UK PharmaScan Skeleton SOP

This skeleton standard operating process (SOP) provides an outline of the potential internal procedures and process required for the management of UK PharmaScan within a pharmaceutical company.

It is intended to be used as a basis for developing a full SOP appropriate to your organisation.

# Key Principles of Best Practice

While companies vary in the approaches they take to managing UK PharmaScan, there are five key principles for success:

1. Assign overall accountability for UK PharmaScan to one individual
2. Include UK PharmaScan as an objective for all company personnel involved in data collation and entering and updating data
3. Have clear roles and responsibilities
4. Have set processes for data collection, collation, entry and updates and good communication and knowledge of these within the company
5. Use the [Excel Product Template](https://www.ukpharmascan.org.uk/Content/Resources/Product_Template.xlsx) detailing all UK PharmaScan fields to collate data.

Education on the importance of UK PharmaScan as an essential component of market access is also a key factor in getting people on board and ensuring understanding of the data requirements and the need to keep data accurate, comprehensive and up to date.

If you require any further information and/or assistance please contact: **[Insert details of company Champion User]**

For technical issues please contact the UK PharmaScan helpdesk: **contactus@ukpharmascan.org.uk**

**[Insert company name here]**

UK PharmaScan SOP

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# Purpose

The purpose of this SOP is to describe the processes and responsibilities in relation to the horizon scanning database UK PharmaScan. The SOP covers the processes for assigning and managing company users, data collation and entry and the updating of records. It also includes a brief overview of UK PharmaScan.

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# UK PharmaScan Overview

UK PharmaScan is a database of information on new medicines, indications and formulations in the pharmaceutical pipeline. It is the primary source of information used by all of the UK’s national horizon scanning organisations and NHS England to enable early engagement in planning and preparing the NHS for the introduction of new medicines, and to support faster NHS adoption. It is populated by companies on a confidential and secure platform.

# How is confidentiality maintained?

Data entered in UK PharmaScan on **[Insert company name**] medicines are ONLY accessible to you, NHS England and horizon scanning organisations. Robust web security safeguards are in place and all organisations are covered by the confidentiality clauses in their signed User Agreements.

# Who has access?

All of the UK’s national horizon scanning organisations and NHS England use UK PharmaScan to enable early engagement in planning and preparing the NHS for the introduction of new medicines.

* NHS England and NHS Improvement
* NIHR Innovation Observatory
* National Institute for Health and Care Excellence (NICE)
* Specialist Pharmacy Service (SPS)
* Scottish Medicines Consortium (SMC)
* All Wales Therapeutics & Toxicology Centre (AWTTC)

# What data needs to be entered?

A UK PharmaScan record contains the following information:

* Information on the new medicine, indication or formulation
* Regulatory information
* Clinical trial information
* Cost and budget impact data.

UK PharmaScan is an efficient way to provide accurate and consistent information to NHS England and all UK national horizon scanning organisations using one channel.

Companies are required to enter data on new medicines, new indications / licence extensions, new formulations for existing medicines and in-licensed medicines developed by a 3rd party, which are in phase III or three years from estimated launch, whichever is the earliest are entered onto UK PharmaScan. Depending on the stage of development it is recognised that companies will not be able to complete all of the UK PharmaScan fields but that all data available at that time should be entered.

There is a requirement to update regulatory fields as soon as new information becomes available and all other fields every 3 months.

# What is the data used for?

UK PharmaScan is an important tool for supporting the access of **[Insert company name]** products to UK markets. It provides a mechanism which ensures the governance of the process of collating, agreeing and communicating key information about **[Insert company name]** products and their potential impact on the NHS by:

* Acting as a centralised resource which consolidates the information **[Insert company name]** provides to external UK organisations
* Providing an efficient and easy way to review, check and update information to ensure that the information communicated to UK organisations is correct and up to date
* Ensuring that UK horizon scanning organisations have accurate, up to date information upon which to develop their horizon scanning documents, rather than inaccurate information taken from publically available information sources, to begin to inform their decision making
* Ensuring the information provided to NHS budget and service planners via each of the horizon scanning organisations can be provided in a timely and accurate manner
* Supporting the UK market access dialogue and activities with UK NHS budget and service planners.

# Is there a charge for using UK PharmaScan?

No. There is no charge on pharmaceutical companies wishing to register and use UK PharmaScan.

Process

# Roles and Responsibilities

The **[Insert company or team name]** owns the internal UK PharmaScan process.

The Champion User will have overall accountability for ensuring that entries in UK PharmaScan relating to **[Insert company name]** products are maintained as accurate and up to date.

The Champion User will have responsibility for:

* Allocating up to 4 standard users.
* Ensuring the total number of activated standard users does not exceed 5
* Ensuring data on **[Insert company name]** medicines are entered onto the database
* Ensuring regulatory data is updated immediately any changes occur
* Ensuring all other record are updated on a 3 monthly basis
* Updating this SOP to reflect any required changes.

# Allocation of Users

A maximum number of 5 activated users will be allocated to use UK PharmaScan and enter data on **[Insert company name]** products.

These will comprise of:

* A Champion User – **[Insert job title]**
* Four Standard Users – these will include relevant regulatory leads.

# Data Collation

All new medicines, new indications / licence extensions, new formulations for existing medicines and in-licensed medicines developed by a 3rd party, which are in phase III or three years from estimated launch (irrespective of the phase), whichever is the earliest will be entered onto UK PharmaScan.

If required, data for entry onto UK PharmaScan can be collated using the [Excel Product Template](https://www.ukpharmascan.org.uk/Content/Resources/Product_Template.xlsx).

Completion of the proforma will be the responsibility of **[Insert details]** who will obtain the relevant information from **[Insert details - could include appropriate departments within the company, global pipeline documents]**. Prior to entry of the data onto UK PharmaScan the completed proforma will be reviewed by **[Insert details]**. The **[Insert details if sign off is required]** will be responsible for final sign off of the proforma and approval of the data to be entered onto UK PharmaScan.

# Data Entry

The **[Insert details]** will be responsible for entering the initial data onto the database. The downloadable pdf function available on UK PharmaScan can be used to provide a record of the data entered.

# Updating Records

Regulatory information should be updated as soon as the information becomes available. All other fields in the record should be updated every 3 months. If there is no new or updated information to add tick the Mark as no change box.

**[Insert details]** will be responsible for initiating all updates. Information will be collected via **[Insert details – this could include circulation of the initial excel template or circulation of the pdf of the recent record with the requirement to highlight required amends]**.

The updated excel spreadsheet/pdf will be stored **[Insert details]**.

**Process Flow**

**[To be completed]** This section should explain the **[Insert company name]** UK PharmaScan process in detail.

Examples of how companies currently manage UK PharmaScan are provided in the [Case Studies](https://www.ukpharmascan.org.uk/Content/Resources/Case_Studies.pdf).

# Email templates

**[To be completed]** You may wish to provide email templates for use within your company covering:

* The role of UK PharmaScan including details of how confidentiality is maintained
* Data requirements
* Responsibilities of the company users.