

**Example of 'ideal' updated record for a product where a regulatory dossier has been submitted (1 year from launch)**

Assura

Rifamilumab

Moderate to severe rheumatoid arthritis

<b>Drug</b>	
<b>Manufacturer</b>	Assurent Pharma Ltd
<b>Branded name</b>	Assura
<b>Generic name</b>	Rifamilumab
<b>Synonyms</b>	PC701, rifpuramab
<b>Indication</b>	
<b>Proposed</b>	In combination with methotrexate for the treatment of moderate to severe, active rheumatoid arthritis in adults for who the response to disease-modifying anti-rheumatic drug (DMARD) therapy, including methotrexate, has been inadequate
<b>Final</b>	
<b>Abbreviated</b>	Moderate to severe rheumatoid arthritis
<b>Identified sub groups</b>	Patients not adequately controlled on methotrexate/DMARDs
<b>Proposed place in therapy</b>	After the failure of two previous conventional disease modifying anti-rheumatic drugs including methotrexate
<b>Stage of disease</b>	Active moderate to severe RA
<b>Is paediatric</b>	No
<b>Formulation</b>	
<b>Formulation</b>	Subcutaneous injection
<b>Details</b>	
<b>Mode of action</b>	Inhibitor of northodeconate dehydrogenase (NDDH), a key enzyme involved in joint destruction. First in a new class of biological drugs.

<b>Technology status</b>	New chemical / biological entity
<b>Nature of SPC amendment</b>	
<b>Route</b>	Parenteral
<b>Presentation</b>	Self-administered autoinjector containing 300mg rifamilumab in 1mL solution. Requires fridge storage.
<b>Proposed dose</b>	300mg
<b>Proposed dosing regimen</b>	Given by subcutaneous injection, initially 300mg at weeks 1 and 4, then every 6 months.
<b>BNF Chapter</b>	10 – Musculoskeletal and joint diseases
<b>Disease state</b>	Rheumatoid arthritis
<b>Is the drug considered a personalised medicine?</b>	No
<b>Is there a companion diagnostic test?</b>	No
<b>Please provide details</b>	
<b>Current treatment options</b>	TNF-inhibitors such as adalimumab, certolizumab pegol, etanercept and golimumab.
<b>Likely Comparators</b>	As above
<b>Has this medicine been formally selected for an AWMSG TDA?</b>	No
<b>Comments</b>	AWMSG confirmed meets exclusion criteria for appraisal by AWMSG
<b>Has this medicine been formally selected for a NICE HTA?</b>	Yes
<b>Comments</b>	Wave 27, single technology appraisal.
<b>Will this medicine be appraised by the SMC?</b>	Yes
<b>Comments</b>	
<b>Who is the originating company?</b>	Assurent Pharma Ltd
<b>Is the drug being co-marketed?</b>	No
<b>Co-marketing company</b>	
<b>Clinical trial information</b>	
<b>Study Name</b>	AS-104/9
<b>National Clinical Trial number from ClinicalTrials.gov</b>	NCT02101234
<b>Trial number from other clinical trial registry</b>	

<b>Publications</b>	Davis H, Randall C, McEntee J et al. Efficacy and safety of rifamilumab in moderate to severe rheumatoid arthritis: a randomised controlled study. Curr Res Opinion 2014; 38: 4-9
<b>Study Name</b>	PC-415-790
<b>National Clinical Trial number from ClinicalTrials.gov</b>	
<b>Trial number from other clinical trial registry</b>	
<b>Publications</b>	Davis H, Randall C, McEntee J et al. Efficacy and safety of rifamilumab in moderate to severe rheumatoid arthritis: a randomised controlled study. Curr Res Opinion 2014; 38: 4-9
<b>Regulatory information</b>	
<b><u>MHRA status</u></b>	
<b>MHRA regulatory procedure</b>	MHRA national assessment procedure - accelerated
<b>MHRA regulatory procedure details</b>	
<b>Estimated UK regulatory submission date (quarter)</b>	Q1/2021
<b>Estimated UK regulatory submission date (month)</b>	January
<b>Estimated UK licence date (quarter)</b>	Q3/2021
<b>Estimated UK licence date (month)</b>	August
<b>UK conditional approval anticipated</b>	
<b>Estimated UK availability date (quarter)</b>	Q3/2021
<b>Estimated UK availability date (month)</b>	October
<b>Actual UK regulatory submission date</b>	
<b>Actual UK licence date</b>	
<b>Actual UK availability date</b>	
<b>MHRA Promising Innovative Medicine (PIM) designation granted?</b>	No
<b>Estimated Early Access to Medicines Scheme (EAMS) submission date</b>	
<b>Actual EAMS submission date</b>	
<b>Estimated EAMS scientific opinion date</b>	
<b>Actual EAMS scientific opinion date</b>	
<b>EAMS scientific opinion decision</b>	

<b><u>International Status (IRP and pre-IRP EU)</u></b>	
Estimated International regulatory submission date (quarter)	Q1/2021
Estimated International regulatory submission date (month)	January
Estimated International licence date (quarter)	Q3/2021
Estimated International licence date (month)	August
International Fast track application anticipated	No
International conditional approval anticipated	
Actual International regulatory submission date	
Estimated International opinion date	Q1/2021
Actual International opinion date	
International opinion	
Actual International licence date	
<b><u>EU status</u></b>	
Current EU stage of development	Pre-registration
EU regulatory procedure	EU Centralised
<b><u>US status</u></b>	
Current US stage of development	Phase III
Response letter issued	Yes
Date response letter issued	Q3/2019
FDA fast tracked?	Yes
FDA orphan drug status?	No
General comments	
<b><u>Orphan Drug / ATMP categorisation</u></b>	
MHRA orphan drug status	No
Date MHRA orphan drug status granted	
MHRA orphan status number	
Orphan drug status in EU	No
Date EU orphan drug status granted	
EU orphan status number	

<b>Classified as an Advanced Therapy Medicinal Product (ATMP) in EU?</b>	No
<b>ATMP classification</b>	
<b>Date of recommendation on classification of ATMP</b>	
<b><u>MHRA / international regulator</u></b> <b><u>Withdrawal, Suspension or Discontinuation status</u></b>	
<b>Withdrawal date</b>	Q2/2019
<b>Withdrawal reason</b>	Need for an additional clinical study to answer questions posed by EMA. Originally submitted in May 2018 but withdrawn 16 June 2019: <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Application_withdrawal_assessment_report//xxxxxxx.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Application_withdrawal_assessment_report//xxxxxxx.pdf</a> . Plan to re-submit on the basis of a 2nd Phase III study.
<b>If suspended, date of suspension</b>	
<b>Reason for suspension</b>	
<b>Are there further plans for trials/refiling?</b>	
<b>If development is discontinued, date of discontinuation</b>	
<b>Reason for discontinuation</b>	
<b>If other reason for archival, date of decision to archive</b>	
<b>Other reason to archive</b>	
<b>Cost and budgetary information</b>	
<b>Proposed average dose</b>	300mg 6 monthly.
<b>Place in therapy</b>	Substitute
<b>Estimated length of treatment</b>	Ongoing
<b>Drug cost range (per patient per year or patient per episode if less than one year)</b>	£20,000 and £30,000
<b>Drug cost notes</b>	Inc. VAT Range above refers to ongoing costs (excluding year 1, which will be higher due to the initiation schedule for the drug)
<b>Is a Patient Access Scheme or alternative discount arrangement planned for this indication?</b>	

<b>Comments</b>	
<b>Is the technology available on a compassionate basis pre-licence in the UK other than clinical trials?</b>	No
<b>Service impact</b>	Substitute for anti-TNFs. Likely to be more expensive. However, following induction, administration is only required every 6 months, less frequently than that for the anti-TNFs. In addition, self-administration so no need for outpatient/GP visits for administration by a healthcare professional.
<b>Impact on patients and carers</b>	Reduced number of injections (every 6 months) and can be self-administered. Fewer visits to health facilities for administration purposes required vs. some of the alternative agents.
<b>UK patient population range</b>	Between 750 and 1,000 per 100,000
<b>UK patient population notes</b>	The estimated prevalence of rheumatoid arthritis in England is 0.86%, equivalent to around 346,000 people (NICE TA225 Rheumatoid arthritis (after the failure of previous anti-rheumatic drugs) - golimumab: costing statement, June 2019).
<b>Estimated eligible patient population</b>	The proportion of patients with RA who are eligible for treatment with biological drugs has been estimated as 10% of the prevalent population: approximately 34,600 people (NICE TA225 Rheumatoid arthritis (after the failure of previous anti-rheumatic drugs) - golimumab: costing statement, June 2019). Possibly 15% of the eligible patient population will receive rifamilumab at peak usage (Company estimate).
<b>Is the drug likely to have a significant service impact?</b>	No
<b>Is the net budget impact for the UK greater than £5million at year 5?</b>	Yes
<b>Estimated uptake</b>	Possibly 15% of the eligible patient population will receive rifamilumab at peak usage (year 5) and uptake is likely to be approximately 5% at year 1. (Company estimate from internal data)

<p><b>Estimated net incremental drug acquisition costs per annum at year 1 and 5</b></p>	<p>The estimated drug acquisition cost of rifamilumab is approximately £20,000 to £25,000 per annum (300mg every 6 months). Rifamilumab would be used in place of drug X (25mg subcutaneously every 2 weeks) and drug Y (100mg sc per week). The alternative treatments (drug X and drug Y) cost approximately £10,000 and £12,000 per annum, respectively. The average of these has been assumed as the cost of alternative treatments.</p>
<p><b>What will be the net budget impact at year 1 and 5?</b></p>	
<p><b>Budget impact model available from the company on request</b></p>	<p>Unknown</p>