# GENERAL GUIDANCE

## About the SMC

The Scottish Medicines Consortium (SMC) is responsible for providing advice to the NHS in Scotland about the use of new medicines, including the value of each new medicine and the patients for whom these would be of most benefit.

In doing so, it undertakes an assessment of clinical and economic information provided by the pharmaceutical company introducing the medicine. It takes account of the assessments undertaken by its own pharmacists and health economists, contacts clinical experts for their views and receives submissions from groups which represent the views of patients, their carers and families.

## Patient Interest Group Submissions

The advice of the SMC can have a significant impact on the lives of people across Scotland. The advice can also have a significant NHS budgetary impact. The overall rigour of the assessment process reflects the importance of the task assigned to the SMC**, and information from patients, carers and their families as to the effects of their illness or condition on their lives and the difference the new medicine could make, is essential.**

The SMC does not accept submissions from individuals. In specifying that information should come from organisations which represent patients, carers and families, it is attempting to get as broad a picture as possible of

- the way people are affected by the disease or condition the new medicine is designed to address;
- patient/carer views on the treatments and medicines that patients currently receive, including the advantages and disadvantages of different medicines, preferences (and the reasons for those preferences) and needs that are met or unmet; and
- the likely impact of the new medicine on the lives of patients and carers, including what the advantages and disadvantages might be and what unmet needs the new medicine might alleviate.

The SMC recognises that it is asking for a considerable commitment of time and effort from organisations to undertake this task but it is one that can

make a very worthwhile contribution to the issues which face us all in the availability of new medicines across Scotland.

The template has been prepared with a view to helping organisations focus on the information that is most useful to the assessment process. It is hoped that it will help make the best possible representation of the evidence from patients, carers and their families. For this reason, and to ensure consistency of approach, **submissions of evidence to the SMC must be made on the Patient Interest Group Submission Template.**

## Information about Patient Interest Organisations

The SMC needs to ensure the integrity of its assessment process and that it is receiving information from knowledgeable, reliable and unbiased sources that can appropriately reflect the experience of patients, carers and their families in Scotland. It therefore requests information about

- the nature of the organisations/groups which are making the submissions,
- aspect of their operation which may influence their comments and
- the way that the organisations/groups ensure they reflect the experience of people in Scotland.

**Organisations/groups making a submission for the first time are asked to submit a copy of their governing document e.g. a constitution, a Memorandum of Articles, a trust deed.** Unincorporated organisations must still provide a written governing document to demonstrate that they operate under a set of rules and that there are at least three people on the governing body or management committee who are not related to each other.

The Patient Interest Group Submission template also asks for declaration of interests:

- a note of interested parties who are represented on the governing body of the organisation
- any funding received from pharmaceutical companies in the last 2 years, as well.
- any interests relating to the individuals responsible for drawing up the Patient Interest Group submission.

It is essential that the submitting organisation is able to demonstrate that they are reflecting the experience of patients, carers and their families in Scotland/UK– this is to ensure that the submission reflects current practice in

Scotland/UK in dealing with a condition or illness and the gaps or unmet needs which exist here. **If you are unable to demonstrate that your evidence reflects this, it may not be considered as part of the assessment process.**

## The SMC Process

The SMC normally meets on the first Tuesday of each month. A list of the SMC members can be found on the SMC website: **www.scottishmedicines.org.uk**. The assessment process for each new medicine is as follows:-

Application for assessment is made by the pharmaceutical company. In doing this, the company provides SMC with epidemiological, clinical, economic and research data (the template for manufacturers can be viewed on the SMC website)

The economic, clinical and pharmaceutical data are reviewed by the scientific sub-committee of the SMC, called the New Drugs Committee (NDC), which includes pharmacists, clinicians and economists. Following assessment of the data, NDC provides a draft Detailed Advice Document (DAD) for presentation to the SMC. The pharmaceutical company is also invited to submit comments on the draft and may be asked for further information at this stage.

The SMC considers the draft DAD and any further clarification provided by the company, responses from clinical experts and Patient Interest Group submissions and issues advice on the use of the medicine within NHS Scotland.

NHS Boards, Area Drug Therapeutics Committees (ADTCs) and the applicant pharmaceutical company are advised of this advice within 3 days of the SMC meeting.

The advice is made public by being published on the SMC website one month after NHS Boards, ADTCs and the applicant pharmaceutical company have been informed. A press release is also made available at this time. Organisations which have made Patient Interest Group submissions are also advised of the recommendation at this point.

If the pharmaceutical company's submission results in a recommendation that the medicine should not be used in Scotland, it is possible for the company to make a resubmission if there is new information available.

Details of the resubmission and appeals process are available on the SMC website. **If the pharmaceutical company makes a resubmission, the SMC Secretariat will contact Patient Interest Groups which previously submitted evidence to invite a further submission from them.**

## How do Patient Interest Groups find out what is being considered?

Patient Interest Groups can sign up to the SMC's alert system which means that, once a month, they will receive information from the SMC about which new medicines will be considered in the next 2 to 3 months

The alert system provides details of the name of the medicines added to the list of forthcoming submissions and the deadline for the Patient Interest Group submission...

Organisations can then check if there is a medicine that is relevant to the group of patients they represent and decide whether they wish to make a submission.

**It is essential that submissions use SMC dedicated template (attached) and are received by the deadlines indicated otherwise it is not possible for the information to be considered.**

The SMC does not restrict the number of patient interest group submissions it receives for each medicine.

## Support for making a submission

If you wish to make a submission, you should, in the first instance, contact the SMC Secretariat to find out if the pharmaceutical company has provided a contact name and/or written materials that can be passed onto patient groups to facilitate their contribution to the evidence***. It is important to bear in mind that this information will have been prepared by the submitting pharmaceutical company and is not endorsed by the SMC***.

The SMC website has a section on Public Involvement, where organisations can access sample submissions to assist them in considering what

information they need to gather, how to do it and how to present that information in the submission.

The SMC Public Involvement Officer can provide further advice to organisations about the requirements of the SMC and can review submissions with a view to indicating where they could be strengthened.

Organisations may wish to consider attending a 'surgery session' to assist in developing their submission: details on these may be obtained from the Public Involvement Officer, based at the Long Term Conditions Alliance

Scotland. Details are on the LTCAS website at **www.ltcas.org.uk.** The Public Involvement Officer can be contacted on **0141 404 0231 or at Venlaw Building, 349 Bath Street, Glasgow, G2 4AA.**

**If you have any problems accessing the internet or, for whatever reason, find it difficult to present information in the way suggested, please contact the Public Involvement Officer or the SMC Secretariat and we will attempt to facilitate your submission. It is not, however, possible for submissions to be presented in person to the SMC. A verbal summary of the submission is presented to the SMC by a Public Partner (lay member).**

## Use of the Patient Interest Group submission

The full Patient Interest Group submission will be made available to all those who attend the meetings of the SMC. All ***patient/carer information*** should therefore, be **anonymised:** organisations should be mindful of the Data Protection Act and Human Rights legislation. Information is available at www.ico.gov.uk/fororganisations/dataprotection.aspx or www.equalityhumanrights.com/human-rights/what-are-human-rights/the-human-rights-act/.

Organisations are asked to provide up to 10 bullet points, summarising the key aspects of the evidence in their submission.

## Feedback

We are keen to offer feedback to organisations on their submissions to help them to improve the effectiveness of their submissions. Any organisation wishing feedback on their submission should contact the SMC Public

Involvement Officer. We are also keen to learn from your experience to develop our process to be as user-friendly as possible. We are, therefore, grateful for feedback or comment from organisations which have made, or are considering making, a submission.

## How to use this template

This template has been designed to suggest areas of information which Patient Interest Groups should consider when presenting evidence to the SMC about the introduction of a new medicine in Scotland. It is also to provide uniformity in the way that this information is structured.

The template has four main sections (following a summary cover sheet):-

- Information on the submitting organisation;
- Information on the experience of patients, carers and their families;
- Views of patients, carers and their families on the difference the new medicine might make to them.
- Additional information to assist SMC in its' decision

**It is compulsory to provide the information requested about the submitting organisation. Groups are asked to complete as much of the rest of the template as possible.**

It is suggested that Patient Interest Groups should adopt a two-stage approach to the completion of the template. The first two sections of the template can be prepared outwith any timescale for the consideration of a new medicine by SMC and can be kept up to date when changes take place. This means that when consideration of a new medicine is notified by SMC, it is only latter sections of the template that will require attention.

When medicines are submitted for consideration by pharmaceutical companies, an 'indication' specifies

- patients to whom the medicine should be available,
- at what stage in their treatment it should be used
- and under what circumstances e.g. where a previous treatment has not been successful.

**This means that patient organisations will need to have a good general knowledge of the views of patients, carers and their families on the range of medicines currently prescribed.** This will assist them to identify which existing medicines will be relevant to the indication for the new medicine under consideration.

## GUIDANCE ON SPECIFIC QUESTIONS

Each questions has a shaded 'text box' for your responses and there are no limitations on the amount of information you may supply*;*

***however you may wish to consider that sometimes 'Less is More' and that it is the richness of the information provided rather than quantity that may have more impact on the reader**.*

**Section 1: questions 1 – 8**

**Submitting organisation**

Q1. Please give the full name of your organisation as it appears in your governing document.

Q2. Please advise of any alternative names by which your organisation is known. If the name of your organisation has changed in the last two years, please list the previous name of the organisation and the date the change occurred.

Q4. If you are using this template for the first time, please submit a copy of your governing document e.g. a constitution, Memorandum of Articles or trust deed. Unincorporated organisations must still provide a written governing document to demonstrate that they operate under a set of rules.

Q8. Please tick either **P,** to indicate a personal interest or **O** to indicate an interest related to the organisation of which they are part. The description should include details of:

- whether the individual is a shareholder or director of the pharmaceutical company who manufacture the medicine
- cash/kind received by person or organisation from the manufacturing company,
- whether the interest relates to the specific medicine under consideration
- whether it relates to clinical trial work for the medicine under consideration.

**Section 2: Question 10 & 11**
**Experience of patients, carers and their families**

Q10. In describing the impact of the health problem on the lives of patients, carers and their families, you should include information about-

- symptoms,
- problems that patients experience carrying out every day activities or tasks where patients require assistance and support ,
- the impact on
  - Personal /family relationships
  - Ability to work
  - Social life.

Q11. This is an opportunity to highlight any needs patients /carers and families have that are **currently not being met** by existing treatment/medicines available, for example:

- Self management information and support
- Access to clinical trials
- services in the community.

**Section 3: questions 12, 13 & 14**

**Views of patients, carers and their families on the difference the new medicine will make.**

Q12. There may be Summary Information for Patients available from the pharmaceutical company to help you with this section of the PIG, however you could canvas your members' views through a focus group, an online or telephone survey, talking to members who have experienced/participated in the clinical trial etc.

Q13. It is advisable **NOT** to cut and paste large pieces of information provided by Pharmaceutical companies as SMC have access to this information already. SMC want to know YOUR views on the difference the new medication would make. For example-

- side effects,
- administration ( liquid form easier to swallow, once a week injection better that daily, tablet form better that injection etc)

- better compliance (stick to treatment regimens and take medication as directed)

- less reliance on health care professionals or carers
- fewer visits to hospital
- shorter recovery times and able to return work

Please list each medicine separately.

Q14. This an opportunity to reflect on **unmet** needs or gaps in treatment choices/support available to patients or people affect by the condition. Does the new medicine

- Fill any of those gaps?
- How does it fill those gaps?
- Will it make a real difference?
- How strongly do you support this medication?

Q15 Summary of key messages you would like SMC to consider.

## Section 4 Additional Information

Q16. May wish to include anonymised patient stories/vignettes or quotes from members.

# Patient Interest Groups
## Submission of Evidence Template

## Summary Cover Sheet

Name of organisation making submission

Haemophilia Scotland

Contact/correspondence details

| | |
|---|---|
| **Name** | **Dan Farthing-Sykes** |
| **Designation** | **Chief Executive Officer** |
| **Address** | **SCVO Charity Business Hub**<br>**4th Floor, Hayweight House**<br>**23 Lauriston Street**<br>**EDINBURGH**<br>**EH3 9DQ** |
| **Telephone Number** | **0131 524 7286** |
| **Email address** | **dan@haemophilia.scot** |

Product to which the submission relates

Harvoni

Date of SMC meeting (if known)

03/02/2015

## Section 1: Submitting Organisation

Q1. **The Hepatitis C Trust**

Haemophilia Scotland

Q2. **Alternative/previous names of organisation (see guidance notes)**

**Date of change**

Q3. **Please tell us your organisation's main or registered address, including post code.**

SCVO Charity Business Hub
4th Floor, Hayweight House
23 Lauriston Street
EDINBURGH
EH3 9DQ

Q4. **Type of organisation (see guidance notes)**

**Please tick as appropriate:**

| | |
|---|---|
| Unincorporated organisation | ☐ |
| Unregistered charity | ☐ |
| Registered charity (Scotland) | x |
| Registered charity (UK) | ☐ |
| Registration Number | SC044298 |
| Other organisation type | ☐ |

Please provide details if you have ticked 'Other':

Q5. **Please provide a short description of the nature and purpose of your organisation. If you are a membership-based organisation, please indicate the number of members and the geographical spread.**

Haemophilia Scotland is a Scottish registered charity (No. SC044298) for individuals and families affected by bleeding disorders, such as Haemophilia or von Willebrand Disease, in Scotland. We are a membership-based organisation with 150 full members and in touch with over 450 people through social media.

We provide independent and patient friendly information; direct support and opportunities for peer to peer support; as well as advocating on behalf of everyone in Scotland affected by a bleeding disorder.

In the 1970's and 1980s an estimated 459 people with bleeding disorders in Scotland were infected with Hepatitis C as a result of being treated by the NHS with contaminated blood products.

Q6. **Please list any pharmaceutical companies that are corporate members of your organisation.**

None

Q7. **Please provide FULL details of any funding received from pharmaceutical companies within the last TWO years. Please note hyperlinks to other documents or website will not be acceptable.**

| Pharmaceutical Company | Amount of funding provided | Purpose of funding |
|---|---|---|
| Pfizer Ltd | £20,250 | Events, Website Development and our Parent Mentoring Project |
| Bayer | £6,000 | Events |
| Sobi | £675 | Attending a conference |
| **Total** | £26,925 | |

Q8. **Please provide details of any individuals who have had a significant role in drawing up your submission who have an interest to declare.** Please refer to the guidance notes further explanation.

| Name | Role in Submission | P | O | Description |
|---|---|---|---|---|
| None | | | | |
| | | | | |

## Section 2: Experience of patients, carers and their families

Q9. **Please tell us how you have gathered information about the experience of patients, carers and their families e.g. helpline, focus groups, published or unpublished research, user-perspective literature (e.g. personal stories), one to one discussions.**

T At our last all member meeting we held sessions specifically for the section of our members affected by blood borne viruses. We are in regular dialogue with affected families on the phone, face to face as well as through social media. We are a Core Participant in the Penrose Inquiry into the contaminated blood disaster and have an detailed knowledge of the evidence, submitted in public, to the Inquiry relating to the experience of people with bleeding disorders and blood borne infections, including Hepatitis C. We have recently been receiving increasing numbers of calls from members asking about access to the new Hepatitis C treatments.

Q10. **Please provide information about how this condition affects the day-to-day lives of patients, carers and their families.** Please refer to the guidance notes.

As a group, people with bleeding disorders and Hepatitis C are long term survivors of infection with Hepatitis C. May were infected when the virus had not been fully identified and was still known as non-A, non B Hepatitis. In many cases this has meant years of knowingly carrying the virus with corresponding impacts on mental wellbeing and, as a result, on family life. Almost all of those with Hepatitis C have attempted currently available treatments and/or predecessor treatments. These attempts have been

unsuccessful or intolerable. Our members report long-term side effects from these unsuccessful treatment attempts as well as a wide range of non-liver manifestations of the condition. They also have had a long experience of the day to day stigma associated with all blood borne viruses. We support the description of Hepatitis C in The Hep C Trust submission.

Q11. **Which aspects of living with this condition, NOT MET by treatments currently available, do patients need most help with?**

As stated above, the majority of people with a bleeding disorder and Hepatitis C in Scotland have been failed by current treatment options. To our knowledge none have been offered an "interferon-free" alternative to date and their health continues to deteriorate. It is, therefore, vital that sufficient new therapies are available to provide a realistic treatment option.

The experience of attempting and failing treatment means that patients considering another attempt with a new product are looking for a high a success rate as possible. As a result of their negative experiences of previous treatment and its side effects they understandably cautious. Similarly, as a result of the infection arising from NHS treatment they are sceptical about product safety data. For these reasons there is a need for a range of combined therapy options for people with bleeding disorders.

It would be unacceptable to these patients for there to be a limited range of "interferon-free" options as this would restrict flexibility should any hint of a safety issue arise. Similarly, as more data becomes available the flexibility to tailor treatment according to genotype or any other relevant factor is desirable to make sure that any new attempt at treatment is the final attempt.

We believe there is a moral obligation to provide the best possible treatment options to a group of patients infected by the NHS. This group of patients have almost universally had direct experience of the side effects of interferon and need the opportunity to access effective treatment without this additional damage to their health, home lives and employability.

**Section 3: Views of patients, carers and their families on the difference the new medicine will make.**

Q12. **Please provide details of your sources of information about the new medicine.** Please refer to the guidance notes.

| |
|---|
| Our information is derived from our engagement with sister organisations and umbrella organisations. In particular, the work of The Hepatitis C Trust, European Haemophilia Consortium and the Irish Haemophilia Society (and their Positive New publication) have been particularly valuable. We have also engaged with the engagement work of the specialist group under Professor Goldberg. |

Q13. **Please advise us of the views of patients, carers and their families on what the advantages or disadvantages of the new medicine might be compared to existing treatments.**

We support The Hepatitis C Trust response to Q13 reproduced below:

| Existing Treatment | Advantages of new medicine | Disadvantages of New medicine |
|---|---|---|
| Pegylated Interferon, with Ribavirin,<br><br>(with in some cases the addition of Telaprevir, Boceprevir, Sofosbuvir, Simeprevir, Daclatasvir) | Harvoni is the first to combine 2 antivirals into a single once a day pill.<br><br>Harvoni offers an interferon-free treatment option for patients who do not wish to experience the significant side-effects of interferon, which can include the onset | We believe that Harvoni represents a major improvement in treatment of chronic hepatitis C, with no additional disadvantages. |

| | | |
|---|---|---|
| | of long-term, serious medical conditions.<br><br>The shorter treatment durations that Harvoni offers will significantly improve accessibility, as well as adherence rates. | |

Q14. **To what extent will this new medication help to address the unmet needs you have previously highlighted in Q11?** Please refer to guidance notes.

Harvoni offers our members who have not been able to achieve SVR with previous treatments a combined therapy option which hasn't previously been available. It offers the prospect of achieving SVR and the reassurance of using a combination therapy to increase the chances of success while reducing the treatment duration. For those who have suffered serious side effects with treatment in the past this is particularly necessary.

A combined therapy treatment will be simpler to adhere too and a reassuring prospect to those with unpleasant memories of existing treatments. The shorter treatment durations will make this a much more attractive treatment option.

## Section 4: Additional Information

Q15. **In 10 bullet points or LESS, please summarise the key aspects of your submission.**

- Many patients with a bleeding disorder and Hepatitis C have been unable to achieve SVR with existing treatment.
- Many have experienced serious side effects both during and after receiving existing treatments.
- Having been unsuccessful with previous combined therapies they would be cautious about attempting treatment again on less than a combined therapy.
- The prospect of a simpler treatment regime and shorter treatment time are particularly attractive to those with bad experiences of existing treatments.

- There is currently no interferon-free option for patients who are not intolerant or ineligible but merely do not wish to take interferon.

Q16**. Please provide any additional information which you believe would be helpful to SMC.**

Without access to an "interferon-free" combined therapy option we believe that many of those who have not achieved SVR with existing treatments may not be prepared to attempt another course of treatment. This would deny them the significant improvements in quality and length of life offered by successful treatment.

**Thank you for your submission of evidence.**

**Please email your completed form to maureen.stark@nhs.net or catherine.tait@nhs.net.**
**A hard copy should also be sent by post.**
**If this is the first time you have made a submission using this template, please also provide a copy of your governing document to:**

Scottish Medicines Consortium Secretariat
Delta House
50 West Nile Street
GLASOW
G1 2NP

**For further assistance, please telephone 0141 225 6989**