</thead>
<tbody>
<tr>
<td>----------/----/-------</td>
<td>____________________________</td>
</tr>
</tbody>
</table>

**Administration/supply:**

- Weekly dispensed only [ ]
- Daily consume on premises [ ]
- Other

**Comments.**

This patient has collected their medicine at the expected times over the past month  Yes / No*

If no, please provide further details

*please circle as appropriate

**Pharmacist declaration.**

I ____________________________ confirm that the information provided for the patient with the above CHI number are correct.

<table>
<thead>
<tr>
<th>Pharmacist Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>____________________</td>
<td></td>
</tr>
</tbody>
</table>

Please complete a form, for each patient, for every month of treatment.

Please e-mail to:---------------------------------------------------------------

Or

Fax to:---------------------------------------------------------------
Appendix 3 – Procurement Form

Request for supply of Sovaldi® (sofosbuvir) or Harvoni® (ledipasvir and sofosbuvir) for the purpose of dispensing by Community Pharmacy to NHS Scotland patients
Faxback on 01420 89594 or e-mail to chlorders@alcura-health.co.uk

To Alcura UK Ltd
Please supply Sovaldi (sofosbuvir) / Harvoni (ledipasvir and sofosbuvir) tablets for the purpose of dispensing to patients presenting to community pharmacy with an NHS Scotland prescription.

1. Pharmacy Details
   * Alcura UK Ltd account number
   * Pharmacy Name
   * Address:
   * Telephone number:
   * Email address:

2. Prescription details
   * Sovaldi (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir) are only supplied to community pharmacies in Scotland in response to the receipt of valid NHS Scotland prescriptions specifying these medicines. The unique prescription number must be referenced to place an order for this product and volumes will be audited against prescriptions issued.
   * Prescription Number (11 digits)
   * Number of boxes of Sovaldi (28 tablets) @ (£11,660.98 per box)
   * Number of boxes of Harvoni (28 tablets) @ (£12,993.33 per box)

3. Pharmacist Declaration
   * I declare that the information I have given on this form is correct and complete. I understand that, if it is not, appropriate legal action may be taken. To enable the Common Services Agency to confirm the amount of products supplied to patients and for the purposes of prevention, detection, and investigation of crime, I consent to the disclosure of relevant information from this form including to and by NHS Scotland Practitioner & Counter Fraud Services. This declaration is made on behalf of the responsible pharmacist detailed below and the Community Pharmacy NHS Contractor

4. Signed confirmed by the responsible pharmacist
   * Full Name* (block capitals)
   * Signature*
   * Date*
   * GPhC Pharmacist registration number*
   * NHS Pharmacy contractor number*

*All sections to be fully completed - please telephone Alcura in the first instance if wishing to open a new account

Alcura UK Ltd, Selbourne House, Mill Lane, Alton, Hampshire, GU34 2GJ
Tel: 01420 540 605
Fax: 01420 89594, Email: chlorders@alcura-health.co.uk
www.alcura-health.co.uk

Alcura is a member of Alliance Boots