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Final report

Rapid Data Analysis – Systemic fluoroquinolones and thrombotic thrombocytopenic purpura (TTP)

Contact for data analysis

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Date	24 August 2021

Request

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Background

Short title of topic	Systemic fluoroquinolones and thrombotic thrombocytopenic purpura (TTP)
Regulatory procedure	Signal procedure (EPITT no. 19669)
Background	The signal originates from a review of case reports within EudraVigilance and signal detection based on disproportionality. The review identified 5 well documented literature reports of TTP for ciprofloxacin. The time to onset was <21 days (4 days, 5 days and 13 days). None of the patients had a history of malignancy or haematopoietic stem cell transplantation. Other known precipitating factors were also excluded. TTP is considered an ultraorphan disease with an incidence rate of 2.1 per million. TTP is listed in the USPI for Cipro®, and the SmPC for the innovator Ciproxin® lists several manifestations of TTP (thrombocytopenia, haemolytic anaemia, convulsions, and confusion).

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Background

Description of research question	Is there evidence of an association between systemic fluoroquinolones and acquired TTP?
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Dissemination

Status	This report is finalised. The contents will be published in the EU PAS register once approved.
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Acknowledgment

IQVIA Medical Research Data (IMRD) incorporates data from THIN, A Cegedim Database. Reference made to THIN is intended to be descriptive of the data asset licensed by IQVIA.

Lay summary

Fluoroquinolone antibiotics (of which ciprofloxacin is an example) are widely used for the treatment of certain types of microbial infection. Recently, their use has been reported as being associated with the onset of Thrombotic Thrombocytopenic Purpura (TTP), a rare but potentially fatal disease that causes blood clots to form in small blood vessels throughout the body. This issue is being evaluated by the European Union's Pharmacovigilance Risk Assessment Committee (PRAC), a regulatory body responsible for assessing and monitoring the safety of human medicines.

This study simply describes how often TTP occurs after patients are prescribed fluoroquinolones. To allow contextualisation of the results, the same analysis has been done in two other groups of patients prescribed other antibiotic medicines. The first group are patients prescribed broad spectrum penicillins. The second group are patients who have been prescribed azithromycin.

The results of this study will be used by the PRAC in its decision-making process by helping to decide if regulatory action needs to be taken to protect patients taking fluoroquinolones.

1. List of abbreviations

<i>MAH</i>	<i>Marketing Authorisation Holder</i>
<i>EMA</i>	<i>European Medicines Agency</i>
<i>PRAC</i>	<i>Pharmacovigilance Risk Assessment Committee</i>
<i>RDA</i>	<i>Rapid Data Analysis</i>

2. Rationale and background

Fluoroquinolone antibiotics act by inhibiting enzymes involved in bacterial DNA synthesis. Fluoroquinolones have been used since the 1980s as broad-spectrum antibiotics with low propensity for development of antibiotic resistance.

Immune-mediated thrombocytopenia is a known rare adverse reaction to fluoroquinolones [1-5]

Thrombotic thrombocytopenic purpura (TTP) is a rare disease that is associated with microangiopathy, haemolytic anaemia, thrombosis and thrombocytopenia. Although the exact cause of TTP is not known it is associated with a deficiency of the von Willebrand factor cleaving protease ADAMTS13, allowing large complexes of von Willebrand factor to circulate in the blood. TTP exists in a congenital form and in an acquired form. The acquired form is caused by antibody to ADAMTS13.

The signal originates from a review of case reports within EudraVigilance and signal detection based on disproportionality.

The review identified 5 well documented literature reports of TTP for ciprofloxacin. The time to onset was <21 days (4 days, 5 days and 13 days). None of the patients had a history of malignancy or haematopoietic stem cell transplantation. Other known precipitating factors were also excluded.

TTP is considered an ultraorphan disease with an incidence rate of 2.1 per million.

TTP is listed in the USPI for Cipro®, and the SmPC for the innovator Ciproxin® lists several manifestations of TTP (thrombocytopenia, haemolytic anaemia, convulsions, and confusion).

3. Research question and objectives

Is there evidence of an association between systemic fluoroquinolones and acquired TTP? (i.e. is there an increased frequency of acquired TTP following treatment with fluoroquinolones?)

4. Research method

4.1. Study design

A descriptive comparative incident cohort design was used where the incidence of TTP in patients initiating systemic fluoroquinolone treatment is compared to broad spectrum penicillins. A separate analysis compared patients initiating systemic fluoroquinolones with patients initiating azithromycin.

We identified patients with a first prescription for either a systemic fluoroquinolone or a systemic broad-spectrum penicillin (or azithromycin) and a minimum look-back period of at least one year at the time of the first prescription. Only the first prescription date for either of the two types of antibiotics was considered. Patients with a concomitant first prescription for both a systemic fluoroquinolone and

a systemic broad-spectrum penicillin (or azithromycin), and patients with a history of TTP were excluded.

Patients were followed for a maximum of 30 days (a sensitivity analysis followed patients up to 60 days) and any occurrence of TTP during this time period was recorded. The 60-day sensitivity analysis was done to allow time for the recording of what is a secondary care diagnosis in the primary care databases. Patients with a history of HIV, disseminated intravascular coagulation (DIC) or haemolytic-uremic syndrome (HUS) were excluded as these conditions can lead to TTP. The follow-up of the patients was the earliest of:

- A TTP outcome event
- End of follow-up (30 or 60 days)
- Use of the alternative treatment (from a fluoroquinolone to a broad-spectrum penicillin and vice versa)
- Occurrence of HIV, DIC or HUS
- End of observation (patient no longer observable in the database)

4.2. Setting

The settings were GP practices (in IMRD-UK) and GP and specialist practices (in IMS® Disease Analyzer Germany).

4.3. Variables

4.3.1. Exposure variables

4.3.1.1. Systemic fluoroquinolones

Systemic fluoroquinolones (oral, parenteral, inhalation) in WHO ATC class J01MA (Fluoroquinolones) were included. Following correspondence from the PRAC secretariat, the scope of the signal was restricted to the following: moxifloxacin, ofloxacin, pefloxacin, prufloxacin, rufloxacin, lomefloxacin, levofloxacin, norfloxacin, delafloxacin and ciprofloxacin. In IMS® Disease Analyzer Germany medicines the relevant products were identified using the EphMRA ATC code J01G (systemic fluoroquinolones). In IMRD-UK systemic fluoroquinolones were identified by ATC class (J01M A) and by searching generic drug names in the database.

The list of identified systemic fluoroquinolone products in IMS® Disease Analyzer Germany is shown in Annex 1. The list of identified systemic fluoroquinolone products in IMRD-UK is in Annex 2.

4.3.1.2. Systemic broad-spectrum penicillins

Systemic broad-spectrum penicillins in WHO ATC class J01CA and J01CR (Combinations of penicillins, including beta-lactamase inhibitors) were included. In IMS® Disease Analyzer Germany medicines the relevant products were identified using the EphMRA ATC code J01C (broad spectrum penicillins). In IMRD-UK systemic broad-spectrum penicillins were identified using ATC code "J01C A" OR "J01C R".

The list of identified systemic broad-spectrum penicillins in IMS® Disease Analyzer Germany is shown in Annex 3. The list of identified systemic broad-spectrum penicillin products in IMRD-UK is in Annex 4.

4.3.1.3. Azithromycin

Systemic azithromycin preparations with the WHO code J01FA10 were used. In IMS® Disease Analyzer Germany medicines the relevant products were identified using the EphMRA ATC code J01F (macrolides and similar types) and selecting the molecule 'azithromycin' (Annex 5). In IMRD-UK systemic broad-spectrum penicillins were identified using ATC code "J01F A10" (Annex 6).

4.3.2. Outcome variables

TTP was identified using ICD 10 code M31.1 (Thrombotic microangiopathy) in IMS® Disease Analyzer Germany. In a sensitivity analysis, the ICD10 code D59.4 (Other nonautoimmune haemolytic anaemias) was added to this.

In IMRD-UK TTP was identified through the use of Read codes corresponding to ICD10 code M31.1:

- G756.00 "Thrombotic microangiopathy";
- G756000 "Moschowitz syndrome";
- G756100 "Thrombotic thrombocytopenic purpura";
- G756z00 "Thrombotic microangiopathy NOS"

In a sensitivity analysis, Read codes corresponding to ICD10 code D59.4 were also included:

- D111.00 Non-autoimmune haemolytic anaemia
- D111000 Mechanical haemolytic anaemia
- D111100 "Microangiopathic haemolytic anaemia";
- D111200 Toxic haemolytic anaemia
- D111y00 Other specified non-autoimmune haemolytic anaemia
- D111z00 Non-autoimmune haemolytic anaemia NOS

4.3.3. Variables for exclusion of patients

4.3.3.1. HIV

In IMS® Disease Analyzer Germany HIV will be identified using ICD 10 codes B20-B24. In IMRD-UK HIV was identified using codes Read codes starting "A788...", "A789...", "AyuC" or by Read codes "43C3.11", "Eu02400" or "L179.00".

4.3.3.2. Disseminated intravascular coagulation (DIC)

In IMS® Disease Analyzer Germany DIC was identified using the ICD 10 code D65. In IMRD-UK DIC was identified using Read code D306.12 "Disseminated intravascular coagulation".

4.3.3.3. Haemolytic-uremic syndrome (HUS)

In IMS® Disease Analyzer Germany DIC was identified using the ICD 10 code D59.3. In IMRD-UK HUS was identified using Read code D111300 "Haemolytic-uraemic syndrome"

4.4. Data sources

4.4.1. IMS® Disease Analyzer Germany

IMS® Disease Analyzer Germany (IMS Germany) version December 2020 was used for the analysis. IMS Germany collects computerised information from specialised and general primary care practices throughout Germany since 1992. Around 3% of GP practices are included in IMS Germany from the different regions in Germany. Data from IMS Germany have been shown to be reasonably representative of German healthcare statistics for demographics and certain diseases [1, 2]. This study included all practices prescribing the antibiotics of interest and was not restricted to GP practices only.

Diagnoses are coded using WHO ICD 10 codes, and prescriptions are coded using EphMRA ATC codes and substance names.

4.4.2. IMRD-UK

IMRD-UK contains longitudinal electronic patient records extracted from the VISION practice management software, which has been contributed to by > 790 general practices across the United Kingdom covering up to 6% of the UK population. Data are largely representative of the UK population in terms of age, sex, deprivation status, and geographic distribution. It contains GP prescriptions with medicinal products identified through a bespoke system of drug codes linked to generic drug names (substance names) or a substitute thereof in a drug and device dictionary. Records are available from 1986 onwards. Version 2101 (January 2021) was used.

GPs play a gatekeeper role in the healthcare system in the UK, as they are responsible for delivering primary health care and specialist referrals. Over 98% of the UK-resident population is registered with a GP, so that GP patient records are broadly representative of the UK population in general. Patients are affiliated to a practice, which centralizes the medical information from GPs, specialist referrals, hospitalizations, and tests.

4.5. Study size

The study was not limited in size. All patients that fulfilled the criteria for inclusion were studied.

4.6. Data management)

All analyses will be carried out using SAS Enterprise Guide version 7.15. Results from IMS® Disease Analyzer Germany were also validated using the Instant Health Data (IHD) software by Panalgo.

4.7. Data analysis

The incidence rate of TTP was calculated from the number of patients with TTP during the follow-up period and the total follow-up time in years of follow-up in each of the two treatment groups. The 95% confidence intervals for the incidence rates were calculated.

Incidence rate = number of patients with TTP ÷ person-time of follow-up in years

In addition, the treatment groups were compared in terms of age and gender structure (percentage of males/females, mean age, median age).

For IMRD-UK the study period was limited to the years 2000 onwards as the TTP diagnosis was seldom used before that date.

For both IMS® Disease Analyzer Germany and IMRD-UK, patients with a history of conditions known to be associated with TTP were excluded. These were HIV, Disseminated Intravascular Coagulation (DIC) and Haemolytic Uremic Syndrome (HUS).

There were a low number of events in the relatively short time windows following exposure: this necessitated the pooling of the results from the German and UK data to prevent the display of low cell counts that could be attributed to either source.

4.8. Quality control

The quality of IMS® Disease Analyzer data is ensured by a series of continuous QA controls and data refinement. These include checking incoming data for criteria such as completeness and correctness, (e.g. linkage between diagnoses and prescriptions), and standardizing certain data values such as laboratory test results in order to enable reliable analysis.

IMRD-UK contains a number of flags indicating potential data issues in the patient, practice, prescribing and clinical (diagnosis) datasets. Analyses were restricted to data that were “acceptable” and practices were only included once they reach the Acceptable Mortality Reporting (AMR) date.

4.9. Protection of human subjects

IMS® Disease Analyzer Germany is a de-anonymized database with electronic health records. No ethics committee approval is required. For IMRD-UK a study protocol must be approved by the Scientific Review Committee (SRC) and the final report approved by IQVIA before the results can be put in the public domain. In doing this, consideration is given to both the scientific validity of the proposal and data privacy, with low cell counts (1-5) being suppressed to prevent identification of individuals. As low numbers of events have been observed, the results of the analysis have been pooled across the two datasets to avoid displaying any low cell counts attributable to any single data source.

5. Results

5.1. fluoroquinolones vs broad-spectrum penicillin

In IMS Germany, a total of 2,959,104 patients received a prescription for a fluoroquinolone (moxifloxacin, ofloxacin, pefloxacin, levofloxacin, norfloxacin, or ciprofloxacin) or a broad-spectrum penicillin. On the date of the first prescription a total of 1,263,587 patients had received a fluoroquinolone and 1,699,547 had received a broad-spectrum penicillin (4,030 patients were prescribed both on the same day). A total of 1,583,234 patients were incident users (n=690,435 for fluoroquinolones and n=894,840 for broad-spectrum penicillins). Of these patients 2,041 had initiated treatment with both a fluoroquinolone and a broad-spectrum penicillin leaving 1,581,193 patients that initiated treatment with either a fluoroquinolone (n=688,394) or a broad-spectrum penicillin (n=892,799) but not both. A total of 1,344 patients were then excluded due to a history of HIV, disseminated intravascular coagulation or haemolytic-uremic syndrome and a further 252 patients were excluded due to a prior history of TTP (narrow or broad definition; for ease of analysis both definitions were used to exclude patients prior to start of treatment).

In IMRD-UK a total of 5,236,884 patients had received a fluoroquinolone (moxifloxacin, ofloxacin, levofloxacin, norfloxacin, or ciprofloxacin) or broad-spectrum penicillin. On the date of the first prescription a total of 308,867 patients had received a fluoroquinolone and 4,928,017 had received a broad-spectrum penicillin. A total of 3,002,249 patients were incident users (n= 218,519 for

fluoroquinolones and n= 2,783,730 for broad-spectrum penicillins). Of these patients 1,140 had initiated treatment with both a fluoroquinolone and a broad-spectrum penicillin on the same day. A total of 1,778 patients were then excluded due to a history of HIV, disseminated intravascular coagulation or haemolytic-uremic syndrome and a further 33 patients were excluded due to a prior history of TTP (narrow definition). The final study cohort consisted of 3,000,438 patients, 218,339 with a first exposure to fluoroquinolones and 2,782,099 with first exposure to broad spectrum penicillins.

The overall number of incident cases, pooled from both data sources, and the incidence rate of TTP outcome events during 30 and 60 days of follow-up is shown in Tables 1 and 2 below.

Table 1. Events of thrombotic thrombocytopenic purpura (TTP) during 30 days of follow-up for fluoroquinolone antibiotics vs. broad-spectrum penicillins (pooled analysis from IMRD-UK and IMD Disease Analyser)

Antibiotic	Total no of patients	Follow-up time in years	No of outcome events	Incidence rate per 100,000 PY (95% CI)
Pooled analysis				
Fluoroquinolone	905,910	69,760	6	8.60 (3.16-18.7)
Broad-spectrum penicillin	3,674,125	292,799	3	1.02 (0.21-2.99)

Table 2. Events of thrombotic thrombocytopenic purpura (TTP) during 60 days of follow-up for fluoroquinolone antibiotics vs. broad-spectrum penicillins (pooled analysis from IMRD-UK and IMD Disease Analyser)

Antibiotic	Total no of patients	Follow-up time in years	No of outcome events	Incidence rate per 100,000 PY (95% CI)
Pooled analysis				
Fluoroquinolone	905,910	137,621	10	7.27 (3.48-13.36)
Broad-spectrum penicillin	3,674,125	580,915	8	1.38 (0.59-2.71)

Patients treated with fluoroquinolones were older than patients treated with broad-spectrum penicillins and had a higher proportion of female vs. male patients (Table 3).

Table 3. Gender and age distribution in patients treated with fluoroquinolones and broad-spectrum penicillins

	Fluoroquinolones	Broad-spectrum penicillin
IMS Germany		
Female/Male gender	398,642/287,885	465,401/425,536
Mean age in years (SD)	55.77 (19.18)	36.26 (25.51)
Median age in years (IQR)	57 (42-71)	35 (12-57)
IMRD-UK		
Female/Male gender	105,221/113,118	1,482,715/1,299,384
Mean age in years (SD)	52.2 (19.5)	38.4 (24.8)
Median age in years (IQR)	51 (37-67)	38 (18-57)

5.2. First prescription for fluoroquinolone or azithromycin

In IMS Germany, a total of 1,999,144 patients received a prescription for fluoroquinolone (moxifloxacin, ofloxacin, pefloxacin, levofloxacin, norfloxacin, or ciprofloxacin) or azithromycin. On the date of the first prescription a total of 1,330,685 patients had received fluoroquinolone and 669,098 had received azithromycin (639 had received both). A total of 1,161,521 patients were incident users (n=746,179 for fluoroquinolones and n=415,615 for azithromycin). Of these patients 273 had initiated treatment with both a fluoroquinolone and azithromycin leaving 1,161,248 patients that initiated treatment with either a fluoroquinolone (n=745,906) or azithromycin (n=415,342) but not both. A total of 1157 patients were then excluded due to a history of HIV, disseminated intravascular coagulation or haemolytic-uremic syndrome and a further 187 patients were excluded due to a prior history of TTP (narrow or broad definition).

In IMRD-UK a total of 918,491 patients had received a fluoroquinolone (moxifloxacin, ofloxacin, levofloxacin, norfloxacin, or ciprofloxacin) or azithromycin. On the date of the first prescription a total of 788,156 patients had received a fluoroquinolone and 130,335 had received azithromycin. A total of 779,326 patients were incident users (n= 672,064 for fluoroquinolones and n= 107,262 for azithromycin). Of these patients 699 had initiated treatment with both a fluoroquinolone and azithromycin on the same day. A total of 642 patients were then excluded due to a history of HIV, disseminated intravascular coagulation or haemolytic-uremic syndrome and a further 16 patients were excluded due to a prior history of TTP (narrow definition). The final study cohort consisted of 778,668 patients, 671,517 with a first exposure to fluoroquinolones and 107,151 with first exposure to azithromycin.

The overall number of incident cases and the incidence rate of TTP outcome events during 30 and 60 days of follow-up is shown in Tables 4 and 5 below. Patients treated with fluoroquinolones were older than patients treated with azithromycin (Table 6).

Table 4. Events of thrombotic thrombocytopenic purpura (TTP) during 30 days of follow-up for fluoroquinolone antibiotics vs. azithromycin (pooled analysis from IMRD-UK and IMD Disease Analyser)

Antibiotic	Total no of patients	Follow-up time in years	No of outcome events	Incidence rate per 100,000 PY (95% CI)
Pooled analysis				
Fluoroquinolone	1,416,532	111,536	8	7.17(3.10-14.13)
Azithromycin	522,040	40,061	1	2.50(0.06-13.91)

Table 5. Events of thrombotic thrombocytopenic purpura (TTP) during 60 days of follow-up for fluoroquinolone antibiotics vs. azithromycin (pooled analysis from IMRD-UK and IMD Disease Analyser)

Antibiotic	Total no of patients	Follow-up time in years	No of outcome events	Incidence rate per 100,000 PY (95% CI)
Pooled analysis				
Fluoroquinolone	1,416,532	220,965	12	5.43 (2.81-9.49)
Azithromycin	522,040	79,388	3	3.78 (0.78-11.04)

Table 6. Gender and age distribution in patients treated with fluoroquinolones and azithromycin

	Fluoroquinolones	Azithromycin
IMS Germany		
Female/Male gender	428,618/315,170	225,918/188,633
Mean age in years (SD)	55.74 (19.29)	37.95 (22.04)
Median age in years (IQR)	57 (42-72)	37 (20-54)
IMRD-UK		
Female/Male gender	342,657/328,860	64,766/42,385
Mean age in years (SD)	54.2 (20.1)	34.1 (22.7)
Median age in years (IQR)	55 (39-70)	27 (19-49)

5.3. Sensitivity analysis

The sensitivity analysis that used a broader range of outcome codes had no impact on the results, with the addition endpoints not occurring in any patients during the 30- or 60-days windows following exposure to fluoroquinolones, broad spectrum penicillin or azithromycin.

6. Limitations of the research methods

6.1. General limitations

The scarcity of the outcome and the short duration of the exposure windows of interest (30 and 60 days) means that single numbers of events were observed in the databases. Such low cell counts have required the results of the analyses to be pooled to prevent identification of individuals. The analysis performed was simplistic and because of the low number of events was not able to adjust for confounding. It also required pooling of potentially heterogeneous data from two countries, although the low number involved made this hard to formally assess. However, it is highly likely that there are differences in the populations exposed: for example it is noted that for both data sources the mean age of the fluoroquinolone exposed patients was 15-20 years older than for the comparators and this age difference was not adjusted for in the analysis: as such, there is a high risk of residual confounding, taking the age distribution of patients with TTP into account. It should be noted that the purpose of the comparator cohort is not to make a statistical inference, but to provide context to the comparators. There is no expectation that the results should be interpreted as implying a causal association between fluoroquinolones (or the other drugs considered) and TTP.

Given that the drugs being studied might be used to treat the symptoms of the condition under investigation as TTP can be associated with infection, there is risk of protopathic bias (reverse causation). In addition, we are not aware that the recording of TTP and related diagnoses has been validated in primary care databases. Given that it is a diagnosis that would be expected to require specialist input, it is possible that ascertainment of the outcome is incomplete.

6.2. IMS® Disease Analyzer Germany

In Germany the patient has free physician choice: in IMS Germany patients can only be followed for as long as they continue to visit the same physician as patients are not identifiable across physician practices for confidentiality reasons. Furthermore, as the patient can visit several physicians concurrently, collected data may be incomplete. Moreover, the completeness of data on outcomes may depend on the extent to which outcomes are captured in primary care vs. secondary care and TTP is a diagnosis likely to be made in secondary care.

6.3. IMRD-UK

IMRD-UK holds primary-care electronic healthcare records. TTP is a diagnosis that will very likely be made – at least in part – in secondary care. As such, the completeness of recording of this diagnosis will be dependent on primary care records being updated to reflect secondary care diagnoses. Although this would be expected for what is a serious condition, we are not aware that the diagnosis of TTP has been validated in IMRD-UK or other primary care databases in the UK.

7. Plans for disseminating and communicating study results

This study will be registered in the EU PAS Register. One approval has been provided from the data providers this report will be considered finalised and will be published on EU PAS.

8. References

1. Moore, J., et al., *Moxifloxacin-Induced Thrombocytopenia Mediated by Moxifloxacin-Dependent IgM and IgG Antiplatelet Antibodies: A Case Report*. Cureus, 2020. **12**(9): p. e10507-e10507.
2. Cheah, C.Y., B. De Keulenaer, and M.F. Leahy, *Fluoroquinolone-induced immune thrombocytopenia: a report and review*. Internal Medicine Journal, 2009. **39**(9): p. 619-623.
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4. Landi, A.J. and R. Burkes, *Probable Levofloxacin-Induced Thrombocytopenia in a Patient Previously on Ciprofloxacin: A Case Report and Literature Review*. Case Reports in Medicine, 2016. **2016**: p. 2860645.
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9. Annexes

9.1. Annex 1

List of identified systemic fluoroquinolone products in IMS® Disease Analyzer Germany

Ciprofloxacin-containing products

Product name	Therapy Numbers
BAYCIP E-M>>	GE1349170, GE1394242, GE1494065, GE2358814
BAYCIP EUP>>	GE2553057
BAYCIP KHP>>	GE1232125, GE1305289, GE243820, GE516582
BAYCIP MTK>>	GE1493960, GE377107
CIPRO BASICS	GE10149155, GE13113973, GE13272512, GE1397833, GE14062949, GE14064442, GE1427567, GE1810267, GE1836966, GE192228, GE217177, GE320730, GE94607, GE9841809
CIPRO LICH	GE209513, GE444444, GE55604, GE81641, GE82574, GE82890
CIPRO-1A PHARMA	GE364197, GE3897909, GE3904382, GE391612, GE3940781, GE3960485, GE433460, GE574133, GE6534305, GE6596280, GE7339960
CIPRO-ACIS	GE2173370, GE252921, GE25700, GE416223
CIPROBAY	GE11024143, GE1204146, GE133409, GE1403939, GE1531805, GE274270, GE285192, GE340076, GE364482, GE376328, GE392844, GE43948, GE47932, GE581444, GE6030, GE6061, GE6069, GE6070, GE6071, GE6072, GE642668
CIPROBAY AC9>>	GE1770766, GE1887673, GE1954286, GE2478572, GE3479147, GE415080, GE533857, GE620100
CIPROBAY BRA>>	GE1414409, GE1571619, GE1812579, GE2302664, GE2511517, GE2722144, GE2862948, GE3144854, GE3180038, GE3261350
CIPROBAY E-M>>	GE11468800, GE11557777, GE1188692, GE1401276, GE1423189, GE1463074, GE157901, GE1593432, GE1872256, GE212235, GE2767053, GE281552, GE37099, GE65603, GE69182, GE73495
CIPROBAY EUP>>	GE1230321, GE154614, GE1608730, GE2761899, GE278959, GE3211662, GE3260867, GE459840, GE507778, GE564126, GE578543, GE690912, GE812870, GE82309

Product name	Therapy Numbers
CIPROBAY KHP>>	GE1042753, GE1420377, GE151782, GE151828, GE154682, GE283152, GE283380, GE365748, GE682041, GE7484202, GE82906, GE9282
CIPROBAY MTK>>	GE172226, GE360676, GE382168, GE396251, GE48303, GE90133
CIPROBAY MVT>>	GE1646247, GE1646375, GE1715553, GE1954463, GE2011150, GE2011364
CIPROBAY ORI>>	GE165705, GE184005, GE225830, GE2302945, GE3407124, GE3892213, GE4021200, GE423203, GE682315, GE957687
CIPROBETA	GE11200698, GE1554906, GE268717, GE47090, GE52778, GE61985, GE68309, GE88728, GE9756029, GE9806403, GE9986865, GE9994910
CIPRODOC AD2	GE9271474, GE9273893, GE9391238, GE9392205
CIPRODOC DOC	GE1301567, GE1532520, GE2324006, GE288008
CIPRODURA	GE111022, GE154128, GE156360, GE204689, GE219026, GE51221, GE54532, GE8991718, GE9179566
CIPROFAT	GE3121416, GE3649027, GE531254, GE534123
CIPROFAT (RER)	GE10301668, GE10310677, GE10316635, GE10335001
CIPROFL.CLARIS DM+	GE9634095
CIPROFL.CLARIS P0E	GE8857124
CIPROFL.CLARIS P6M	GE14615257, GE15291218
CIPROFLO.RAT.A8K>>	GE4646599, GE4715616, GE4734816, GE4798277
CIPROFLO.RAT.E-M>>	GE5575564, GE5617714, GE5629024, GE6009485
CIPROFLO.RAT.EUP>>	GE272005, GE375437, GE436146, GE682961
CIPROFLO.RAT.ORI>>	GE5539351, GE5546040, GE5629373, GE5931174
CIPROFLOX PUREN	GE154935, GE155310, GE198392, GE208064, GE340270
CIPROFLOX TAD	GE8064140
CIPROFLOX-CT	GE10095639, GE42387, GE46171, GE46655, GE55868, GE61252
CIPROFLOX.HEU WB-	GE4197767
CIPROFLOX.HEUM.H2U	GE9217272, GE9228803, GE9268165, GE9323759
CIPROFLOX.HEUM.HEU	GE10020419, GE10116898, GE10359994, GE13685279, GE13687460, GE13767840, GE14145225, GE154409, GE193502, GE206283, GE57211, GE88172, GE9793627
CIPROFLOX.HEUM.NO&	GE10599120, GE9518016, GE9518723, GE9564220, GE9715670, GE9783595, GE9807149
CIPROFLOXA.ATV(DM+	GE10720217, GE11635277, GE7263567, GE7279210, GE7299703, GE7353774
CIPROFLOXA.DM+ ALT	GE7051350, GE7093797, GE7095294, GE7201432
CIPROFLOXA.FAIR-M	GE13649559, GE13813281, GE14005890, GE14121247, GE14168811, GE14169575, GE14239092, GE14537980, GE14822593
CIPROFLOXA.FARMAPL	GE18832937, GE18907765
CIPROFLOXAC.ACCEDO	GE5503693, GE5598045, GE5627928, GE5802370
CIPROFLOXAC.AXSAN	GE3355981
CIPROFLOXAC.HEC PH	GE15173731, GE15237529, GE15325217, GE15494390, GE15544100, GE15859033, GE15865802, GE16137850, GE16258233, GE16278007, GE16605458, GE16859423, GE16998496
CIPROFLOXAC.HIKMA	GE7333344
CIPROFLOXAC.R(DOL)	GE16211641, GE16253221, GE16540168, GE16940720, GE18519687
CIPROFLOXAC.RE.ALT	GE1471277, GE1953970, GE2013904, GE205423, GE215546, GE2491950, GE274405, GE3474687, GE491082, GE557863, GE7423961, GE7798762
CIPROFLOXAC.SANDOZ	GE10411, GE111907, GE1571448, GE212045, GE25530, GE2705674, GE85257
CIPROFLOXACI.ALMUS	GE7001064, GE7193894, GE7212995, GE7289106

Product name	Therapy Numbers
CIPROFLOXACI.STADA	GE166131, GE196623, GE19802, GE25791, GE39228, GE4523, GE5002
CIPROFLOXACIN AZU	GE148439, GE156138, GE157574, GE196699, GE420105, GE88437, GE88996
CIPROFLOXACIN BAX	GE6914321, GE7802610
CIPROFLOXACIN DO3	GE15753612, GE15957233
CIPROFLOXACIN EBH	GE6265649, GE6415659, GE6603435, GE7432698
CIPROFLOXACIN KSK	GE1000999, GE153167, GE209994, GE4495784, GE4535470, GE4678637, GE729815
CIPROFLOXACIN SOH	GE1463949, GE29505, GE3500138, GE364154, GE37078, GE442454, GE63004
CIPROFLOXACIN ABZ	GE1201399, GE508609, GE5295586, GE5870804, GE790495, GE852267
CIPROFLOXACIN AL	GE16439928, GE16468625, GE16525851, GE16637598, GE16649513, GE176882, GE1812764, GE1865273, GE200958, GE26755, GE278680, GE302029
CIPROFLOXACIN ARIS	GE5217268, GE8744236, GE8808568, GE8812771, GE8844263, GE8854385, GE8991668, GE9047673, GE9178752, GE9217441
CIPROFLOXACIN AURU	GE10045612, GE8325464, GE8407836, GE8595655, GE8609709, GE9034186, GE9173942, GE9180497, GE9237325, GE9243674, GE9934092
CIPROFLOXACIN AWD	GE2793446, GE327866, GE3610, GE445039
CIPROFLOXACIN AXC.	GE10012776, GE10229410, GE4240678, GE4276050, GE4288432, GE4352048, GE9874932, GE9937759
CIPROFLOXACIN KABI	GE11430859, GE5704929, GE6988192, GE8658027, GE9480638
CIPROFLOXACIN NORM	GE16275170, GE16941188
CIPROFLOXACIN TAD	GE153855, GE160090, GE174588, GE195678, GE195690
CIPROFLOXACIN TEVA	GE12198510, GE14390642
CIPROFLOXACIN-BIOM	GE6683619, GE6687578, GE6734611, GE6760805, GE6806297, GE6902179, GE7291124
CIPROFLOXACIN-CHEP	GE8098976, GE8120145
CIPROFLOXACIN-RAT.	GE13965, GE15604018, GE340044, GE38474, GE423523, GE45762, GE49359, GE56930, GE9924530
CIPROFLOXACIN-UROP	GE2786718, GE2786720, GE921649, GE965870
CIPROGAMMA	GE326548, GE369292, GE419267, GE42389, GE569431
CIPROHEXAL	GE10107619, GE154206, GE222415, GE34479, GE3771925, GE3778815, GE3780092, GE3791537, GE5579569, GE5869478, GE5887828, GE61808, GE75556, GE85346, GE86914, GE9914949
CIPROVERT	GE11552419
CIPROX	GE2330954, GE2722825, GE2956902, GE377069
CIPROXIN KHP>>	GE843554, GE970419, GE970479
GYRACIP	GE1043020, GE1387745, GE1832656, GE305476, GE3861205, GE691011, GE7315258, GE7326830, GE7431850, GE7576234, GE7908148
GYRASTOP	GE1700909, GE198506, GE198523, GE244725, GE333684, GE505295
INFECTOCIPRO	GE4808601, GE4818886, GE4832726, GE4985514, GE6772769, GE7258635, GE7279430, GE7528677
KECIFLOX	GE1191625, GE1202421, GE213686, GE27306, GE365795, GE51983, GE91036
UTIMINX	GE9432753

Levofloxacin-containing products

Product name	Therapy Numbers
LEVITIS	GE14800131, GE18406075

Product name	Therapy Numbers
LEVOFLOX-CT	GE10718816, GE10719797, GE10725450, GE10725677, GE10725905, GE10734301, GE10740790
LEVOFLOX-DENK	GE17186234
LEVOFLOX-HEC	GE17780211, GE17847224, GE17872806, GE17940543, GE18033296, GE18149890
LEVOFLOXA.MACL.MA5	GE19163237
LEVOFLOXAC.HEC PH.	GE15130904, GE15151009, GE15250781, GE15450562, GE15888675, GE15940333, GE19577376, GE19604955, GE19712535, GE19744621, GE19760811, GE19802049
LEVOFLOXACIN DO3	GE15429707
LEVOFLOXACIN ABZ	GE10720939, GE10744058, GE10752974
LEVOFLOXACIN AL	GE10541423, GE10549904, GE10568290, GE10643015, GE10708668, GE10740288, GE10745649
LEVOFLOXACIN AMNEA	GE18737469
LEVOFLOXACIN ARIST	GE11613163, GE11614494, GE11628998, GE11632390, GE11636771, GE11706466, GE12086094
LEVOFLOXACIN AUROB	GE12736580, GE12789790, GE12895938, GE13318876, GE13574811, GE13594643, GE13937001
LEVOFLOXACIN BLUEF	GE10964400, GE10970720, GE11039529, GE11344865, GE11469657, GE11808564, GE5385177
LEVOFLOXACIN DENK	GE11049285, GE11176193, GE14392235, GE14494281
LEVOFLOXACIN DURA	GE10725837, GE10740622, GE10783859, GE10783860, GE10811531, GE10960672
LEVOFLOXACIN EBER.	GE10895041, GE16861117, GE17785433, GE18751336
LEVOFLOXACIN HEUM.	GE10546907, GE10573505, GE10593715, GE10594310, GE10647645, GE13822239, GE5385402
LEVOFLOXACIN HEXAL	GE10540968, GE10541479, GE10542604, GE10545173, GE10545709, GE10546135, GE10558218, GE10977016, GE12709557
LEVOFLOXACIN HOSPI	GE15374365
LEVOFLOXACIN IBISQ	GE16328413, GE19643320
LEVOFLOXACIN KABI	GE10931563, GE13805740
LEVOFLOXACIN RATIO	GE10544630, GE10546872, GE10556233, GE10563154, GE10575993, GE11255998, GE5227610
LEVOFLOXACIN STADA	GE10552809, GE10554028, GE10562553, GE10563734, GE10567359, GE10585263, GE5328015
LEVOFLOXACIN-1A PH	GE10540761, GE10578083, GE10581859, GE10607712, GE10630439, GE11069242, GE1943847, GE5417627, GE5419182
LEVOFLOXACIN-ACTAV	GE10558593, GE10769207, GE10783208, GE10836152, GE10875260, GE11054260, GE11181161, GE11710356, GE14646899
LEVOFLOXACIN-HAMEL	GE16149942
QUINSAIR ALT	GE16138296
QUINSAIR (HZP)	GE16862996
QUINSAIR KHP>>	GE19544060
TAVANIC	GE1305645, GE1344642, GE164078, GE2202065, GE2250323, GE272013, GE28770, GE29645, GE29723, GE53755, GE6969, GE71420, GE911
TAVANIC E-M>>	GE2437943
TAVANIC MZG>>	GE2094563

Moxifloxacin-containing products

Product name		Therapy Numbers
ACTIMAX		GE1504895, GE34571, GE49330, GE524016
ACTIRA	E-M>>	GE9042453, GE9364145, GE9466882
ACTIRA	EUP>>	GE10244393, GE7808347
ACTIRA	KHP>>	GE8717259, GE8981167
AVALOX		GE109528, GE1528285, GE185001, GE3062, GE4529686
AVALOX	A4X>>	GE6791138, GE6795921, GE8640809
AVALOX	AC9>>	GE8769227, GE8817258
AVALOX	BRA>>	GE4488895, GE4585926, GE4625312
AVALOX	CC4>>	GE10469976, GE10583714, GE12676670, GE16635844, GE16646303, GE16723293
AVALOX	E-M>>	GE6024978, GE6091224, GE6281637
AVALOX	EUP>>	GE3727491, GE3788080, GE3882617
AVALOX	GRK>>	GE13208246, GE13253669, GE13254619
AVALOX	KHP>>	GE1387750, GE261822, GE4098087
AVALOX	ML8>>	GE10047820, GE10051703, GE10083955
AVALOX	MVT>>	GE6696290, GE6731581, GE6767937
AVALOX	ORI>>	GE3710516, GE3714400, GE3762985
AVELOX	A4X>>	GE7870026, GE7904917
AVELOX	AC9>>	GE10202987, GE9930096, GE9999569
AVELOX	CC4>>	GE10429954, GE10805408, GE10903707
AVELOX	E-M>>	GE3675705, GE3680147, GE7663979
AVELOX	EUP>>	GE8814372, GE8865263, GE9696687
AVELOX	GRK>>	GE13183298, GE13602170, GE13697583
AVELOX	KHP>>	GE3675688, GE3904705, GE4071115
AVELOX	ORI>>	GE4455909, GE4563642, GE5688675
MOXIFLOX.NORID.DO3		GE15998726
MOXIFLOX.STADA AM6		GE14329018
MOXIFLOX.STADA SAD		GE14282575, GE14490320, GE14560569, GE16213160
MOXIFLOXAC.HEC PH.		GE16244725, GE16250102, GE16264627, GE16267050, GE16342380, GE16541309
MOXIFLOXACIN ABZ		GE14367206, GE14375216, GE14389505, GE14469092
MOXIFLOXACIN AL		GE14283431, GE14344915, GE14487803
MOXIFLOXACIN ARIST		GE10284755, GE18904969, GE18913095, GE18950336
MOXIFLOXACIN AUROB		GE14159394, GE14269577, GE15459991
MOXIFLOXACIN HEUM.		GE14456054, GE14456288, GE14532119, GE19693780, GE19773954
MOXIFLOXACIN HEXAL		GE14362023, GE14371378, GE14528708, GE14921291
MOXIFLOXACIN HOLST		GE16753373, GE16877292, GE16976922, GE19878886
MOXIFLOXACIN IBISQ		GE15234094
MOXIFLOXACIN INRES		GE16143672, GE18325357
MOXIFLOXACIN KABI		GE16439751
MOXIFLOXACIN M.LAB		GE17389120
MOXIFLOXACIN PUREN		GE16508214, GE16543376, GE16737169, GE19528199
MOXIFLOXACIN TAD		GE14277758, GE14292947, GE14312910
MOXIFLOXACIN TILL.		GE18827333, GE18896187, GE19798192, GE19884778
MOXIFLOXACIN-1A PH		GE14288018, GE14296985, GE14302319, GE16811211
MOXIFLOXACIN-ACTAV		GE14254441, GE14272829, GE14278080

Product name	Therapy Numbers
MOXIFLOXACIN-RATIO	GE14287213, GE14298590, GE14428369, GE14503997

Ofloxacin-containing products

Product name	Therapy Numbers
GYROFLOX	GE215375, GE2357008, GE2422041, GE257033, GE2821792, GE2956447
OFLO TAD	GE1631108, GE1894928, GE7978082
OFLODURA	GE155309, GE155843, GE183734, GE264535, GE379326, GE51214
OFLOHEXAL	GE157056, GE1592667, GE159511, GE160692, GE450840
OFLOX AZU	GE149410, GE338357, GE89696
OFLOX BASICS	GE338767, GE373951, GE420185, GE450867, GE47847, GE88950, GE9725745
OFLOX CT	GE422344, GE46061, GE46250, GE56868, GE83727
OFLOX PUREN	GE1704593, GE1954632, GE2160507
OFLOX SANDOZ	GE116671, GE302287, GE434672, GE653590
OFLOX-WOLFF	GE1955400, GE1993936, GE2011484
OFLOXACIN SOH	GE100760, GE113308, GE1880252, GE2814215, GE430233, GE64595
OFLOXACIN ABZ	GE128656, GE1508955, GE1582655, GE1604389
OFLOXACIN AL	GE106225, GE1405562, GE154084, GE155842, GE1776916
OFLOXACIN BILLIX	GE8769762, GE8850437, GE9907700
OFLOXACIN HEUMANN	GE2440630, GE326225, GE3867429, GE450285, GE670217, GE8694187, GE8710793, GE8752136
OFLOXACIN HOECHST	GE1647920, GE375640
OFLOXACIN STADA	GE153383, GE338687, GE338704, GE46211, GE48110, GE65708
OFLOXACIN-1A PHARM	GE4430778, GE4459752, GE4484948, GE4488411, GE4524467
OFLOXACIN-RA.E-M>>	GE5542379, GE5659204, GE5734471, GE6599201
OFLOXACIN-RA.EUP>>	GE4439258, GE4467045, GE4522220, GE4539829, GE4995365, GE6336044
OFLOXACIN-RATIOPH.	GE152796, GE16308, GE22371, GE301431, GE30263, GE46382, GE498104, GE56837
OFLOXACINE-R.E-M>>	GE5560589, GE5898113
OFLOXBETA	GE264489, GE372990, GE400932
SURNOX KHP>>	GE1538794, GE1647440, GE1646777
TARIVID	GE1061624, GE1181020, GE1420948, GE144076, GE205278, GE28607, GE28608, GE28609, GE34103, GE715455
TARIVID A+S>>	GE360779, GE528294
TARIVID A1H>>	GE1040197, GE1040565, GE1050169
TARIVID AC9>>	GE1195056, GE350078, GE72209
TARIVID ARW>>	GE743007, GE892008
TARIVID BRA>>	GE536912, GE536913, GE848334
TARIVID CM/>>	GE1772467, GE2439873
TARIVID E-M>>	GE1516637, GE155432, GE160342, GE503624, GE573230, GE982006
TARIVID EUP>>	GE1296603, GE1329540, GE284589, GE536797, GE536910, GE568475
TARIVID GPP>>	GE1215181, GE379327, GE429601
TARIVID GRK>>	GE391869, GE893123
TARIVID GWL>>	GE434936, GE456564, GE536819
TARIVID KHP>>	GE113961, GE116677, GE156285, GE340200, GE71032
TARIVID ME->>	GE1439368, GE266719

Product name		Therapy Numbers
TARIVID	MTK>>	GE172384, GE63743, GE707764
TARIVID	MVT>>	GE1023179, GE703510
TARIVID	ORI>>	GE229211, GE847236
TARIVID	OTI>>	GE1166312, GE468863, GE980984
TARIVID	PW9>>	GE1099510
TARIVID	REA>>	GE1016448
TARIVID	SVP>>	GE1297359, GE536798
URO TARIVID		GE107959

Norfloxacin-containing products

Product name		Therapy Numbers
BACTRACID		GE29315, GE432600, GE4962
BARAZAN	(MSD)	GE4620599, GE4779163, GE4822247
BARAZAN	(DKM)ALT	GE120352, GE80846, GE80847
BARAZAN	(MSD)ALT	GE3555, GE3556, GE3557
FIRIN		GE11375, GE19367, GE254566, GE395965
NORFLOHEXAL		GE379604, GE46132, GE53652, GE8695
NORFLOSAL		GE191750, GE3178, GE432658, GE93466
NORFLOX	AZU	GE254516, GE260168, GE340175, GE395583
NORFLOX	URM	GE209900, GE422876, GE45482
NORFLOX CT		GE1384813, GE170280, GE187390
NORFLOX PUREN		GE106009, GE208105, GE508836
NORFLOX SANDOZ		GE1365424, GE3369537, GE365992, GE91863
NORFLOX-1A PHARMA		GE11140220, GE152664, GE37342, GE421741
NORFLOXA.RAT.E-M>>		GE6070057, GE6230202, GE6279890
NORFLOXA.RAT.EUP>>		GE4436476, GE4496043, GE4530694
NORFLOXACIN	ACS	GE1192038, GE368422
NORFLOXACIN	SOH	GE357327, GE47697, GE832638
NORFLOXACIN	ABZ	GE10092783, GE269514, GE89309
NORFLOXACIN	AL	GE16648914, GE207287, GE278163, GE334067
NORFLOXACIN	HEUM.	GE507959, GE508864, GE516178
NORFLOXACIN	STADA	GE1208482, GE232262, GE254446, GE415708
NORFLOXACIN-1A PH.		GE16393270, GE16449601, GE16473964
NORFLOXACIN-RATIO.		GE12744, GE443430, GE89797
NORFLOXBETA		GE153384
NORFLUXX		GE263716, GE362872, GE740076

Remaining fluoroquinolone products

Molecule	Product name	Therapy Numbers
Enoxacin	ENOXOR	GE27723, GE27834
Enoxacin	GYRAMID	GE13861, GE13864, GE13865, GE13866
Fleroxacin	QUINODIS	GE414986, GE503587, GE506987, GE800581
Gatifloxacin	BONOQ	GE170878, GE195647, GE195650, GE210032

Molecule	Product name	Therapy Numbers
Grepafoxacin	VAXAR	GE1053611, GE1053615, GE1053616, GE1065395
Pefloxacin	PEFLACIN	GE276695
Sparfloxacin	ZAGAM	GE1185833
Temafoxacin	TEFLOX	GE250582, GE250586, GE250587, GE250590, GE259469
Trovafoxacin	TROVAN	GE1166055, GE1166159

9.2. Annex 2

List of identified systemic fluoroquinolone products in IMRD-UK

Drugcode	Generic name
93079997	Ciprofloxacin 100mg tablets
93080997	Ciprofloxacin 100mg tablets
95686990	Ciprofloxacin 100mg tablets
96045990	Ciprofloxacin 100mg tablets
87680998	Ciprofloxacin 100mg/50ml solution for infusion bottles
87683998	Ciprofloxacin 100mg/50ml solution for infusion vials
69636979	Ciprofloxacin 100mg/5ml oral suspension
69628979	Ciprofloxacin 170mg/5ml oral suspension
84063998	Ciprofloxacin 200mg/100ml infusion bags
87679998	Ciprofloxacin 200mg/100ml infusion bags
87682998	Ciprofloxacin 200mg/100ml infusion bags
91225998	Ciprofloxacin 200mg/100ml infusion bags
94912997	Ciprofloxacin 200mg/100ml infusion bags
94913997	Ciprofloxacin 200mg/100ml infusion bags
61014979	Ciprofloxacin 250mg tablets
93870979	Ciprofloxacin 250mg tablets
94912998	Ciprofloxacin 250mg tablets
94913998	Ciprofloxacin 250mg tablets
95212990	Ciprofloxacin 250mg tablets
95430990	Ciprofloxacin 250mg tablets
95629990	Ciprofloxacin 250mg tablets
95823990	Ciprofloxacin 250mg tablets
95867990	Ciprofloxacin 250mg tablets
95948990	Ciprofloxacin 250mg tablets
96024990	Ciprofloxacin 250mg tablets
96044990	Ciprofloxacin 250mg tablets
96049990	Ciprofloxacin 250mg tablets
96052990	Ciprofloxacin 250mg tablets
96058990	Ciprofloxacin 250mg tablets
96067990	Ciprofloxacin 250mg tablets
93079996	Ciprofloxacin 250mg/5ml oral suspension
93080996	Ciprofloxacin 250mg/5ml oral suspension
69622979	Ciprofloxacin 375mg/5ml oral suspension
71174979	Ciprofloxacin 400mg/200ml infusion bags
78929979	Ciprofloxacin 400mg/200ml infusion bags
78930979	Ciprofloxacin 400mg/200ml infusion bags
84062998	Ciprofloxacin 400mg/200ml infusion bags
87681998	Ciprofloxacin 400mg/200ml infusion bags
89122998	Ciprofloxacin 400mg/200ml infusion bags
93891979	Ciprofloxacin 500mg tablets
94023990	Ciprofloxacin 500mg tablets
94912996	Ciprofloxacin 500mg tablets
94913996	Ciprofloxacin 500mg tablets
95429990	Ciprofloxacin 500mg tablets
95628990	Ciprofloxacin 500mg tablets
95822990	Ciprofloxacin 500mg tablets
95866990	Ciprofloxacin 500mg tablets
95947990	Ciprofloxacin 500mg tablets
96023990	Ciprofloxacin 500mg tablets
96043990	Ciprofloxacin 500mg tablets

Drugcode	Generic name
96048990	Ciprofloxacin 500mg tablets
96051990	Ciprofloxacin 500mg tablets
96057990	Ciprofloxacin 500mg tablets
96066990	Ciprofloxacin 500mg tablets
69616979	Ciprofloxacin 500mg/5ml oral suspension
61441979	Ciprofloxacin 750mg tablets
93079998	Ciprofloxacin 750mg tablets
93080998	Ciprofloxacin 750mg tablets
94009979	Ciprofloxacin 750mg tablets
96022990	Ciprofloxacin 750mg tablets
96042990	Ciprofloxacin 750mg tablets
96047990	Ciprofloxacin 750mg tablets
96056990	Ciprofloxacin 750mg tablets
88261998	Levofloxacin 250mg tablets
88267998	Levofloxacin 250mg tablets
88261997	Levofloxacin 500mg tablets
88267997	Levofloxacin 500mg tablets
61676979	Levofloxacin 500mg/100ml solution for infusion vials
88249998	Levofloxacin 500mg/100ml solution for infusion vials
88254998	Levofloxacin 500mg/100ml solution for infusion vials
93838979	Levofloxacin 500mg/100ml solution for infusion vials
79927978	Moxifloxacin 0.3mg/0.3ml solution for injection pre-filled syringes
89356998	Moxifloxacin 400mg tablets
89361998	Moxifloxacin 400mg tablets
84614998	Moxifloxacin 400mg/250ml solution for infusion bottles
93255998	Norfloxacin 400mg tablets
93256998	Norfloxacin 400mg tablets
96705990	Norfloxacin 400mg tablets
84864998	Ofloxacin 100mg/50ml intravenous infusion
66812979	Ofloxacin 100mg/5ml oral solution
93552998	Ofloxacin 200mg tablets
93554998	Ofloxacin 200mg tablets
95956990	Ofloxacin 200mg tablets
96187990	Ofloxacin 200mg tablets
96188990	Ofloxacin 200mg tablets
84865998	Ofloxacin 200mg/100ml solution for infusion bottles
97809998	Ofloxacin 2mg/ml infusion
93552997	Ofloxacin 400mg tablets
93554997	Ofloxacin 400mg tablets
95274990	Ofloxacin 400mg tablets
95344990	Ofloxacin 400mg tablets
96099990	Ofloxacin 400mg tablets
96185990	Ofloxacin 400mg tablets
96186990	Ofloxacin 400mg tablets

9.3. Annex 3

List of identified systemic broad-spectrum penicillin products in IMS® Disease Analyzer Germany

Broad-spectrum penicillin-containing products

Products containing single substance amoxicillin

Product name	Therapy Numbers
ALOXYN (LTP)	GE1182, GE1183, GE1184
AMAGESAN (PBA)	GE196004, GE238264, GE376498, GE427964, GE862108
AMAGESAN (AES)ALT	GE1047522, GE1048957, GE1053925, GE1054118, GE1055162, GE1058205, GE1079199, GE828077

Product name	Therapy Numbers
AMAGESAN (JOA)ALT	GE309560, GE316002, GE56968, GE724920, GE73155, GE73156, GE733139, GE733503, GE736442, GE737401, GE743245, GE747057, GE80047, GE80124, GE806365
AMC PUREN	GE1071342, GE1083127, GE186637, GE338104, GE391151, GE491632
AMOXI KS/	GE275708, GE341415, GE92319
AMOXI ABZ	GE317085, GE408384, GE410157, GE410175
AMOXI BASF	GE1477, GE1487, GE1495679, GE1500, GE1501, GE1502, GE33524, GE57069
AMOXI CT	GE13234, GE1480, GE1481, GE1482, GE1483, GE1484, GE1485, GE180802, GE246459, GE396109, GE465536, GE466, GE8000, GE817007
AMOXI HEFA	GE162343, GE169032, GE30803, GE486412, GE64767, GE80333, GE80428, GE87115, GE88967
AMOXI HEFA ALT	GE567891, GE631203, GE631204, GE670673, GE680772, GE813098
AMOXI HP	GE356849, GE785534, GE786462
AMOXI LICHTENSTEIN	GE1038133, GE1039865, GE1043188, GE1050285, GE855755, GE997629
AMOXI LUT	GE251527, GE289399
AMOXI PUREN HP	GE405777
AMOXI SANORANIA	GE631198, GE709924
AMOXI WOLFF	GE1491, GE1494, GE1495, GE1496, GE1497, GE1498, GE1499, GE299167, GE340292, GE44269, GE516471, GE67164
AMOXI-1A PHARMA	GE1573974, GE158586, GE162076, GE410100, GE564277, GE57955, GE71740, GE827149, GE8741714, GE8832454, GE8845722
AMOXI-DIOL(ENG)ALT	GE1172717, GE1200147, GE1202060, GE1212202, GE134195, GE186745, GE241834, GE538995
AMOXI-DIOLAN ALT	GE1083211, GE309651, GE33537, GE33538, GE57079, GE57081, GE57082, GE57086
AMOXI-DIOLAN (BR&)	GE1201851, GE1221015, GE168799, GE199826, GE2286270, GE29047, GE413300, GE448257
AMOXI-INFANT	GE446597
AMOXI-LICH	GE403602, GE502362, GE68964, GE85587
AMOXI-SAAR	GE7800774, GE7813808, GE7847512, GE7876936, GE7894752, GE8074404
AMOXI-SANDOZ	GE1041208, GE138442, GE201880, GE235469, GE2723911, GE326573, GE498993, GE571421, GE988518
AMOXI-TABLINEN	GE1054707, GE226288, GE283752, GE30470, GE340805, GE409977, GE410171, GE57055, GE6380656, GE91811
AMOXIBETA	GE152926, GE183815, GE189881, GE190013, GE2072, GE277294, GE28851, GE306346, GE40631, GE420031, GE503046, GE68501, GE80050, GE81648, GE973806, GE992954
AMOXIBIOCI(DOR)ALT	GE134172, GE196855, GE269786, GE273633, GE295800, GE309634, GE316041, GE322391
AMOXIBIOCIN ALT	GE710347
AMOXIBIOCIN (G&H)	GE1062293, GE1066748, GE1066944, GE1091023, GE175383, GE527551, GE795760
AMOXICIL.RAT.E-M>>	GE4716583, GE4724564, GE4730906, GE4742801, GE4754299
AMOXICIL.RAT.EUP>>	GE13538, GE295229, GE65112, GE999165
AMOXICILL. RKR ALT	GE13193390
AMOXICILL.3MM(RKR)	GE134178, GE134180, GE134181, GE141434

Product name	Therapy Numbers
AMOXICILL.HEUM.H2U	GE9125387, GE9133337, GE9220722, GE9241068, GE9253966, GE9322203, GE9358534, GE9413034, GE9532972
AMOXICILL.HEUM.HEU	GE100651, GE13669074, GE13928330, GE159872, GE161198, GE187138, GE196795, GE222365, GE284252, GE284555, GE289405, GE295809, GE316050, GE375522, GE404605, GE489450, GE82464, GE8714870, GE91041, GE9651929
AMOXICILLIN ACS	GE1298883, GE13619, GE144037, GE145223, GE2428, GE250217, GE265595, GE33597, GE413353, GE455345, GE88577
AMOXICILLIN AZU	GE36656
AMOXICILLIN HEY	GE275244, GE578331, GE641422, GE641423, GE670680
AMOXICILLIN IM3	GE1384296
AMOXICILLIN 1 SOH	GE1040664, GE165321, GE1989866, GE2344077, GE292949, GE3470300, GE4154820, GE4220413, GE436166, GE4425265, GE511045, GE631214, GE64646, GE66852, GE73228, GE80932, GE81313, GE9904482
AMOXICILLIN 2 SOH	GE103217, GE114279, GE1209256, GE13298085, GE1427301, GE14837204, GE1505, GE1633099, GE165314, GE1677010, GE1721809, GE1730094, GE1759632, GE191214, GE219111, GE2498628, GE2498668, GE2575104, GE2741964, GE293358, GE301963, GE308358, GE309641, GE3433617, GE3814718, GE399157, GE4169307, GE4511115, GE4585449, GE499993, GE50823, GE57072, GE5774975, GE619098, GE6297005, GE65873, GE691725, GE710869, GE7469841, GE85270
AMOXICILLIN ABZ	GE4374410, GE4417038, GE4533454, GE4539120
AMOXICILLIN AL	GE11534981, GE11560444, GE11614444, GE16547010, GE17239190, GE280795, GE327874, GE335109, GE335438, GE344235, GE344236, GE3989688, GE42043, GE87944, GE9251
AMOXICILLIN ARISTO	GE15587892, GE15596709, GE15598266, GE15608080, GE15612608, GE15642047, GE15675650, GE15700821, GE15735675
AMOXICILLIN AXCOU.	GE7729835, GE8271000, GE9043310, GE9133639
AMOXICILLIN BASICS	GE1081727, GE147719, GE462756
AMOXICILLIN BILLIX	GE8687921, GE8703212, GE8787971, GE8823999, GE8831931, GE8864761, GE8914497, GE9399567
AMOXICILLIN DENK	GE16165607, GE16195305
AMOXICILLIN DURA	GE8055983, GE8149073, GE8646997, GE8663252, GE8674350, GE8764818
AMOXICILLIN MICR.L	GE15776759, GE15790779, GE15888612, GE16404810, GE16511286, GE16709044, GE16832012, GE16832475, GE17018009, GE17040528, GE17105555, GE17455154, GE17498168, GE17668467, GE18613548
AMOXICILLIN PB ALT	GE936484, GE940726, GE968786, GE970452, GE974990, GE980629
AMOXICILLIN PB(PBA	GE160665, GE178088, GE179111, GE339818
AMOXICILLIN STADA	GE1009, GE10405, GE11263, GE127017, GE1506, GE1507, GE1508, GE17819, GE240719, GE35170, GE50451, GE56230
AMOXICILLIN-RATIO.	GE127019, GE1503, GE1504, GE1510, GE1512, GE1513, GE1514, GE1517, GE182300, GE238987, GE297081, GE359788, GE405731, GE45230, GE46376, GE86848, GE90299
AMOXIDOC	GE1072644, GE579168
AMOXIHEXAL	GE124141, GE125130, GE134188, GE141795, GE1478, GE1520, GE1521, GE1522, GE1523, GE1524, GE192451, GE196858, GE327882, GE33533, GE378342, GE39933, GE417810, GE417879, GE4388786, GE4408785, GE46380, GE503660, GE57074, GE6680646, GE90291

Product name	Therapy Numbers
AMOXIHEXAL EUP>>	GE6175900, GE6215686
AMOXILLAT	GE1212510, GE1525, GE1528, GE1529, GE1530, GE180852, GE33535, GE404288, GE503581, GE567161, GE73227
AMOXIMERCK MD3	GE1009739, GE1013416, GE1212203, GE1358480, GE358325, GE487863, GE598150, GE67260
AMOXIWIEB	GE161439, GE297284
AMOXYPEN	GE1322167, GE1531, GE1535, GE1537, GE1538, GE1539, GE1540, GE1541, GE1545, GE1549, GE1550, GE1551, GE1552, GE190413, GE231482, GE244532, GE251530, GE251531, GE5523, GE699610
BAKTOCILLIN	GE8092561
BYK AMOXICILLIN	GE174366
CLAMOXYL ALT	GE3934015
CLAMOXYL (B/W)	GE135181, GE135182, GE252120, GE35417, GE35418, GE506609, GE6140, GE6141, GE6142, GE6145, GE6146, GE6147, GE6148, GE652269
CLAMOXYL EUP>>	GE247156, GE35415
CUXACILLIN	GE7276, GE7278, GE7279
DIGNOAMOXICILLIN	GE653069, GE653070, GE663275, GE697987, GE708680, GE900434
DURA AX	GE11047, GE128841, GE36820, GE9697, GE9698, GE9699, GE9700, GE9701
EASYMOX	GE5780156, GE6187183
ESPA MOXIN	GE1085351, GE339250, GE527428
FLUI AMOXICILLIN	GE123966, GE158941, GE386854, GE393999
GLASSATAN	GE116544
INFECTOMOX	GE111080, GE111081, GE157907, GE205455, GE217351, GE243110, GE25345, GE3581190, GE387211, GE4125077, GE7933, GE8594686, GE8656456, GE8971840, GE9174923
JEPHOXIN	GE623271, GE645497, GE655282, GE805586, GE870695, GE952238, GE958280
JUTAMOX	GE199401, GE338407, GE342211, GE342212, GE343932, GE343933, GE427644
OSPAMOX	GE247240, GE338981, GE338982, GE392018
PHAMOXI	GE1216447, GE338912, GE578429
SIGAMOPEN ALT	GE101798, GE26892, GE54716, GE78406, GE78407, GE88047, GE95525
SIGAMOPEN (PFZ)	GE2151695
SILAMOX (KPH)	GE189539, GE71573
ULCOLIND AMOXI	GE1023082, GE702262, GE715739

Products containing amoxicillin in combination with clavulanic acid

Product name	Therapy Numbers
ABICLAV LINDOPHARM	GE7040267, GE7061093
ABICLAV SOLUTAB	GE1656280, GE310079, GE3119153, GE3440234, GE3694176, GE999312
AMOCLAN EUP>>	GE3947956, GE4078182
AMOCLANHEXAL EUP>>	GE5906756, GE5924427
AMOCNAV	GE10152071, GE111654, GE11541, GE16209798, GE231195, GE25525, GE296928, GE3000, GE3614757, GE45271, GE4834007, GE533714, GE5651432, GE61184, GE700045, GE74064, GE9467
AMOX.CLAVULANS.A3P	GE7732613

Product name	Therapy Numbers
AMOXCLAV HEXAL	GE10558174, GE10740579, GE11710141, GE17712652, GE7333627, GE7804387, GE8621200, GE9845632
AMOXCLAV-SAN.BBF>>	GE16613224, GE16656543
AMOXCLAV-SAN.ORI>>	GE6881120, GE7030721, GE7199245
AMOXCLAV-SANDOZ	GE1533902, GE1796989, GE1985391, GE2728387, GE2855883, GE289964, GE3875891, GE4160921, GE4212788, GE88745, GE88760
AMOXI-CLAV.HEUMANN	GE15541754, GE15560386, GE15599870, GE15647631, GE15670526
AMOXI-CLAV.STA.ALI	GE15259196, GE15498503
AMOXI-CLAV.STA.SAD	GE10101323, GE116273, GE12236, GE144977, GE150731, GE410772, GE414414, GE68447
AMOXI-CLAV.ZENTIVA	GE19950796, GE20051352, GE5398555
AMOXI-CLAVULAN AL	GE1397623, GE14906121, GE15027892, GE15131016, GE15197920, GE205460, GE320551, GE343564, GE683125, GE852045
AMOXI-CLAVULAN AUR	GE10883015, GE10900686, GE10911132, GE11802348, GE11846787
AMOXI-CLAVULAN PUR	GE19773877, GE19841869
AMOXI-SAAR PLUS	GE2431842, GE3229906, GE8938570, GE9185750
AMOXI.CLAVULAN.AAA	GE19808786, GE19808788
AMOXI.CLAVULAN.DEV	GE18315453, GE18335034, GE18361899
AMOXIC.CLAV.MICR.L	GE16880227, GE17160725, GE17505674, GE17546037, GE17811506, GE17950548
AMOXIC.PL.HEUM.NO&	GE12335135, GE14854394, GE9317523, GE9540339, GE9577584
AMOXIC.RAT.C.EUP>>	GE6758246, GE6784646, GE6788713, GE7276105, GE7300111
AMOXIC.RAT.C.ORI>>	GE7009631, GE7060532
AMOXICI.PLUS EUP>>	GE6762064, GE6768938
AMOXICILL.COMP.ABZ	GE9818675, GE9853457, GE9859995, GE9900051
AMOXICILL.COMP.SOH	GE1169209, GE12815678, GE15721182, GE2299088, GE297158, GE3137331, GE3270630, GE3298860, GE3456702, GE3760427, GE4176291, GE4248303, GE4462589, GE4610631, GE690437, GE7713362, GE8192000
AMOXICILL.PLUS HEU	GE10237, GE2157617, GE3786482, GE3791212, GE8690139, GE8738106
AMOXICILL.RAT.COMP	GE10183, GE156868, GE162776, GE213075, GE298341, GE341701, GE55622
AMOXICLAV ACCEDO	GE3638550, GE3662412
AMOXICLAV ALKEM	GE17543811, GE17579932, GE17603372, GE17704773, GE17706868, GE17709143, GE17977622, GE18067149, GE18289787
AMOXICLAV ARISTO	GE14307643, GE14373222, GE15557628, GE15653962
AMOXICLAV AWD	GE4925378, GE4972035
AMOXICLAV BASICS	GE13748843, GE13792333, GE13913049, GE13930997, GE2066068, GE2137084
AMOXICLAV BETA	GE228399, GE259667
AMOXICLAV FAIR-MED	GE13634989, GE13680395
AMOXICLAV HIKMA	GE7866829, GE8478097
AMOXICLAV PUREN	GE1634822, GE236286, GE38383, GE46995
AMOXICLAV-1A PHARM	GE4157450, GE4171386, GE4242929, GE4372279, GE4871805, GE4962857, GE7642788, GE7734826
AMOXICLAV-CT	GE241198, GE31450, GE409772, GE4132791, GE414814, GE462147, GE690948

Product name	Therapy Numbers
AMOXICLAV-ELPEN	GE19942865
AMOXICLAVULAN-1AP	GE3889461, GE3898582
AMOXIDURA PLUS	GE110793, GE14200, GE243404, GE367613, GE410765, GE47530, GE83613
AMOXILLAT CLAV	GE123907, GE157585, GE160414, GE168731, GE244678, GE2588691, GE404305, GE50368
AMOXIP.RAT.C.E-M>>	GE5538666, GE5591237, GE5601819, GE5649436, GE5655723
AMOXIP.RAT.C.EUP>>	GE1006026, GE158223, GE3153817, GE543517, GE978812
AUGMENTAN (B/W)	GE141719, GE166145, GE166146, GE170421, GE17308214, GE17363941, GE183556, GE2689788, GE3187, GE3188, GE3189, GE3190, GE3191, GE3192, GE410860, GE603712, GE61312, GE7170968, GE97383
AUGMENTAN A4X>>	GE16599480, GE16658948
AUGMENTAN AC9>>	GE7317297, GE7452346
AUGMENTAN EUP>>	GE1045882, GE169499
AUGMENTAN GRK>>	GE1990379
AUGMENTAN KHP>>	GE210982, GE338906, GE382649, GE425117, GE505645, GE507605, GE508967, GE574439, GE88593
AUGMENTAN MTK>>	GE1572114, GE1653156, GE1688570, GE210433, GE419606, GE421799, GE536404, GE854242
AUGMENTAN ORI>>	GE1573266, GE1716147, GE45698
AUGMENTIN AC9>>	GE2651736
AUGMENTIN BRA>>	GE2439127, GE2637514, GE522039, GE988325
AUGMENTIN E-M>>	GE1490910, GE1555793, GE1886953, GE2724556, GE2790824, GE2855632, GE2867930, GE3570505
AUGMENTIN EUP>>	GE2790827
AUGMENTIN GRK>>	GE102972, GE1903196, GE244414, GE2886112
AUGMENTIN KHP>>	GE1088261
AUGMENTINE E-M>>	GE2695894, GE3865365, GE4985667
AUGMENTINE EUP>>	GE3483709, GE6115229
BIOCLAVID	GE1195073, GE213567, GE213591, GE328182, GE363195
CO-AMOXICLAV BLUEF	GE15307355, GE15328695, GE15387063, GE15478976
INFECTOSUPRAMOX	GE4426481, GE4427627

Products containing single substance ampicillin

Product name	Therapy Numbers
AMBLOSIN	GE342854
AMPENSAAR (GOM)	GE715899
AMPI ABZ	GE266638, GE849866
AMPI-TABLINEN 1000	GE65885
AMPICILLAT	GE1576, GE1577
AMPICILLIN B-C	GE631242
AMPICILLIN JNA	GE273646
AMPICILLIN SOH	GE16475547, GE2393562, GE3286316, GE39454, GE46400, GE6398381, GE73237, GE755726
AMPICILLIN WFF	GE165400, GE33550
AMPICILLIN ZVA	GE1580, GE46399, GE57098

Product name	Therapy Numbers
AMPICILLIN HEXAL	GE114691, GE295827, GE46402
AMPICILLIN STADA	GE1147383, GE1581, GE33551, GE57097
AMPICILLIN-RATIOPH	GE143182, GE1582, GE1583, GE1584, GE1836907, GE210824, GE213015, GE2344935, GE344688, GE46397, GE572260, GE651024
BINOTAL ALT	GE103636, GE34722, GE4391, GE4392, GE4393, GE5520078, GE66539, GE66540, GE692133, GE73874
BINOTAL (BAY)	GE1060937, GE1215676, GE340042, GE425253
DURAAMPICILLIN	GE36831, GE36832
JENAMPIN	GE635388, GE635389
PEN-BRISTOL	GE983281
PENSTABIL M2P	GE1015501

Products containing ampicillin in combination with sulbactam

Product name	Therapy Numbers
AMPIC.SULB.ATV(DM+	GE13329216, GE7282014, GE7906641, GE8891600
AMPIC.SULB.DM+ ALT	GE3685382, GE4020499
AMPIC.SULBACT.AURO	GE15693628, GE15927498
AMPIC.SULBACT.EBER	GE16223989, GE16354567, GE16915743
AMPIC.SULBACT.IBIS	GE13555743, GE16877763, GE8346823
AMPIC.SULBACT.KABI	GE6556091, GE6941836, GE9596367
AMPIC.SULBACT.PURE	GE17531164, GE19024733
AMPIC.SULBACT.RAT.	GE7345484, GE8157373, GE8182538
AMPIC.SULBACT.TEVA	GE10154506, GE9825673
AMPICILLIN HEX.COM	GE10832743, GE10904601, GE4276184, GE6527615, GE9260848
AMPICILLIN-RAT.COM	GE3754001, GE3915030, GE4070581
UNACID	GE1478146, GE174461, GE198348, GE2312470, GE423118, GE4932189, GE5004544, GE548640, GE835192

Products containing single substance piperacillin

Product name	Therapy Numbers
PIPERACILL.ATV(DM+	GE10769634, GE9247795
PIPERACILL.EBERTH	GE11437145, GE16551572, GE19639740, GE9086035
PIPERACILLIN FK2	GE1220539, GE3173572, GE4799068, GE9980840
PIPERACILLIN SOH	GE14960035
PIPERACILLIN HEXAL	GE1339356, GE1429105, GE2190740, GE362204
PIPERACILLIN HIKMA	GE15057370
PIPERACILLIN IBISQ	GE15879104, GE19171008
PIPERACILLIN-RATIO	GE2916984, GE3371925, GE5823832
PIPRIL	GE1254631, GE4021512

Products containing piperacillin in combination with tazobactam

Product name	Therapy Numbers
PIPERAC.COMP.HEXAL	GE11373870

Product name	Therapy Numbers
PIPERAC.TAZOB.AURO	GE12913443
PIPERAC.TAZOB.EBER	GE13322932, GE16397840
PIPERAC.TAZOB.HEXA	GE13813027, GE17187377
PIPERAC.TAZOB.IBIS	GE16204730
PIPERAC.TAZOB.KABI	GE10710677, GE14537666
PIPERAC.TAZOB.NORI	GE16728236
PIPERAC.TAZOB.ORCH	GE9629641
PIPERAC.TAZOB.PFIZ	GE15021451
PIPERAC.TAZOB.PUR.	GE18597318
PIPERAC.TAZOB.RAT.	GE8313948
PIPERAC.TAZOB.STRA	GE10529400
PIPERAC.TAZOB.TEVA	GE15495560
TAZOBAC	GE1530924, GE2258536, GE2662546, GE4725205
TAZOCIN CC4>>	GE14115664

Products containing single substance sultamicillin

Product name	Therapy Numbers
SULTAMICILLIN-RAT.	GE11083962, GE11397813
UNACID PD	GE11049520, GE134543, GE180798, GE28994, GE81308, GE946821
UNASYN PD A4X>>	GE16856832, GE17210567
UNASYN PD AC9>>	GE19788473, GE19856915
UNASYN PD E-M>>	GE12492857, GE13107365
UNASYN PD EUP>>	GE10313794, GE10542489
UNASYN PD KHP>>	GE15244674, GE15376650

Remaining products containing broad-spectrum penicillins

Molecule	Product name	Therapy Numbers
Amoxicillin + flucloxacillin	FLANAMOX	GE170317, GE87022
Ampicillin + oxacillin	LUCIPEN	GE4337420
Azlocillin	SECUROPEN	GE1006716, GE6392213, GE963110
Bacampicillin	AMBACAMP	GE1260, GE1261
Bacampicillin	PENGLOBE	GE101135, GE23573, GE53547, GE86971
Ciclacillin	ULTRACILLIN	GE8590125
Mezlocillin	BAYPEN	GE1212246, GE1238264, GE1307753, GE1351306, GE154994, GE157677, GE226513, GE289767, GE356147, GE681206, GE883832
Mezlocillin	MEZLOCILLIN CUN	GE857605
Mezlocillin	MEZLOCILLIN CARINO	GE16628332
Pivmecillinam + pivampicillin	MIRAXID	GE19644

9.4. Annex 4

List of identified systemic broad-spectrum penicillin products in IMRD-UK

Drugcode	Generic name
96256998	Amoxicillin 125mg sugar free chewable tablets
97131996	Amoxicillin 125mg sugar free chewable tablets
95086996	Amoxicillin 125mg sugar free powder
99830988	Amoxicillin 125mg sugar free powder
96944997	Amoxicillin 125mg/1.25ml oral suspension paediatric
98354998	Amoxicillin 125mg/1.25ml oral suspension paediatric
47746978	Amoxicillin 125mg/5ml oral suspension
51959978	Amoxicillin 125mg/5ml oral suspension
52582979	Amoxicillin 125mg/5ml oral suspension
83268978	Amoxicillin 125mg/5ml oral suspension
94071990	Amoxicillin 125mg/5ml oral suspension
94334979	Amoxicillin 125mg/5ml oral suspension
94335979	Amoxicillin 125mg/5ml oral suspension
94699996	Amoxicillin 125mg/5ml oral suspension
94794998	Amoxicillin 125mg/5ml oral suspension
96239996	Amoxicillin 125mg/5ml oral suspension
96307988	Amoxicillin 125mg/5ml oral suspension
96313996	Amoxicillin 125mg/5ml oral suspension
96383988	Amoxicillin 125mg/5ml oral suspension
98803988	Amoxicillin 125mg/5ml oral suspension
99836988	Amoxicillin 125mg/5ml oral suspension
99837988	Amoxicillin 125mg/5ml oral suspension
99838988	Amoxicillin 125mg/5ml oral suspension
99839988	Amoxicillin 125mg/5ml oral suspension
99840989	Amoxicillin 125mg/5ml oral suspension
99841988	Amoxicillin 125mg/5ml oral suspension
99842988	Amoxicillin 125mg/5ml oral suspension
99843988	Amoxicillin 125mg/5ml oral suspension
99844988	Amoxicillin 125mg/5ml oral suspension
99846989	Amoxicillin 125mg/5ml oral suspension
99849990	Amoxicillin 125mg/5ml oral suspension
17373978	Amoxicillin 125mg/5ml oral suspension sugar free
18535978	Amoxicillin 125mg/5ml oral suspension sugar free
46488978	Amoxicillin 125mg/5ml oral suspension sugar free
47747978	Amoxicillin 125mg/5ml oral suspension sugar free
52583979	Amoxicillin 125mg/5ml oral suspension sugar free
83269978	Amoxicillin 125mg/5ml oral suspension sugar free
93041990	Amoxicillin 125mg/5ml oral suspension sugar free
93253992	Amoxicillin 125mg/5ml oral suspension sugar free
93372996	Amoxicillin 125mg/5ml oral suspension sugar free
93377996	Amoxicillin 125mg/5ml oral suspension sugar free
93592990	Amoxicillin 125mg/5ml oral suspension sugar free
94338979	Amoxicillin 125mg/5ml oral suspension sugar free
94339979	Amoxicillin 125mg/5ml oral suspension sugar free
94341979	Amoxicillin 125mg/5ml oral suspension sugar free
94342979	Amoxicillin 125mg/5ml oral suspension sugar free
94343979	Amoxicillin 125mg/5ml oral suspension sugar free
94792998	Amoxicillin 125mg/5ml oral suspension sugar free
96928989	Amoxicillin 125mg/5ml oral suspension sugar free
96931988	Amoxicillin 125mg/5ml oral suspension sugar free
97133989	Amoxicillin 125mg/5ml oral suspension sugar free
97790988	Amoxicillin 125mg/5ml oral suspension sugar free
97868998	Amoxicillin 125mg/5ml oral suspension sugar free
98334989	Amoxicillin 125mg/5ml oral suspension sugar free
99831989	Amoxicillin 125mg/5ml oral suspension sugar free
99832989	Amoxicillin 125mg/5ml oral suspension sugar free
99845988	Amoxicillin 125mg/5ml oral suspension sugar free
88557996	Amoxicillin 125mg/5ml sugar free suspension
89889998	Amoxicillin 125mg/5ml sugar free suspension
93407996	Amoxicillin 125mg/5ml sugar free suspension
88557998	Amoxicillin 125mg/5ml syrup

Drugcode	Generic name
97808997	Amoxicillin 125mg/5ml syrup
6035978	Amoxicillin 1g dispersible tablets sugar free
94945998	Amoxicillin 1g powder for solution for injection vials
98353996	Amoxicillin 1g powder for solution for injection vials
99847989	Amoxicillin 1g powder for solution for injection vials
88556998	Amoxicillin 250mg capsules
89177998	Amoxicillin 250mg capsules
92456990	Amoxicillin 250mg capsules
93377998	Amoxicillin 250mg capsules
93407998	Amoxicillin 250mg capsules
93465998	Amoxicillin 250mg capsules
93686992	Amoxicillin 250mg capsules
94074990	Amoxicillin 250mg capsules
94438979	Amoxicillin 250mg capsules
94444979	Amoxicillin 250mg capsules
94699998	Amoxicillin 250mg capsules
95225990	Amoxicillin 250mg capsules
96239998	Amoxicillin 250mg capsules
96307990	Amoxicillin 250mg capsules
96313998	Amoxicillin 250mg capsules
96383990	Amoxicillin 250mg capsules
96931990	Amoxicillin 250mg capsules
97050990	Amoxicillin 250mg capsules
97131998	Amoxicillin 250mg capsules
97133990	Amoxicillin 250mg capsules
97790990	Amoxicillin 250mg capsules
97808998	Amoxicillin 250mg capsules
98803990	Amoxicillin 250mg capsules
99836990	Amoxicillin 250mg capsules
99837990	Amoxicillin 250mg capsules
99838990	Amoxicillin 250mg capsules
99839990	Amoxicillin 250mg capsules
99841990	Amoxicillin 250mg capsules
99842990	Amoxicillin 250mg capsules
99843990	Amoxicillin 250mg capsules
99845990	Amoxicillin 250mg capsules
99848990	Amoxicillin 250mg capsules
99849988	Amoxicillin 250mg capsules
99962998	Amoxicillin 250mg capsules
96943997	Amoxicillin 250mg powder for solution for injection vials
98353998	Amoxicillin 250mg powder for solution for injection vials
96256997	Amoxicillin 250mg sugar free chewable tablets
96309998	Amoxicillin 250mg sugar free chewable tablets
18534978	Amoxicillin 250mg/5ml oral suspension
52579979	Amoxicillin 250mg/5ml oral suspension
52581979	Amoxicillin 250mg/5ml oral suspension
83265978	Amoxicillin 250mg/5ml oral suspension
93040990	Amoxicillin 250mg/5ml oral suspension
93591990	Amoxicillin 250mg/5ml oral suspension
94070990	Amoxicillin 250mg/5ml oral suspension
94316979	Amoxicillin 250mg/5ml oral suspension
94318979	Amoxicillin 250mg/5ml oral suspension
94328979	Amoxicillin 250mg/5ml oral suspension
94333979	Amoxicillin 250mg/5ml oral suspension
94792997	Amoxicillin 250mg/5ml oral suspension
94794997	Amoxicillin 250mg/5ml oral suspension
96255998	Amoxicillin 250mg/5ml oral suspension
96306990	Amoxicillin 250mg/5ml oral suspension
96365998	Amoxicillin 250mg/5ml oral suspension
96377990	Amoxicillin 250mg/5ml oral suspension
96928988	Amoxicillin 250mg/5ml oral suspension
96928990	Amoxicillin 250mg/5ml oral suspension
96965990	Amoxicillin 250mg/5ml oral suspension
97133988	Amoxicillin 250mg/5ml oral suspension
97789990	Amoxicillin 250mg/5ml oral suspension

Drugcode	Generic name
98334988	Amoxicillin 250mg/5ml oral suspension
99828990	Amoxicillin 250mg/5ml oral suspension
99829990	Amoxicillin 250mg/5ml oral suspension
99830990	Amoxicillin 250mg/5ml oral suspension
99831988	Amoxicillin 250mg/5ml oral suspension
99831990	Amoxicillin 250mg/5ml oral suspension
99832988	Amoxicillin 250mg/5ml oral suspension
99832990	Amoxicillin 250mg/5ml oral suspension
99834990	Amoxicillin 250mg/5ml oral suspension
99840988	Amoxicillin 250mg/5ml oral suspension
99846988	Amoxicillin 250mg/5ml oral suspension
99849989	Amoxicillin 250mg/5ml oral suspension
17372978	Amoxicillin 250mg/5ml oral suspension sugar free
47744978	Amoxicillin 250mg/5ml oral suspension sugar free
93372998	Amoxicillin 250mg/5ml oral suspension sugar free
93375998	Amoxicillin 250mg/5ml oral suspension sugar free
93404998	Amoxicillin 250mg/5ml oral suspension sugar free
93446998	Amoxicillin 250mg/5ml oral suspension sugar free
94317979	Amoxicillin 250mg/5ml oral suspension sugar free
94320979	Amoxicillin 250mg/5ml oral suspension sugar free
97868997	Amoxicillin 250mg/5ml oral suspension sugar free
89889997	Amoxicillin 250mg/5ml sugar free suspension
88557997	Amoxicillin 250mg/5ml syrup
94698998	Amoxicillin 250mg/5ml syrup
95086998	Amoxicillin 375mg soluble tablets
95077998	Amoxicillin 375mg sugar free dispersible tablets
96156990	Amoxicillin 3g oral powder sachets sugar free
96943998	Amoxicillin 3g oral powder sachets sugar free
97790989	Amoxicillin 3g oral powder sachets sugar free
97956990	Amoxicillin 3g oral powder sachets sugar free
98673998	Amoxicillin 3g oral powder sachets sugar free
99830989	Amoxicillin 3g oral powder sachets sugar free
14847978	Amoxicillin 500mg capsules
18536978	Amoxicillin 500mg capsules
28554978	Amoxicillin 500mg capsules
46495978	Amoxicillin 500mg capsules
47752978	Amoxicillin 500mg capsules
52591979	Amoxicillin 500mg capsules
61452979	Amoxicillin 500mg capsules
83274978	Amoxicillin 500mg capsules
88556997	Amoxicillin 500mg capsules
92455990	Amoxicillin 500mg capsules
93372997	Amoxicillin 500mg capsules
93377997	Amoxicillin 500mg capsules
93407997	Amoxicillin 500mg capsules
94068992	Amoxicillin 500mg capsules
94073990	Amoxicillin 500mg capsules
94416979	Amoxicillin 500mg capsules
94417979	Amoxicillin 500mg capsules
94418979	Amoxicillin 500mg capsules
94419979	Amoxicillin 500mg capsules
94420979	Amoxicillin 500mg capsules
94421979	Amoxicillin 500mg capsules
94422979	Amoxicillin 500mg capsules
94423979	Amoxicillin 500mg capsules
94426979	Amoxicillin 500mg capsules
94428979	Amoxicillin 500mg capsules
94434979	Amoxicillin 500mg capsules
94699997	Amoxicillin 500mg capsules
95224990	Amoxicillin 500mg capsules
96239997	Amoxicillin 500mg capsules
96307989	Amoxicillin 500mg capsules
96313997	Amoxicillin 500mg capsules
96383989	Amoxicillin 500mg capsules
96931989	Amoxicillin 500mg capsules

Drugcode	Generic name
97050989	Amoxicillin 500mg capsules
97131997	Amoxicillin 500mg capsules
98334990	Amoxicillin 500mg capsules
99836989	Amoxicillin 500mg capsules
99838989	Amoxicillin 500mg capsules
99840990	Amoxicillin 500mg capsules
99841989	Amoxicillin 500mg capsules
99842989	Amoxicillin 500mg capsules
99843989	Amoxicillin 500mg capsules
99845989	Amoxicillin 500mg capsules
99846990	Amoxicillin 500mg capsules
99848989	Amoxicillin 500mg capsules
99962997	Amoxicillin 500mg capsules
96944998	Amoxicillin 500mg dispersible tablets
98353997	Amoxicillin 500mg powder for solution for injection vials
96256996	Amoxicillin 500mg sugar free chewable tablets
96309997	Amoxicillin 500mg sugar free chewable tablets
99962996	Amoxicillin 500mg sugar free dispersible tablets
24215978	Amoxicillin 500mg/50ml infusion bags
96943996	Amoxicillin 500mg/50ml infusion bags
97047990	Amoxicillin 500mg/50ml infusion bags
95086997	Amoxicillin 750mg soluble tablets
95077997	Amoxicillin 750mg sugar free dispersible tablets
96944996	Amoxicillin 750mg sugar free powder
97868996	Amoxicillin 750mg sugar free powder
95029997	Amoxicillin with clavulanic acid dispersible tablets
94069992	Amoxycillin 125 mg cap
99743992	Amoxycillin 500 mg tab
96092992	Amoxycillin fiztab 125 mg tab
96822992	Amoxycillin fiztab 250 mg tab
95032998	Ampicillin 60mg / cloxacillin 30mg/0.6ml sugar free oral suspension
94936996	Ampicillin & cloxacillin 125mg+125mg/5ml syrup
99792992	Ampicillin & cloxacillin 125mg+125mg/5ml syrup
94936997	Ampicillin & cloxacillin 250mg+250mg capsules
99793992	Ampicillin & cloxacillin 250mg+250mg injection (powder for reconstitution)
98218998	Ampicillin & cloxacillin 50mg+25mg injection (powder for reconstitution)
99960998	Ampicillin & cloxacillin 60mg+30mg/0.6ml sugar free suspension
99171998	Ampicillin / cloxacillin 500mg capsules
96944992	Ampicillin 125 mg cap
96582992	Ampicillin 125 mg tab
94519992	Ampicillin 125mg tablets
98357998	Ampicillin 125mg/1.25ml paediatric suspension
84356998	Ampicillin 125mg/5ml oral suspension
88549996	Ampicillin 125mg/5ml oral suspension
96815990	Ampicillin 125mg/5ml oral suspension
97130996	Ampicillin 125mg/5ml oral suspension
98885998	Ampicillin 125mg/5ml oral suspension
98968996	Ampicillin 125mg/5ml oral suspension
99275996	Ampicillin 125mg/5ml oral suspension
99822988	Ampicillin 125mg/5ml oral suspension
99826988	Ampicillin 125mg/5ml oral suspension
95034998	Ampicillin 125mg/5ml paediatric oral suspension
97129997	Ampicillin 125mg/5ml sugar free suspension
99821989	Ampicillin 125mg/5ml sugar free suspension
99171996	Ampicillin 250mg / cloxacillin 250mg/vial injection
86675998	Ampicillin 250mg capsules
88549998	Ampicillin 250mg capsules
94375979	Ampicillin 250mg capsules
94642992	Ampicillin 250mg capsules
97130998	Ampicillin 250mg capsules
98802990	Ampicillin 250mg capsules
98968998	Ampicillin 250mg capsules
99275998	Ampicillin 250mg capsules
99822990	Ampicillin 250mg capsules
99824990	Ampicillin 250mg capsules

Drugcode	Generic name
99964998	Ampicillin 250mg capsules
95033997	Ampicillin 250mg injection
92973998	Ampicillin 250mg injection (powder for reconstitution)
98356998	Ampicillin 250mg injection (powder for reconstitution)
84355998	Ampicillin 250mg/5ml oral suspension
97129998	Ampicillin 250mg/5ml oral suspension
98884998	Ampicillin 250mg/5ml oral suspension
98967998	Ampicillin 250mg/5ml oral suspension
99274998	Ampicillin 250mg/5ml oral suspension
97129996	Ampicillin 250mg/5ml sugar free suspension
95030998	Ampicillin 500mg / flucloxacillin 500mg injection
86777998	Ampicillin 500mg capsules
94641992	Ampicillin 500mg capsules
96926989	Ampicillin 500mg capsules
97130997	Ampicillin 500mg capsules
97788989	Ampicillin 500mg capsules
98968997	Ampicillin 500mg capsules
99275997	Ampicillin 500mg capsules
99822989	Ampicillin 500mg capsules
99826989	Ampicillin 500mg capsules
99964997	Ampicillin 500mg capsules
95033998	Ampicillin 500mg powder for solution for injection vials
98356997	Ampicillin 500mg powder for solution for injection vials
98883997	Ampicillin 500mg powder for solution for injection vials
95032997	Ampicillin 50mg / cloxacillin 25mg/vial injection
99171997	Ampicillin with cloxacillin 250mg/5ml oral solution
94643992	Ampilar 125 mg syr
96931997	Azlocillin 1g/vial injection
98089998	Azlocillin 2g/vial injection
96931996	Azlocillin 5g/vial injection
96919998	Bacampicillin hcl 400mg tablets
96918998	Bacampicillin hydrochloride 400mg tablets
95883992	Carbenicillin 1 inj
96879998	Carbenicillin 1g injection (powder for reconstitution)
96880998	Carbenicillin 1g sterile powder
94760992	Ciclacillin 125mg/5ml suspension
99861998	Ciclacillin 250mg tablets
99861997	Ciclacillin 500mg tablets
96660997	Clavulanic acid with amoxicillin dispersible tablets
95028996	Co-amoxiclav 1000mg/200mg powder for solution for injection vials
97792997	Co-amoxiclav 1000mg/200mg powder for solution for injection vials
93849997	Co-amoxiclav 1000mg/200mg/100ml infusion bags
52243979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
59159978	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
86034998	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
86035998	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
86055998	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
92340996	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
93225996	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
94410979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
94411979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
94412979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
94414979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
94415979	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
95029996	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
95040990	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
95315990	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
96539988	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
96660996	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
96731989	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
96975988	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
97010988	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
98363998	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
99836992	Co-amoxiclav 125mg/31mg/5ml oral suspension sugar free
99927997	Co-amoxiclav 125mg+250mg sugar free dispersible tablets

Drugcode	Generic name
93225997	Co-amoxiclav 250mg/125mg dispersible tablets sugar free
88536998	Co-amoxiclav 250mg/125mg tablets
92340998	Co-amoxiclav 250mg/125mg tablets
93225998	Co-amoxiclav 250mg/125mg tablets
94027990	Co-amoxiclav 250mg/125mg tablets
94383979	Co-amoxiclav 250mg/125mg tablets
94384979	Co-amoxiclav 250mg/125mg tablets
94385979	Co-amoxiclav 250mg/125mg tablets
94386979	Co-amoxiclav 250mg/125mg tablets
94387979	Co-amoxiclav 250mg/125mg tablets
94389979	Co-amoxiclav 250mg/125mg tablets
95029998	Co-amoxiclav 250mg/125mg tablets
95872990	Co-amoxiclav 250mg/125mg tablets
96137990	Co-amoxiclav 250mg/125mg tablets
96189990	Co-amoxiclav 250mg/125mg tablets
96343990	Co-amoxiclav 250mg/125mg tablets
96539990	Co-amoxiclav 250mg/125mg tablets
96637990	Co-amoxiclav 250mg/125mg tablets
96660998	Co-amoxiclav 250mg/125mg tablets
96731990	Co-amoxiclav 250mg/125mg tablets
96975990	Co-amoxiclav 250mg/125mg tablets
97010990	Co-amoxiclav 250mg/125mg tablets
99927998	Co-amoxiclav 250mg/125mg tablets
86036998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
86037998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
86056998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
93224998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
94376979	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
94379979	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
95028998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
95039990	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
95314990	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
96538990	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
96731988	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
96974990	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
97009990	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
97708998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
98364998	Co-amoxiclav 250mg/62mg/5ml oral suspension sugar free
52588979	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
91014998	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
93224996	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
94391979	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
94392979	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
94394979	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
97708996	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
99111997	Co-amoxiclav 400mg/57mg/5ml oral suspension sugar free
93849998	Co-amoxiclav 500mg/100mg powder for solution for injection vials
94738990	Co-amoxiclav 500mg/100mg powder for solution for injection vials
95028997	Co-amoxiclav 500mg/100mg powder for solution for injection vials
97792998	Co-amoxiclav 500mg/100mg powder for solution for injection vials
92031990	Co-amoxiclav 500mg/125mg tablets
93224997	Co-amoxiclav 500mg/125mg tablets
94399979	Co-amoxiclav 500mg/125mg tablets
94401979	Co-amoxiclav 500mg/125mg tablets
94402979	Co-amoxiclav 500mg/125mg tablets
94403979	Co-amoxiclav 500mg/125mg tablets
94404979	Co-amoxiclav 500mg/125mg tablets
94408979	Co-amoxiclav 500mg/125mg tablets
94409979	Co-amoxiclav 500mg/125mg tablets
95070990	Co-amoxiclav 500mg/125mg tablets
95585990	Co-amoxiclav 500mg/125mg tablets
95618990	Co-amoxiclav 500mg/125mg tablets
96391990	Co-amoxiclav 500mg/125mg tablets
96539989	Co-amoxiclav 500mg/125mg tablets
96637989	Co-amoxiclav 500mg/125mg tablets

Drugcode	Generic name
96975989	Co-amoxiclav 500mg/125mg tablets
97010989	Co-amoxiclav 500mg/125mg tablets
97708997	Co-amoxiclav 500mg/125mg tablets
99110998	Co-amoxiclav 500mg/125mg tablets
99111998	Co-amoxiclav 500mg/125mg tablets
93214997	Co-fluampicil 125mg/125mg/5ml oral suspension
94355979	Co-fluampicil 125mg/125mg/5ml oral suspension
94356979	Co-fluampicil 125mg/125mg/5ml oral suspension
95031997	Co-fluampicil 125mg/125mg/5ml oral suspension
96531997	Co-fluampicil 125mg/125mg/5ml oral suspension
97254998	Co-fluampicil 125mg/125mg/5ml oral suspension
93214998	Co-fluampicil 250mg/250mg capsules
95031998	Co-fluampicil 250mg/250mg capsules
96183990	Co-fluampicil 250mg/250mg capsules
96531998	Co-fluampicil 250mg/250mg capsules
96896990	Co-fluampicil 250mg/250mg capsules
96908990	Co-fluampicil 250mg/250mg capsules
97167990	Co-fluampicil 250mg/250mg capsules
97770990	Co-fluampicil 250mg/250mg capsules
97975990	Co-fluampicil 250mg/250mg capsules
99452998	Co-fluampicil 250mg/250mg capsules
93214996	Co-fluampicil 250mg/250mg powder for solution for injection vials
95031996	Co-fluampicil 250mg/250mg powder for solution for injection vials
96531996	Co-fluampicil 250mg/250mg powder for solution for injection vials
98362998	Co-fluampicil 250mg/250mg powder for solution for injection vials
97133998	Co-fluampicil 250mg+250mg capsules
93213998	Co-fluampicil 500mg with 500mg injection
98362997	Co-fluampicil 500mg+500mg injection (powder for reconstitution)
95921997	Mecillinam 400mg/vial injection
95811997	Mezlocillin 1g/vial injection
95811998	Mezlocillin 50mg/vial injection
95510998	Piperacillin 1g/vial injection
93109998	Piperacillin 2g / Tazobactam 250mg powder for solution for injection vials
53782979	Piperacillin 2g/50ml / Tazobactam 250mg/50ml infusion bags
93108998	Piperacillin 2g/50ml / Tazobactam 250mg/50ml infusion bags
95510997	Piperacillin 2g/vial injection
93108997	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials
93109997	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials
94354979	Piperacillin 4g / Tazobactam 500mg powder for solution for infusion vials
95510996	Piperacillin 4g/infusion bottle infusion
98451998	Pivampicillin & pivmecillinam 125mg+100mg tablets
94872998	Pivampicillin & pivmecillinam 250mg+200mg tablets
95491998	Pivampicillin & pivmecillinam 250mg+200mg tablets
95494998	Pivampicillin 125mg with pivmecillinam 100mg tablet
95495996	Pivampicillin 175mg sachet
95495997	Pivampicillin 175mg/5ml oral solution
97918992	Pivampicillin 175mg/sachet granules
98820998	Pivampicillin 175mg/sachet granules
95494997	Pivampicillin 250mg with pivmecillinam 200mg tablet
95495998	Pivampicillin 500mg tablet
99236998	Pivampicillin 500mg tablets
95490998	Pivmecillinam 100mg/sachet
95490997	Pivmecillinam 200mg tablets
98823998	Pivmecillinam 200mg tablets
30552978	Pivmecillinam 200mg/5ml oral suspension
98450998	Pivmecillinam 46.2mg with pivampicillin 62.5mg/5ml oral solution
99147998	Pivmecillinam hydrochloride 100mg/sachet suspension
95218997	Talampicillin 125mg/5ml syrup
96478992	Talampicillin 250 mg syr
95218998	Talampicillin 250mg tablets
98355998	Talampicillin hydrochloride 125mg/5ml syrup
99075998	Talampicillin hydrochloride 250mg tablets
93602997	Temocillin 1g injection (powder for reconstitution)
86418998	Temocillin 1g powder for solution for injection vials
93601997	Temocillin 1g powder for solution for injection vials

Drugcode	Generic name
97245997	Ticarcillin & clavulanic acid 1.5g+100mg injection (powder for reconstitution)
95164998	Ticarcillin 1g injection (powder for reconstitution)
95166998	Ticarcillin 1g/vial injection
94923998	Ticarcillin 3g / Clavulanic acid 200mg powder for solution for infusion vials
97245998	Ticarcillin 3g / Clavulanic acid 200mg powder for solution for infusion vials
95164996	Ticarcillin 5g injection (powder for reconstitution)
95166996	Ticarcillin 5g/vial injection

9.5. Annex 5

List of identified systemic azithromycin products in IMS® Disease Analyzer Germany

Product name	Therapy Numbers
AZI-TEVA	GE4870210, GE6789852, GE4813994, GE6896877
AZIBACT	GE4772882, GE4774678
AZITHRO MEDA	GE4502419, GE4484827
AZITHROBETA	GE4484075, GE4517538
AZITHROM. HEUM.H2U	GE9449451, GE9253789
AZITHROMY.WINTHROP	GE4525371, GE4499096
AZITHROMYC.ACCEDO	GE4803847, GE4751360
AZITHROMYC.HEUMANN	GE8824276, GE8730071
AZITHROMYC.KWIZDA	GE4497166, GE4513466
AZITHROMYC.SANDOZ	GE4488636, GE4484775, GE5965825, GE6127858, GE6027772
AZITHROMYCI.EBERTH	GE14380615, GE20002074, GE12197139
AZITHROMYCIN SOH	GE6087596, GE4484760, GE5905173, GE1819431, GE4596578, GE4650561, GE4533566
AZITHROMYCIN ABZ	GE4498135, GE4539095
AZITHROMYCIN AL	GE4497696, GE8113896, GE4531556, GE8086061, GE8073714
AZITHROMYCIN ALMUS	GE7100953, GE7462567
AZITHROMYCIN ARIST	GE8683215, GE8858572, GE8734469
AZITHROMYCIN AWD	GE4493239, GE4499278, GE6570770, GE6387377, GE6556405
AZITHROMYCIN DENK	GE18913408, GE16279784, GE18924502, GE16284938
AZITHROMYCIN DURA	GE4486502, GE4571371
AZITHROMYCIN HEXAL	GE4487069, GE4484263, GE6005449, GE5995559, GE5971801
AZITHROMYCIN ORIFA	GE9833430, GE9888445
AZITHROMYCIN STADA	GE8291875, GE8289834, GE4485253, GE4483600, GE8340723
AZITHROMYCIN-1A PH	GE4494759, GE7661140, GE7518069, GE6562121, GE6374877, GE6360874, GE4613741, GE4505059
AZITHROMYCIN-CT	GE4491322, GE4487473
AZITHROMYCIN-HEC	GE12844084, GE11886524, GE14724859
AZITHROMYCIN-RATIO	GE4483895, GE6196849, GE6060212, GE4499937
ULTREON	GE1496738, GE1153700
ZITHROMAX (P/B)	GE9638648, GE549380, GE162149, GE29941, GE3651967, GE154105, GE27577, GE6336, GE121885, GE45124, GE1519578, GE276546, GE1082845
ZITHROMAX AAB>>	GE2209743, GE2014812
ZITHROMAX E-M>>	GE419120, GE154160, GE404307, GE85534, GE378170
ZITHROMAX EUP>>	GE102335, GE408047, GE2899192, GE1717602, GE1173809
ZITHROMAX GRK>>	GE366008, GE295365

Product name	Therapy Numbers
ZITHROMAX KHP>>	GE180432, GE388932, GE45340, GE338138, GE1787907
ZITHROMAX MTK>>	GE426910, GE367563, GE333856, GE115962
ZITHROMAX MVT>>	GE331163
ZITHROMAX MZG>>	GE2204972, GE1611509
ZITHROMAX (PFZ)ALT	GE688844, GE272729, GE688843
ZITROMAX E-M>>	GE6692897
ZITROMAX ORI>>	GE130036

9.6. Annex 6

List of identified systemic azithromycin products in IMRD-UK

Drugcode	Generic name
47988978	Azithromycin 200mg/5ml oral suspension sugar free
58805979	Azithromycin 250mg tablets
59438979	Azithromycin 200mg/5ml oral suspension
61233979	Azithromycin 250mg tablets
71003979	Azithromycin 250mg tablets
71007979	Azithromycin 250mg tablets
83543998	Azithromycin 500mg tablets
85408998	Azithromycin 250mg capsules
92595990	Azithromycin 250mg capsules
92605990	Azithromycin 250mg capsules
92661990	Azithromycin 200mg/5ml oral suspension
92798990	Azithromycin 200mg/5ml oral suspension
92997990	Azithromycin 500mg tablets
93171990	Azithromycin 250mg tablets
93177990	Azithromycin 500mg tablets
94059979	Azithromycin 500mg tablets
94065979	Azithromycin 200mg/5ml oral suspension
94066979	Azithromycin 200mg/5ml oral suspension
94069979	Azithromycin 250mg capsules
94512996	Azithromycin 500mg tablets
94512997	Azithromycin 200mg/5ml oral suspension
94512998	Azithromycin 250mg capsules
94523996	Azithromycin 500mg tablets
94523997	Azithromycin 200mg/5ml oral suspension
94523998	Azithromycin 250mg capsules

10. Comments received on draft analysis plan

10.1. PRAC Member: Norway

In general we agree on the draft analysis plan. We support the study design.

We have no knowledge about the databases to be used in the study, the IMS Disease Analyzer Germany and the IMRD-UK. However, we notice the limitations described, and agree that it is a limitation of the research method that the diagnosis of TTP is likely to be made in secondary care and may not be completely captured in primary care databases.

As regards outcome variables, only the ICD 10 code M31.1 (Thrombotic microangiopathy) is proposed to be used for the German database. We propose that the same diagnosis codes used for the UK database should also be applied to the German database:

The following codes are available in ICD-10 and should be included as outcome variables for the German database:

- D59.4 Microangiopathic hemolytic anemia*
- M31.1 Moschowitz' disease*
- M31.1 Thrombotic thrombocytopenic purpura*

We suggest that patients with HIV should be excluded as HIV can lead to TTP. In addition, efforts should be taken to exclude cases of DIC and HUS as these syndromes can overlap with TTP.

EMA Response: Regarding microangiopathic hemolytic anaemia, we have now included a sensitivity analysis where also the ICD 10 code D59.4 (other nonautoimmune haemolytic anaemias) is included.

The proposed analysis could be considered as an analysis of narrow (codes that only include the condition of interest) and broad (including also overlapping codes that are not specific for the condition of interest) event definitions. Similarly, the analysis in IMRD-UK has been split into an analysis of narrow and broad TTP events.

We have also as you suggest excluded patients with HIV, DIC and HUS.

10.2. Country: Germany

We agree with the proposed Analysis plan and have some additional comments:

- It is our understanding that the study refers only to incident users and that a patient is observed only once during the study period. The EMA is asked to briefly clarify if this is correctly understood or if the observation of multiple treatment periods is possible.*
- If a patient is only observed once within the proposed study period, the EMA is asked to also provide information on incidence proportions.*
- In some epidemiological studies focusing on FQs, azithromycin has often been used as a comparator. We wonder whether azythromycin could also be included in this data analysis, if feasible.*
- In general we support the proposed study design. However, we would like to know, also in view of future analyses, whether the case-control design is generally suitable for the conduct of these rapid analyses. This is only because we would have expected a case-control design due to the rarity of the observed events.*

EMA Response: Regarding the first bullet point, it is correctly understood that a patient is observed only once during the study period.

Regarding the second bullet point, we could provide the proportion of cases with TTP as proportion of patients initiating treatment. Please let us know if this is not what you request, and you want instead

to know the number of patients who are excluded from the analysis because they are “prevalent” exposures.

Regarding the third bullet point, a comparison with azithromycin will also be provided.

Regarding the fourth bullet point, we don’t think the case-control approach has any advantage over the cohort design in most of the analyses we currently do. Our starting point is to assess the extent of drug exposure on the databases. From there we then assess whether the event of interest occurs in the exposed subjects. This is a logical order. As the potential harms of medicines are typically described as rates (for example in SmPCs as events per 100, 1000, 10000, etc.) an understanding of the extent of exposure is required and this naturally follows from having defined and then followed an exposed cohort. It should be noted that recent commentators have questioned the validity of the case control approach (see *Statistics in Medicine* 2019;38:4199–4208).