South Tyneside and Sunderland
Area Prescribing Committee

APPLICATION FOR A NEW PRODUCT TO BE ADDED TO THE SOUTH TYNESIDE AND SUNDERLAND JOINT FORMULARY

GENERAL

- This form is to be used for applications for new medicines and new formulations of medicines and other relevant prescribable pharmaceutical products, as defined in the South Tyneside and Sunderland Area Prescribing Committee (APC) terms of reference.
- Requests must be made by a consultant, general practitioner, or other appropriate senior professional, e.g. CCG medicines optimisation pharmacist, hospital pharmacist, dentist, optician, senior dietician and non-medical prescribers.
- Please note that the applicant or appropriate deputy (with the expertise to present and discuss the application) **MUST** attend the APC meeting in order to present the application. The application will be deferred if there is no appropriate person in attendance.
- Applications must consist of evidence-based data outlining the efficacy, therapeutic advantage, safety, or cost relative to the products already listed in the Formulary. Ideally, supporting data should be from randomised-controlled studies from peer review journals.
- Please complete **ALL** details (including signatures) – **INCOMPLETE FORMS WILL BE RETURNED**.
- The application **MUST** be supported/authorised by the relevant Clinical Director for secondary care or CCG GP Prescribing Lead for primary care before submission.
- Authorisation from the authorising manager may be via direct email if physical signature unavailable.
- An application for a medicine that has been rejected within the last twelve months will normally be refused, unless it is for a different indication, is based on new evidence/new national guidance or in circumstances deemed exceptional by the Committee.
- The manufacturer/supplier (pharmaceutical company) may provide information, but the application **MUST** come from an appropriate applicant. Obvious applications completed by pharmaceutical companies may be rejected.
- Where possible electronic versions of any references and other supporting documents (preferably as Word, rtf or pdf documents) should be emailed at the same time.
- Hospital consultants may find it helpful to discuss their request and obtain support from their Clinical Director, and/or other consultants working in their speciality prior to submitting a request. If this is done please give details in the appropriate section of this form.
- All applications will be reviewed by the Formulary Pharmacist prior to APC meeting to ensure applications are complete, appropriate and have been considered by appropriate forums e.g. STSFT cancer forum.
- It is suggested that applicants should check decisions made by other independent bodies

before making a submission.

- National Institute for Health and Care Excellence (NICE) – http://www.nice.org.uk/
- Northern Treatment Advisory Group (NTAG) – http://ntag.nhs.uk/
- Regional Medicines Optimisation Committee (RMOC) - https://www.sps.nhs.uk/category/rmoc-recommendation-or-resource/
- Scottish Medicines Consortium (SMC) – http://www.scottishmedicines.org/
- Midlands Therapeutics Review and Advisory Committee (MTRAC) - http://centreformedicinesoptimisation.co.uk/mtrac/

- The APC may consult and concur with their decisions which may result in rejection of applications if decisions are unfavourable. However, applications can still be made, but exceptional evidence needs to be provided for a successful application.
- **NOTE:** For successful applications, stock may not be purchased by STSFT until receipt of the first prescription.

To ensure that requests are processed as quickly as possible, please return completed forms as soon as possible before the meeting.

The closing date for receipt of requests is currently **TWO WEEKS** prior to the meeting.

Requests received after this time or if incomplete / inappropriate will normally be deferred to the next meeting.

Submit electronically by e-mail as a Word document to

sunccg.apc@nhs.net

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DETAILS OF PRODUCT		
Generic name:		
Brand name:		
Dosage form and strength:		
Pack size and cost:		
Please indicate source of cost information: *(Please click the appropriate button)*	○ BNF ○ DRUG TARIFF ○ PHARMACEUTICAL REP ○ RDTC CCC	

INDICATIONS		
Is this an unlicensed medicine or unlicensed indication? *(Please click on YES or NO)*	○ YES ○ NO	**SEE GUIDANCE NOTES AT THE END - AN ADDITIONAL FORM NEEDS TO COMPLETED FOR AN UNLICENSED MEDICINE**
Licensed indication for this medicine:		
See the current BNF – http://www.medicinescomplete.com/mc/bnf/current/ or Summary of Product Characteristics (SPC) – http://www.medicines. org.uk/emc/		
Indication for which the medicine is requested:		

REASONS FOR REQUEST	
Please classify reason for request *(Please click the most appropriate button)*	○ Has a therapeutic advantage over an existing formulary drug ○ A cheaper alternative to an existing formulary drug ○ No formulary alternative ○ Improve compliance ○ New Formulation ○ Other, please specify below
Claimed **advantage(s) over existing formulary medicine(s)** for same indication (s) in terms of EFFICACY, SAFETY, CONVENIENCE, or COST EFFECTIVENESS	
Details of any **perceived clinical problems** with product — such as adverse reactions, training issues and cost effectiveness	

ANTICIPATED PLACE IN THERAPY	
Please give a clear guideline including algorithms or flowcharts as necessary, indicating **EXACTLY which group(s) of patients should or should not be eligible to receive this medicine**. Include details of whether the medicine is **first-line** or not and the **suggested criteria** for selecting or not selecting the product *(Continue on a separate sheet if necessary)*	

FORMULARY MEDICINES		
Existing formulary medicine(s) for the same indication (s)		
Would the medicine be: *(Please click on YES or NO)*	1. An **addition** to existing formulary medicine(s) *OR*	○ YES ○ NO
	2. A **replacement** for existing formulary medicine(s)	○ YES ○ NO
If 2 applies, which medicine(s) can be deleted:		

SUPPORTING EVIDENCE FOR THE PRODUCT *(Continue on a separate sheet if necessary)*

PRESCRIBING AND MONITORING	
Dosage regimen proposed for this application:	
Monitoring for proposed use (including criteria for stopping treatment): Please list potential issues that the Committee should consider (*e.g. adverse reactions, special storage conditions or funding if the product is expensive*)	

REVIEW OF USE FOLLOWING APPROVAL OF MEDICINE	
As a condition of approval of new medicines/indications, the applicant must **review use in the first six months after the decision is made**. Please describe how prescribing will be audited against the terms for which it has been approved.	

GUIDELINES			
Guidelines *(Please click on YES or NO)*	1. Are there existing guidelines?	◉ YES	○ NO
	2. Are there any proposed guidelines?	○ YES	○ NO
If 1 applies, please send an electronic copy or attach as a separate document If 2 applies, please outline below giving details of proposed guidelines. *Continue on a separate sheet or attach as a separate document*			
Prescriber restrictions (*e.g. Hospital only, Consultant only, Only on microbiologist advice etc.*).			

PLANS FOR PRODUCT INTRODUCTION	
Steps to be taken to ensure the safe introduction of this product into clinical practice (training, awareness sessions, information to patients etc.).	

SHARED CARE ARRANGEMENTS			
'Traffic Light' status In your opinion, what would be the appropriate designation? *(Please click the appropriate button)*	○ RED ○ AMBER ○ GREEN + ○ GREEN		
Explanation of Traffic Light status RED — Medicines that should only be prescribed by a hospital clinician or specialist within specialist centre AMBER — Initiation by the hospital but prescribing could potentially be transferred to GPs as part of shared care arrangements GREEN + — Initiation by a specialist but then can be prescribed by a GP without the need of routine or specialist intervention and monitoring GREEN — Freely prescribable without the need of routine or specialist intervention and monitoring			
For AMBER medicines, are there shared care guidelines already available?	○ YES ○ NO		
If YES applies, please attach existing agreement If NO applies, A SHARED CARE AGREEMENT MUST BE DRAFTED AND PRESENTED TO THE COMMITTEE WITH THIS APPLICATION			
For GREEN + medicines, when would GPs be expected to take over prescribing? NB When the application is presented; the Committee will discuss whether a GREEN+ information leaflet is necessary. It is a condition of approval that a GREEN + information leaflet is drafted as soon as possible if this deemed necessary by the Committee.			

ESTIMATED USAGE AND COST			
Estimated number of patients per month:		Would any non-medicine costs be incurred? *(e.g. giving sets, syringes etc.)*	○ YES ○ NO
If YES, please give details:			
The above information will be used to review usage and costs after six months, which will be reported to the APC as well as the relevant Directorate Manager(s) and Clinical Director.			

COMMISSIONING IMPLICATIONS	
How is this medicine funded?	○ Tariff ○ Off Tariff (CCG funded) ○ Off Tariff (NHSE funded) ○ Other
What are the financial implications for STSFT and/or the requesting Directorate?	
What are the activity implications for STSFT and/or the requesting Directorate (e.g. will this medicine increase or decrease clinic attendances)?	
What are the financial implications for South Tyneside and Sunderland CCGs?	
Applicants please note formulary changes with financial implications for CCGs will be considered from that perspective. Any final decision is not binding upon other CCGs	

CLINICAL AND FINANCIAL SUPPORT / AUTHORISATION FOR APPLICATION			
Secondary care applicants should seek support / authorisation from the relevant Clinical Director and discuss with Directorate Finance Manager prior to submitting the application to the APC Primary care applicants should seek support / authorisation from the CCG GP Prescribing Lead and CCG Lead Pharmacist prior to submitting the application to the Joint Formulary Committee.			
STSFT CLINICAL DIRECTOR / CCG GP PRESCRIBING LEAD			
Name:			
Signature:		Date:	
STSFT DIRECTORATE MANAGER / CCG CHIEF PHARMACIST			
Name:			
Signature:		Date:	

APPLICANT DETAILS			
Name:			
Speciality:		Directorate:	
Address for correspondence:			
Confirmation of attendance at the Area Prescribing Committee meeting.	I will attend the Area Prescribing Committee meeting on ……. [INSERT DATE] to present the application		

DECLARATION OF INTERESTS			
*Please declare any relevant association with the medicine or company concerned. If none, please state **NONE**. Examples include funding from pharmaceutical company for research or attending conferences; involvement in any clinical trial; personal involvement with the pharmaceutical company (shareholder).*			
Signature:		Date:	

PLEASE ATTACH ANY RELEVANT SUPPORTING INFORMATION AND ENSURE THAT THE RELEVANT SECTIONS ARE SIGNED AND DATED

NHS

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SUPPLEMENTARY FORM FOR REQUESTING AN UNLICENSED MEDICINE

This supplementary form provides additional information for unlicensed medicines to that already given in the main application. Please refer to the guidance notes at the end before completing this form. If approved, justification for individual patients may be necessary if the medicine concerned has been withdrawn in the UK due to safety reasons.

UNLICENSED STATUS

Name of medicine:				
Other information (if known) including brand and country of origin				
Are you aware of any licensed alternative to this product: *(Please click YES or NO)*	○ YES ○ NO	Are you aware if a product licence is likely to be granted in the future? *(Please click YES or NO)*	○ YES ○ NO	If YES, when (if known)?

INDICATIONS

Justification for use (including any risks if patients do not receive this medicine)	
Are there any other centres using this medicine? *(Please click YES or NO)*	○ YES ○ NO
If YES, please give details	

I have read and taken note of the Guidance Notes on the Use of Unlicensed Medicines

Signature		Date:	

NOTE

Approval to use an unlicensed medicine may be withdrawn following consultation with the prescriber should problems arise with safety, or a suitable licensed alternative becomes available

Use of unlicensed medicines should be reviewed on a regular basis. A case for continued use may be requested by the Area Prescribing Committee every six months

NOTES ON THE USE OF UNLICENSED MEDICINES

1. Unlicensed medicines are medicines that have not been approved by the licensing authority (The Medicines and Healthcare products Regulatory Agency – MHRA). Medicines that are not manufactured in the EU, USA, Canada, Australia, New Zealand, or Japan may not be manufactured to the same high standards as licensed medicines and, in general, greater risks may be associated with their use.
2. Unlicensed medicines should not therefore be used unless their use can be justified. Justification may include recognised clinical guidelines, common practice, peer support, or advice of a specialist. Responsibility for deciding if the patient has 'special needs' which a licensed product cannot meet falls upon the doctor responsible for the patient's care.
3. The prescriber assumes legal liability when he/she prescribes an unlicensed medicine. If the prescribing of an unlicensed medicine (which is not due to a defect in that medicine) harms a patient, then it may be alleged that the prescriber and/or pharmacist have been negligent. The test of whether a doctor or pharmacist is negligent is referred to as the Bolam test. This broadly states that a professional person will not be negligent if what he/she does would be approved of by a responsible body of opinion in his/her profession.
4. Where possible the clinician should give the patient (or appropriate relatives/carers) sufficient information about the medicine and its possible adverse effects. In circumstances where the patient may be considered to be at increased risk clinicians are strongly advised to obtain further informed consent from the patient (or relative) regarding the use of the product. It is advisable for this consent to be given in writing. Failure to give adequate information/obtain consent may cause problems should there be an event that results in litigation.
5. In hospital, it is important that junior medical and nursing staff is aware of the additional risks and their additional responsibilities with regard to the use of unlicensed medicines.

   They should also be given sufficient information to allow them to carry out their duties relating to the handling and administration of the product, monitoring the patient, dealing with possible adverse events etc. The pharmacy staff may be able to help with the provision of this information if required.
6. Many unlicensed medicines are only available to hospitals. However, if it is anticipated that the patient's general practitioner should continue treatment, then it is important that this is done with his/her consent. In such cases, sufficient information must be given to allow general practitioner to monitor treatment. This information should include details of how the patient's community pharmacist can obtain the medicine.
7. Any adverse drug reactions (ADRs), which may be due to the product, should be reported to the Commission on Human Medicines (CHM) using the "yellow card" system. Further advice on ADR reporting is available from the SRH Pharmacy Medicines Information Service (Ex 49031).
8. Any defect, or suspected defects, in the product must be reported either to the CCG or the hospital pharmacy. If appropriate, the staff will then notify the Medicines and Healthcare products Regulatory Agency (MHRA) and the manufacturer/supplier.
9. Prescribers are advised to read the General Medical Council (GMC) guidance on prescribing unlicensed medicines: http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp

PLEASE NOTE

This form is for general information as part of the submission to Area Prescribing Committee. If approved, justification for individual patients may be necessary if the medicine concerned has been withdrawn in the UK due to safety reasons.