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Adverse Drug Reactions Reported in the German Democratic Republic: A Retrospective Analysis of Reports to the WHO-ADR Database

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Abstract

The German Democratic Republic (GDR) joined the WHO collaboration on drug safety in 1983 in order to strengthen their national pharmacovigilance system. We aim to characterize adverse drug reaction (ADR) reports which were forwarded to the WHO-ADR database by the GDR health authorities, as these data is unknown to the public. ADR reports were analysed with respect to time, type of reporter, age and sex of the patient, category of ADR (System Organ Class [SOC]), seriousness and suspected medicines. The unit of analysis was one ADR. A total of 180 individual ADR reports covering 329 ADRs were forwarded from 1985 to 1990. The largest share of ADRs was reported for psychotropic medicines (23% of total ADRs) followed by anti-infectives for systemic use (19% of ADRs), and medicines for the cardiovascular system (16% of ADRs). The largest share of reported ADRs was from the SOC "hepatobiliary disorders" (16% of total ADRs), followed by the SOCs "skin and subcutaneous disorders" (14% of total ADRs) and "blood and lymphatic disorders" (11% of total ADRs). Approximately 10% of ADRs were serious and included fatal cases. In conclusion, only a limited number of ADR cases occurring in the former GDR, the majority being non-serious, were located in the WHO database. However from government files we know that a large number of serious and fatal ADRs were reported, but information about these were never communicated to the public.

Keywords: Pharmacovigilance, Spontaneous Reporting Systems, VigiBase, German Democratic Republic

1. Introduction

During the 1960s, in the wake of the *thalidomide* catastrophe in the late 1950s [1], pharmacovigilance systems were established in many western European countries, Canada and Australia [2]. The World Health Organization (WHO) established an international reporting system in 1968 and over the years an ever-increasing number of countries have joined this collaboration [3]. In the second half of the 20th century, a separate pharmaceutical policy system was established in the previous *Council for Mutual Economic Assistance* (*Comecon*) countries, but little is known to the public about the principles of this system. The German Democratic Republic (GDR) was well-known for its large production of pharmaceuticals, often copies of medications developed by pharmaceutical companies in capitalistic countries, produced in large state-owned companies which supplied the other Comecon members [4]. New medicines were introduced years later in the GDR than in western European countries, and due to safety reasons *thalidomide* was never marketed in the GDR. Medicines safety was of great importance to the East German politicians and to increase medicines safety in the GDR, a national ADR reporting system was established in 1964 [4-5]. Limited information about data reported to this system was communicated to the prescribers and patients, as such type of information was considered as being a state secret and only available to

people working with drug regulation. Available product information and/or patient leaflets were of very limited quality or non-existing and difficult to get access to, as these documents were only produced in a limited number of copies [4].

Internal documents from the GDR health authorities revealed that from 1981 to 1983 spontaneous reports covering information about more than 120 deaths from use of anti-rheumatic medications containing *indometacin* (*Metindol/Amuno*), *diclofenac* (*Rewodina*), *phenylbutazone* (*Butazolidin*), *aminophenazone + phenylbutazone* (*Wofapyrin*) and the antidiarrheal *Mexaform plus* (*phanquinon + dichlorhydroxychinolin*) and *dichlorhydroxychinolin* (*Endiaron*) existed, but no restrictions for the use of these products were made [4]. For the X-ray contrast agent *iomeglamic acid* (*Falignost*) several serious cases of allergies and anaphylactic shocks were reported which led to changes in the production, as radiographic examination were frequently used as a diagnostic method in the GDR [4].

Of political reasons the GDR were not able to join the international WHO collaboration on medicines safety until 1983, despite that other Comecon countries such as Bulgaria, the Czech Republic, Poland and Romania had already joined this collaboration in the 1970s. From 1985 until the German reunification in 1990, ADR reports were forwarded to the WHO ADR database, VigiBase by the GDR health authorities [4,6-7].

We aim to characterize these ADRs reports, as these data has never been published before, and therefore would be of interest to the public.

2. Methods

2.1. Design

We retrospectively analysed all ADR reports occurring in the GDR which were reported to VigiBase from July 1985 to May 1990. ADR data were placed at the disposal of this study in anonymous form with encrypted identification of the medicine user. ADR reports were provided by the Uppsala Monitoring Centre (UMC) as CIOMS reports, and data from these reports were manually entered into Microsoft Excel. The unit of analysis was one ADR.

We analysed the reports with regard to type of reporter, age and gender of the patient, type (system organ class [SOC]) and seriousness of reported ADRs with respect to medications involved.

2.2. Seriousness and Causality Criteria

The severity of ADRs was rated as certain, probable or possible according to the CIOMS scale [1]. Causality was rated as established, probable, possible, improbable and not to be ascertained. Reports were later classified as being serious or non-serious according to international criteria.

2.3. Classification of reported ADRs

Any ADRs reported were classified according to the international classification system Medicinal Dictionary for Regulatory Activities (MedDRA) by preferred term (PT) and (SOC) [8].

2.4. Setting

A national ADR reporting system was established in 1964 by law by the GDR's Ministry of Health [5]. The system was managed by the "Institut für Arzneimittelwesen der DDR" (IfAr), and physicians and pharmacists were required to report ADRs [4-5].

An official reporting form ("Meldung von Schädlichen Arzneimittelwirkungen") had to be completed, and the following information was required: age and gender of the patient; severity and characteristics of the ADR(s), suspected and concomitant medicines, indication for use, dosage, treatment period, date of onset of ADR, causality assessment and other relevant information such as laboratory data if available (internal documents).

2.5. Medicine Use in the GDR

Medicines licensed for use in the GDR were listed in the "Arzneimittel Verzeichnis", published periodically by the IfAr and containing information about the active ingredients of available medicines, dosage, warnings, ADRs and contra-indications [6]. From 1945 to 1990 approximately 1770 different types of medicines (prescription medicine, over-the-counter medicine, complementary medicine, herbals, homeopathic medicine, allergen extracts, blood products and radioactive medications) were licensed for use in the GDR [7]. The number and assortment varied over time. In the same period, up to 57,000 different pharmaceutical products were licensed for use in West Germany [7]. In the beginning of the 1960s, the number of medicines imported into the GDR constituted 5% of all licensed medicines in the GDR, but this share increased up to approximately 30% of all licensed medicine in 1989/1990 [6]. The imported medicines were produced by pharmaceutical companies located in COMECON member states (estimated 20%) or in Western European countries (estimated 10%), and imported in the GDR by the special office/pharmacy: "Beratungsbüro für Arzneimittel", which worked for the

GDR Ministry of Health. Medicines imported from Western countries had to be paid with Western currencies, therefore the import was limited, and the aim was in most cases to substitute in the future with GDR or COMECON production [6]. Prescription medicines were free in the GDR, and over-the-counter medicines were inexpensive. Medicine prices were fixed by the state, and rarely changed from 1945 to 1990 [6].

3. Results

In total 180 individual ADR reports covering 329 ADRs were reported from 1985 to 1990. The ADR reports were of high quality and very detailed with information about causality assessment and reaction outcome. Approximately 10% of reported ADRs were serious and 13 fatal cases were located (**Table 1**), however these ADRs were all known ADRs. Two-thirds of the total ADRs were reported by hospital physicians, 23% of ADRs by general practitioners and 12% of ADRs were reported by specialist physicians. Serious ADRs were only reported by hospital physicians. No ADRs were reported by pharmacists.

3.1. ADRs by Age and Sex

The majority of reported ADRs (88% of total) occurred in adults, followed by 6% of ADRs reported in children from ages 3 to 10. Less than six percent of ADRs was reported in children up to two years of age and in adolescents (ages 11 - 17). Forty percent of ADRs was reported for males and sixty percent of ADRs for females.

3.2. ADRs by Type and Seriousness

The largest share of reported ADRs was from the SOC "hepatobiliary disorders" (16% of total ADRs), followed by the SOCs "skin and subcutaneous disorders" (14% of total ADRs) and "blood and lymphatic disorders" (11% of total ADRs).

3.3. ADRs by Medication

Less than 10% of ADRs were reported for medications imported from non-socialistic countries. The largest share of ADRs was reported for psychotropic medicines (23% of total ADRs) followed by anti-infectives for systemic use (19% of ADRs), and medicines for the cardiovascular system (16% of ADRs).

4. Discussion

This is the first study to retrospectively analyse spontaneous ADR reports from the former German Democratic Republic submitted to the WHO-ADR database. From 1985 to 1990 only a selected number of ADR reports

Table 1. Characteristics of serious adverse drug reactions leading to death reported to Vigibase, German Democratic Republic, 1985-1990.

Case no.	Year	ATC group	Medicine	Active substance	Adverse drug reaction (ADR)	Indication	Gender	Age (year)
1	1985	M01AB05	Rewodina	Diclofenac	Pancytopenia	Spondolysis	Female	64
2	1988	P01BD01	Tindurin	Pyrimethamine	Agranulocytosis	Perinatal condition	Male	1
3	1988	N02BB02	Analgin	Metamizole/lidocain	Agranulocytosis	Nasopharyngitis	Male	49
4	1988	J01ED07	Mebacid	Sulfamerazine	Epidermal necrolysis	Chronic bronchitis	Female	61
5	1988	J01BA01	Berlicetin	Chloramphenicol	Marrow depression	Chronic bronchitis	Female	49
7	1989	J01CA01	Ampicillin	Ampicillin	Anaphylactic shock	Chronic bronchitis	Female	52
8	1989	M01AA06	Ketazone	Kebuzone	Purpura Thrombocytopenia	Effusion of joint	Female	74
9	1988	N02BB04 M01AA06	Eufibron Ketazone	Propyphenazone Kebuzone	Disseminated intravascular coagulation Marrow depression Cardiomyopathy	NA	Male	17
10	1989	P01AB01	Clont	Metronidazole	Anaphylactic shock	NA	Female	51
11	1990	V08AA01	Visotrast	Amidotrizoic acid	Anaphylactic shock	Hydronephrosis	Male	68
12	1990	M03CA01	Pavulon	Pancuronium	Bradycardia Cardiac arrest	NA	Male	5 mo.
13	1990	N05AH02	Alemoxan	Clozapine	Agranulocytosis	NA	Male	50

NA: not *vailable; mo: months.

were forwarded to VigiBase despite that around 400 to 500 ADR reports were reported annually to the GDR health authorities [4]. The low number of reports submitted to VigiBase was due to the fact that when the GDR joined the WHO collaboration the IfAr decided that only unknown and severe ADRs should be reported to VigiBase. The ADR reports located in VigiBase were in line with observations from other western European countries with respect to type and suspected medication [9-10]. Few serious cases were reported, however causality was only established in three cases. Only a small number of serious ADRs was reported in the GDR, however, several cases of hepatitis and anaphylactic shock were classified as non-serious although causality was rated as being certain or possible. In the cases of anaphylactic shock the reported medicines were often administered intravenously (IV) or subcutaneously (SC). Only one case of pancytopenia reported for diclofenac was located despite that many other serious ADR cases were reported in the 1970s and 1980s [4].

As we only have ADR data from the last six years of the existence of the GDR, it was not possible to conduct a time trend analysis. The UMC could not guarantee that the actual number of ADR reports from the GDR authorities had been higher, but reports included in this study only represent those reported to VigiBase. In general, the ADR reports were of high quality and thorough, but due to their low number, they only represent a limited number of the ADRs which eventually occurred in the former GDR. To explore whether a greater number of ADRs was reported elsewhere in East Germany, one would need access to the archives from the former East Germany.

5. Conclusions

Only selected information about ADRs occurring in the former GDR was located in the WHO database. However from government files we know that a large number of serious and fatal ADR cases were reported to national authorities, but information was never communicated to the patients or prescribers.

6. References

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Supporting Information

Additional supporting information may be found in the online version of this article in **Table S1**.

Table S1. Characteristics of adverse drug reaction reports from the German Democratic Republic (GDR) to Vigibase, 1985 to 1990.

Case no.	Year	ATC	Medicine	Manufacturer	Active substance	Adverse drug reaction	Serious	Indication	Gender	Outcome	Causality	Dose	Admin.	Reporter	Age (years)
1	1985	H02AB06	Prednisolut	GDR	Prednisolon	Bradycardia	No	Bronchitiss	Male	Recovered	Certain	25 mg	IV	Hospital	59
	1985	H02AB06	Prednisolut	GDR	Prednisolon	Apnoea	No	Bronchitis	Male	Recovered	Certain	25 mg	IV	Hospital	59
	1985	H02AB06	Prednisolut	GDR	Prednisolon	Anaphylactic shock	No	Bronchitis	Male	Recovered	Certain	25 mg	IV	Hospital	59
2	1986	N05CM02	Distraneurin	AstraZeneca	Clomethiazole	Hypotonia	No	Psychoses	Male	Recovered	Certain	3 DF	Oral	Hospital	46
	1986	N05CM02	Distraneurin	AstraZeneca	Clomethiazole	Bradycardia	No	Psychoses	Male	Recovered	Certain	3 DF	Oral	Hospital	46
s	1986	N05CM02	Distraneurin	AstraZeneca	Clomethiazole	Circulatory failure	No	Psychoses	Male	Recovered	Certain	3 DF	Oral	Hospital	46
	1986	N05CM02	Distraneurin	AstraZeneca	Clomethiazole	Anaphylactic shock	No	Psychoses	Male	Recovered	Certain	3 DF	Oral	Hospital	46
3	1986	C05BX01	Calcium dobesilate	GDR	Calcium dobesilate	Fever	No	Retinal disorders	Female	NA	Probable	750 mg	Oral	SP	71
4	1986	N05AD01	Haloperidol	Hungary	Haloperidol	Palpitation	No	Psychoses	Female	Recovered	Certain	3 mg	Oral	GP	10
	1986	N05AD01	Haloperidol	Hungary	Haloperidol	Somnolence	No	Psychoses	Female	Recovered	Certain	3 mg	Oral	GP	10
	1986	N05AD01	Haloperidol	Hungary	Haloperidol	Dyskinesia tardive	No	Psychoses	Female	Recovered	Certain	3 mg	Oral	GP	10
	1986	N05AD01	Haloperidol	Hungary	Haloperidol	Anxiety	No	Psychoses	Female	Recovered	Certain	3 mg	Oral	GP	10
5	1986	N03AB02	Phenytoin	GDR	Phenytoin	Nausea	No	Epilepsy	Female	Recovered	Possible	300 mg	Oral	GP	45
	1986	C02AB01	Dopegyt	Hungary	Methyldopa	Ataxia	No	Hypertension	Female	Recovered	Possible	300 mg	Oral	GP	45
	1986	C02AB01	Dopegyt	Hungary	Methyldopa	Diplopia	No	Hypertension	Female	Recovered	Possible	300 mg	Oral	GP	45
6	1986	N03AF01	Finlepsin	GDR	Carbamazepine	Rash maculo-papular	No	Trigeminal nerve disorder	Female	Recovered	Certain	400 mg	Oral	SP	61
7	1987	J01XE01	Nitrofurantin	GDR	Nitrofurantoin	Alveolitis allergic	No	Urinary tract infection	Female	Recovered	Certain	NA	Oral	GP	70
	1987	J01XE01	Nitrofurantin	GDR	Nitrofurantoin	Fever	No	Urinary tract infection	Female	Recovered	Certain	NA	Oral	GP	70
8	1987	C02AB01	Dopegyt	Hungary	Methyldopa	Fever	No	Hypertension	Male	Recovered	Certain	500 mg	Oral	Hospital	59
9	1988	M01AB05	Rewodina	GDR	Diclofenac	Anaphylactic shock	No	Cervical spondylosis	Female	Recovered	Possible	2 DF	Oral	Hospital	55
	1988	M01AB05	Rewodina	GDR	Diclofenac	Bronchospasm	No	Cervical spondylosis	Female	Recovered	Possible	2 DF	Oral	Hospital	55
10	1989	H02AB06	Prednisolut	GDR	Prednisolon	Anaphylactic shock	No	Myeloid leukaemia	Female	Recovered w. sequaelae	Certain	100 mg	IV	SP	54
	1989	H02AB06	Prednisolut	GDR	Prednisolon	Cardiac arrest	No	Myeloid leukaemia	Female	Recovered w. sequaelae	Certain	100 mg	IV	SP	54
	1989	H02AB06	Prednisolut	GDR	Prednisolon	Apnoea	No	Myeloid leukaemia	Female	Recovered w. sequaelae	Certain	100 mg	IV	SP	54
11	1989	A07EC01	Sulfasalazine	Yugoslavia	Sulfasalazine	Hepatic necrosis	No	Ulcerative colitis	Male	Recovered w. sequaelae	Certain	8 DF	Oral	Hospital	48
	1989	A07EC01	Sulfasalazine	Yugoslavia	Sulfasalazine	Hepatitis	No	Ulcerative colitis	Male	Recovered w. sequaelae	Certain	8 DF	Oral	Hospital	48
12	1989	A02BA01	Altramet	GDR	Cimetidine	Alopecia	No	Duodenal ulcer	Male	Recovered	Probable	800 mg	Oral	Hospital	30
13	1989	J01XE01	Nifurantin	GDR	Nitrofurantoin	Bronchospasm	No	Pyelonephritis	Male	Recovered	Certain	200 mg	Oral	Hospital	35

	1989	J01XE01	Nifurantin	GDR	Nitrofurantoin	Cyanosis	No	Pyelonephritis	Male	Recovered	Certain	200 mg	Oral	Hospital	35
	1989	J01XE01	Nifurantin	GDR	Nitrofurantoin	Coughing	No	Pyelonephritis	Male	Recovered	Certain	200 mg	Oral	Hospital	35
	1989	J01XE01	Nifurantin	GDR	Nitrofurantoin	Fever	No	Pyelonephritis	Male	Recovered	Certain	200 mg	Oral	Hospital	35
14	1989	D10AX05	Avlosulfon	Wyeth-Ayerst	Dapsone	Anaemia haemolytic	No	Erythematous conditions	Female	Recovered	Certain	2.5 DF	Oral	Hospital	33
	1989	D10AX05	Avlosulfon	Wyeth-Ayerst	Dapsone	Conjunctivitis	No	Erythematous conditions	Female	Recovered	Certain	2.5 DF	Oral	Hospital	33
	1989	D10AX05	Avlosulfon	Wyeth-Ayerst	Dapsone	Methaemoglobinaemia	No	Erythematous conditions	Female	Recovered	Certain	2.5 DF	Oral	Hospital	33
	1989	D10AX05	Avlosulfon	Wyeth-Ayerst	Dapsone	Sgpt increased	No	Erythematous conditions	Female	Recovered	Certain	2.5 DF	Oral	Hospital	33
	1989	D10AX05	Avlosulfon	Wyeth-Ayerst	Dapsone	Sgot increased	No	Erythematous conditions	Female	Recovered	Certain	2.5 DF	Oral	Hospital	33
15	1989	N06BX01	Cerutil	GDR	Meclofenoxate	Arrhytmia	No	Stress	Male	Recovered	Certain	300 mg	Oral	GP	54
	1989	N06BX01	Cerutil	GDR	Meclofenoxate	Headache	No	Stress	Male	Recovered	Certain	300 mg	Oral	GP	54
16	1985	M01AB05	Rewodina	GDR	Diclofenac	Pancytopenia	Yes	Spondolysis	Female	Died	Possible	50 mg	Oral	Hospital	64
	1985	M01AB05	Rewodina	GDR	Diclofenac	Death	Yes	Spondolysis	Female	Died	Possible	50 mg	Oral	Hospital	64
17	1988	P01BD01	Tindurin	Hungary	Pyrimethamine	Agranulocytosis	Yes	Perinatal condition	Male	Died	Certain	450 mg	Oral	Hospital	1
	1988	P01BD01	Tindurin	Hungary	Pyrimethamine	Death	Yes	Perinatal condition	Male	Died	Certain	450 mg	Oral	Hospital	1
18	1988	N02BB02	Analgin	GDR	Metamizole/ lidocain	Agranulocytosis	Yes	Nasopharyngitis	Male	Died	Possible	14 g	Oral	Hospital	49
	1988	N02BB02	Analgin	GDR	Metamizole/ lidocain	Death	Yes	Nasopharyngitis	Male	Died	Possible	14 g	Oral	Hospital	49
19	1988	J01ED07	Mebacid	GDR	Sulfamerazine	Epidermal necrolysis	Yes	Bronchitis	Female	Died	Probable	1 g	Oral	Hospital	61
	1988	J01ED07	Mebacid	GDR	Sulfamerazine	Death	Yes	Bronchitis	Female	Died	Probable	1 g	Oral	Hospital	61
20	1988	J01BA01	Berlicetin	GDR	Chloramphenicol	Marrow depression	Yes	Bronchitis	Female	Died	Probable	2g	Oral	Hospital	49
	1988	J01BA01	Berlicetin	GDR	Chloramphenicol	Death	Yes	Bronchitis	Female	Died	Probable	2g	Oral	Hospital	49
21	1989	J01CA01	Ampicillin	Bulgaria	Ampicillin	Anaphylactic shock	Yes	Bronchitis	Female	Died	Probable	4g	IV	Hospital	52
	1989	J01CA01	Ampicillin	Bulgaria	Ampicillin	Death	Yes	Bronchitis	Female	Died	Probable	4g	IV	Hospital	52
22	1989	M01AA06	Ketazon	CSSR	Kebuzone	Purpura	Yes	Effusion of joint	Female	Died	Certain	0.5 g	Oral	Hospital	74
	1989	M01AA06	Ketazon	CSSR	Kebuzone	Thrombocytopenia	Yes	Effusion of joint	Female	Died	Certain	0.5 g	Oral	Hospital	74
	1989	M01AA06	Ketazon	CSSR	Kebuzone	Death	Yes	Effusion of joint	Female	Died	Certain	0.5 g	Oral	Hospital	74
23	1988	M01AA06	Ketazon	CSSR	Kebuzone	Death	Yes	NA	Male	Died	Probable	NA	Oral	Hospital	17
	1988	N02BB04	Eufibron	GDR	Propyphenazone	Dic	Yes	NA	Male	Died	Probable	NA	Oral	Hospital	17
	1988	N02BB04	Eufibron	GDR	Propyphenazone	Marrow depression	Yes	NA	Male	Died	Probable	NA	Oral	Hospital	17
	1988	N02BB04	Eufibron	GDR	Propyphenazone	Cardiomyopathy	Yes	NA	Male	Died	Probable	NA	Oral	Hospital	17
24	1989	P01AB01	Clont	Bayer	Metronidazole	Anaphylactic shock	Yes	NA	Female	Died	Probable	500 mg	IV	Hospital	51
	1989	P01AB01	Clont	Bayer	Metronidazole	Death	Yes	NA	Female	Died	Probable	500 mg	IV	Hospital	51
25	1990	V08AA01	Visotrast	GDR	Amidotrizoic acid	Anaphylactic shock	Yes	Hydronephrosis	Male	Died	Certain	35 ml	IV	Hospital	68

	1990	V08AA01	Visotrast	GDR	Amidotrizoic acid	Death	Yes	Hydronephrosis	Male	Died	Certain	35 ml	IV	Hospital	68
26	1990	N05AH02	Alemoxan	GDR	Clozapine	Agranulocytosis	Yes	NA	Male	Died	Probable	200 mg	Oral	Hospital	50
27	1985	N05AH02	Clozapine	Novartis	Clozapine	Agranulocytosis	No	Schizophrenia	Male	Recovered	Certain	250 mg	Oral	Hospital	49
	1985	N05AH02	Clozapine	Novartis	Clozapine	Fever	No	Schizophrenia	Male	Recovered	Certain	250 mg	Oral	Hospital	49
	1985	N05AH02	Clozapine	Novartis	Clozapine	Rash erythematous	No	Schizophrenia	Male	Recovered	Certain	250 mg	Oral	Hospital	49
28	1985	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatitis necrosis	No	Hypertension	Female	NA	Certain	1.5 DF	Oral	Hospital	52
	1985	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatitis	No	Hypertension	Female	NA	Certain	1.5 DF	Oral	Hospital	52
29	1986	M01AE01	Ibuprofen	Poland	Ibuprofen	Haematuria	No	Pain	Female	Recovered	Probable	600 mg	Oral	GP	35
30	1986	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis	No	Ankylosing spondylitis	Female	NA	Probable	1.5 g	Oral	Hospital	46
31	1986	J01X E01	Nitrofurantin	GDR	Nitrofurantoin	Spasm generalized	No	Cystitis	Female	NA	Certain	100 mg	Oral	GP	34
	1986	J01X E01	Nitrofurantin	GDR	Nitrofurantoin	Tachycardia	No	Cystitis	Female	NA	Certain	100 mg	Oral	GP	34
	1986	J01X E01	Nitrofurantin	GDR	Nitrofurantoin	Hypotension	No	Cystitis	Female	NA	Certain	100 mg	Oral	GP	34
	1986	J01X E01	Nitrofurantin	GDR	Nitrofurantoin	Pruritus	No	Cystitis	Female	NA	Certain	100 mg	Oral	GP	34
	1986	J01X E01	Nitrofurantin	GDR	Nitrofurantoin	Vomiting	No	Cystitis	Female	NA	Certain	100 mg	Oral	GP	34
32	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Hypotonia	No	Cerebral ischaemia	Male	Recovered	Certain	10 ml	IV	Hospital	84
	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Tachycardia	No	Cerebral ischaemia	Male	Recovered	Certain	10 ml	IV	Hospital	84
	1986	B05CB10	Infukoll m40	GDR	Sodium schlo-ride/ dextran 40	Anaphylactic shock	No	Cerebral ischaemia	Male	Recovered	Certain	10 ml	IV	Hospital	84
33	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Hypotonia	No	Atherosclerosis	Female	Recovered	Probable	250 ml	IV	Hospital	70
	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Dyspnoea	No	Atherosclerosis	Female	Recovered	Probable	250 ml	IV	Hospital	70
34	1986	A03FA01	Cerucal	GDR	Metoclopramide	Depression	No	Acute gastritis	Female	NA	Possible	30 mg	Oral	GP	60
35	1986	N05BA01	Faustan	GDR	Diazepam	Rash erythematous	No	Cardiovascular malfunction	Female	Recovered	Possible	15mg	Oral	GP	35
36	1986	J01XE01	Nitrofurantin	GDR	Nitrofurantoin	Urticaria acute	No	Urinary tract infection	Female	Recovered	Certain	100 mg	Oral	GP	35
37	1986	J01EE07	Berlocombin	GDR	Sulfamerazine /trimethoprim	Pruritus	No	Respiratory infection	Female	Recovered	Probable	4 DF	Oral	GP	42
	1986	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Rash erythematous	No	Respiratory infection	Female	Recovered	Probable	4 DF	Oral	GP	42
	1986	B05CA01	Trachiform	GDR	Benzocaine/ cetylpyridinium	Pruritus	No	Respiratory infection	Female	Recovered	Probable	6 DF	Oral	GP	42
	1986	B05CA01	Trachiform	GDR	Benzocaine/ cetylpyridinium	Rash erythematous	No	Respiratory infection	Female	Recovered	Probable	6 DF	Oral	GP	42
38	1986	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Rash erythematous	No	Respiratory infection	Female	Recovered	Probable	4 DF	Oral	GP	76
39	1986	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Erythema exudativum	No	Respiratory infection	Male	Recovered	Certain	6DF	Oral	Hospital	57
40	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Bronchospasm	No	Cerebral ischaemia	Female	Recovered	Certain	10 ml	IV	Hospital	70
	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Circulatory failure	No	Cerebral ischaemia	Female	Recovered	Certain	10 ml	IV	Hospital	70
	1986	B05CB10	Infukoll m40	GDR	Sodium chloride/ dextran 40	Anaphylactic shock	No	Cerebral ischaemia	Female	Recovered	Certain	10 ml	IV	Hospital	70
41	1986	C02DB01	Depressan	GDR	Dihydralazine	Hepatocellular damage	No	Hypertension	Female	Recovered	Certain	75 mg	Oral	Hospital	48

42	1986	C08CA05	Corinfar	GDR	Nifedipine	Oedema legs	No	Hypertension	Male	Recovered	Probable	30 mg	Oral	GP	49
43	1986	C02AB01	Dopegyt	Hungary	Methyldopa	Anaemia haemolytic	No	Hypertension	Male	NA	Probable	2g	Oral	Hospital	55
44	1986	V03AB14	Protamin	GDR	Protamin	Anaphylactic shock	No	Neoplasms	Female	Recovered	Certain	45 mg	IA	NA	33
45	1986	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatocellular damage	No	Hypertension	Female	Recovered	Certain	1 DF	Oral	Hospital	78
	1986	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Jaundice	No	Hypertension	Female	Recovered	Certain	1 DF	Oral	Hospital	78
	1986	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Sgot increased	No	Hypertension	Female	Recovered	Certain	1 DF	Oral	Hospital	78
	1986	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Sgpt increased	No	Hypertension	Female	Recovered	Certain	1 DF	Oral	Hospital	78
	1986	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Bilirubinaemia	No	Hypertension	Female	Recovered	Certain	1 DF	Oral	Hospital	78
46	1986	J04AB02	Rifampicin	Romania	Rifampicin	Thrombocytopenia	No	Tuberculosis	Male	Not recovered	Possible	600 mg	Oral	SP	65
47	1986	A03FA01	Cerucal	GDR	Metoclopramide	Dystonia	No	Gastritis	Female	Recovered	Probable	50 mg	Oral	Hospital	18
	1986	A03FA01	Cerucal	GDR	Metoclopramide	Oculogyric crisis	No	Gastritis	Female	Recovered	Probable	50 mg	Oral	Hospital	18
	1986	A03FA01	Cerucal	GDR	Metoclopramide	Torticollis	No	Gastritis	Female	Recovered	Probable	50 mg	Oral	Hospital	18
48	1986	M01AB05	Rewodina	GDR	Diclofenac	Anaphylactoid reaction	No	Spondylosis	Female	Recovered	Probable	25 mg	Oral	GP	54
49	1986	N02BB02	Analgin	GDR	Metamizole/ Lidocain	Agranulocytosis	No	Respiratory infection	Male	Recovered	Probable	1.5 DF	Oral	Hospital	76
50	1986	A01AA01	Koreberon	GDR	Sodium fluoride	Parasthesia	No	Osteoporosis	Male	Not recovered	Possible	60 mg	Oral	GP	49
51	1986	J01XE01	Nitrofurantin	GDR	Nitrofurantoin	Anaphylactic shock	No	Urinary tract infection	Female	Recovered	Probable	100 mg	Oral	Hospital	54
52	1986	B03AB02	Ferrum-III-Saccharose	Bulgaria	Ferrum-III-Saccharose	Anaphylactic shock	No	Iron deficiency anaemia	Female	Recovered	Certain	400 mg	IV	SP	29
53	1986	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis cholestatic	No	Crystal arthropahy	Female	Recovered	Certain	250 mg	Oral	SP	21
54	1986	J01AA02	Doxymycin	GDR	Doxycycline	Hepatocellular damage	No	Diseases of endocardium	Male	Recovered	Probable	1 DF	Oral	Hospital	50
55	1986	J04AC01	INH_Tabletten	GDR	Isoniazid	Muscle atrophy	No	Pulmonary uberculosis	Male	Recovered w. sequaelae	Probable	NA	Oral	SP	45
	1986	J04AC01	INH-Tabletten	GDR	Isoniazid	Neuropathy	No	Pulmonary uberculosis	Male	Recovered w. sequaelae	Probable	NA	Oral	SP	45
56	1986	A06AB02	Pyrilax	GDR	Bisacodyl	Anaphylactoid reaction	No	Constipation	Female	Recovered	Probable	10 mg	Rectal	Hospital	75
57	1986	A06AB02	Pyrilax	GDR	Bisacodyl	Anaphylactoid reaction	No	Constipation	Female	Recovered	Probable	10 mg	Rectal	Hospital	61
58	1986	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Hepatitis cholestatic	No	Kidney infection	Female	Recovered	Certain	18 DF	Oral	Hospital	36
59	1986	N02BB02	Analgin	GDR	Metamizole/ lidocain	Thrombocytopenia	No	Calculus of gallbladder	Female	NA	Possible	NA	NA	Hospital	77
	1986	N02BB02	Analgin	GDR	Metamizole/ lidocain	Marrow depression	No	Calculus of gallbladder	Female	NA	Possible	NA	NA	Hospital	77
	1986	N02BB02	Analgin	GDR	Metamizole/ lidocain	Leucopenia	No	Calculus of gallbladder	Female	NA	Possible	NA	NA	Hospital	77
60	1987	N03AA03	Primidone	USSR	Primidone	Nausea	No	Epilepsy	Female	Recovered	Probable	250 mg	Oral	Hospital	45
61	1987	M01CB01	Tauredon	Byk Gulden	Aurothiomalate	Rash erythematous	No	Rheumatoid arthritis	Female	Not recovered	Certain	520 mg	IM	SP	52
62	1987	G03AA07	Minisiston	GDR	Ethinylestradiol/ levonorgestrel	Hepatocellular damage	No	NA	Female	Recovered	Certain	1 DF	Oral	SP	18
63	1987	C02DB01	Depressan	GDR	Dihydralazine	Hepatocellular damage	No	Hypertension	Female	NA	Probable	50 mg	Oral	GP	48
64	1987	A11GA01	Vitamin C	GDR	Ascorbic acid	Vertigo	No	Urinary tract infection	Female	Recovered	Probable	NA	Oral	GP	53

	1987	A11GA01	Vitamin C	GDR	Ascorbic acid	Coordination abnormal	No	Urinary tract infection	Female	Recovered	Probable	NA	Oral	GP	53
65	1987	J01MB02	Negram	Yugoslavia	Nalidixic acid	Rash erythematous	No	Kidney infection	Male	Recovered	Probable	4 DF	Oral	SP	78
66	1986	M01AB05	Rewodina	GDR	Diclofenac	Vertigo	No	Osteoarthrosis	Female	Not recovered	Possible	150 mg	Oral	GP	77
	1986	N04BA01	Dopaflex	Hungary	Levodopa	Oedema legs	No	Parkinson's disease	Female	Not recovered	Possible	4 DF	Oral	GP	77
	1986	N04BA01	Dopaflex	Hungary	Levodopa	Catatonic reaction	No	Parkinson's disease	Female	Not recovered	Possible	4 DF	Oral	GP	77
67	1986	N04BA01	Dopaflex	Hungary	Levodopa	Haemorrhage nos	No	Parkinson's disease	Female	Recovered	Probable	0.5 mg	Oral	SP	77
	1986	N04BA01	Dopaflex	Hungary	Levodopa	Thrombocytopenia	No	Parkinson's disease	Female	Recovered	Probable	0.5 mg	Oral	SP	77
68	1987	G03BA02	Oral-turinabol	GDR	Testosterone	Hepatitis	No	Nutritional deficiencies	Male	Recovered	Probable	15 mg	Oral	Hospital	70
69	1987	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Female	NA	Probable	75 mg	Oral	SP	34
70	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Tachycardia	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	56
	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Parasthesia	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	56
	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Nausea	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	56
71	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Tachycardia	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	67
	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Parasthesia	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	67
	1987	N06BX01	Cerutil	GDR	Meclofenoxate	Nausea	No	Cerebrovascular disease	Female	Recovered	Possible	500 mg	IV	Hospital	67
72	1987	P01BA01	Chlorochin	GDR	Chloroquine	Amnesia	No	Lichen	Female	Recovered	Possible	250 mg	Oral	Hospital	49
	1987	P01BA01	Chlorochin	GDR	Chloroquine	Psychosis	No	Lichen	Female	Recovered	Possible	250 mg	Oral	Hospital	49
73	1987	H03BB02	Thiamazole	Merck	Thiamazole	Hepatitis cholestatic	No	Thyrotoxicosis	Female	Recovered	Probable	30 mg	Oral	Hospital	36
74	1987	P03AB02	Hch-Salbe	GDR	Lindane	Convulsions local	No	Scabies	Male	Recovered	Probable	80 g	Top.	Hospital	20
	1987	P03AB02	Hch-Salbe	GDR	Lindane	Mydriasis	No	Scabies	Male	Recovered	Probable	80 g	Top.	Hospital	20
	1987	P03AB02	Hch-Salbe	GDR	Lindane	Tremor	No	Scabies	Male	Recovered	Probable	80 g	Top.	Hospital	20
	1987	P03AB02	Hch-Salbe	GDR	Lindane	Sweating increased	No	Scabies	Male	Recovered	Probable	80 g	Top.	Hospital	20
	1987	P03AB02	Hch-Salbe	GDR	Lindane	Tachycardia	No	Scabies	Male	Recovered	Probable	80 g	Top.	Hospital	20
75	1988	N03AF01	Finlepsin	GDR	Carbamazepine	Hepatocellular damage	No	Epilepsy	Male	NA	Probable	1 DF	Oral	GP	28
	1988	N03AF01	Finlepsin	GDR	Carbamazepine	Vomiting	No	Epilepsy	Male	NA	Probable	1 DF	Oral	GP	28
	1988	N03AF01	Finlepsin	GDR	Carbamazepine	Weight decrease	No	Epilepsy	Male	NA	Probable	1 DF	Oral	GP	28
76	1988	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis cholestatic	No	Gout	Male	Not recovered	Probable	9 DF	Oral	Hospital	59
77	1988	N03AF01	Finlepsin	GDR	Carbamazepine	Rash erythematous	No	Epilepsy	Female	Recovered	Probable	150 mg	Oral	Hospital	5
	1988	N03AF01	Finlepsin	GDR	Carbamazepine	Epidermal necrolysis	No	Epilepsy	Female	Recovered	Probable	150 mg	Oral	Hospital	5
78	1988	C05BX01	Calcium dobesilate	GDR	Calcium dobesilate	Angioedema	No	Phlebitis	Female	Recovered	Probable	2 DF	Oral	SP	42
79	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Petechiae	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44
	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Oedema legs	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44

	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Circulatory failure	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44
	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Dyspnoea	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44
	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Rash erythematous	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44
	1988	J04AC01	INH-Tabletten	GDR	Isoniazid	Fever	No	Tuberculosis	Male	NA	Probable	3 DF	Oral	GP	44
80	1988	M01AB05	Rewodina	GDR	Diclofenac	Bronchospasm	No	Sciatica	Male	NA	Certain	2 DF	Oral	Hospital	44
	1988	M01AB05	Rewodina	GDR	Diclofenac	Cyanosis	No	Sciatica	Male	NA	Certain	2 DF	Oral	Hospital	44
	1988	M01AB05	Rewodina	GDR	Diclofenac	Dyspnoea	No	Sciatica	Male	NA	Certain	2 DF	Oral	Hospital	44
81	1988	N02BB02	Analgin	GDR	Metamizole/ lidocain	Anaphylactoid reaction	No	Nasopharyngitis	Male	Recovered	Probable	500 mg	Oral	GP	36
82	1988	M01AC01	Piroxicam	GDR	Piroxicam	Gastric ulcer	No	Spondolysis	Male	Not recovered	Probable	40 mg	Oral	Hospital	73
83	1988	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis	No	Lumbalgia	Female	Recovered	Probable	500 mg	Oral	Hospital	60
84	1988	B02BA01	Kanavit	GDR	Phytomenadione	Anaphylactic shock	No	Coagulation factor deficiency	Female	Recovered	Certain	20 mg	IV	Hospital	56
85	1988	N02BB02	Analgin	GDR	Metamizole/ lidocain	Anaphylactic shock	No	Respiratory infection	Male	Recovered	Probable	750 mg	Oral	GP	57
86	1988	C02AB01	Dopegyt	Hungary	Methyldopa	Hepatitis	No	Hypertension	Female	Recovered	Certain	500 mg	Oral	Hospital	48
87	1988	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Female	Recovered	Probable	25 mg	Oral	Hospital	27
88	1988	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Male	Recovered	Probable	75 mg	Oral	Hospital	46
89	1988	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Female	Recovered	Certain	75 mg	Oral	Hospital	61
90	1988	H02AB06	Prednisolut	GDR	Prednisolon	Dyspnoea	No	Asthma	Female	Recovered	Certain	50 mg	IV	SP	24
	1988	H02AB06	Prednisolut	GDR	Prednisolon	Vomiting	No	Asthma	Female	Recovered	Certain	50 mg	IV	SP	24
	1988	H02AB06	Prednisolut	GDR	Prednisolon	Rash erythematous	No	Asthma	Female	Recovered	Certain	50 mg	IV	SP	24
91	1988	M01AC01	Piroxicam	GDR	Piroxicam	Rash erythematous	No	Rheumatoid arthritis	Female	Not recovered	Probable	40 mg	Oral	GP	46
	1988	M01AC01	Piroxicam	GDR	Piroxicam	Pruritus	No	Rheumatoid arthritis	Female	Not recovered	Probable	40 mg	Oral	GP	46
92	1988	R05DB04	Nullatuss	GDR	Isoaminile	Dizziness	No	Cough	Female	Recovered	Possible	20 gtt	Oral	GP	30
	1988	R05DB04	Nullatuss	GDR	Isoaminile	Headache	No	Cough	Female	Recovered	Possible	20 gtt	Oral	GP	30
	1988	R05DB04	Nullatuss	GDR	Isoaminile	Sweating increased	No	Cough	Female	Recovered	Possible	20 gtt	Oral	GP	30
	1988	R05DB04	Nullatuss	GDR	Isoaminile	Nausea	No	Cough	Female	Recovered	Possible	20 gtt	Oral	GP	30
93	1988	J01MB02	Negram	Yugoslavia	Nalidixic acid	Vision abnormal	No	Kidney infection	Female	Not recovered	Possible	750 mg	Oral	SP	12
94	1988	M01AB05	Rewodina	GDR	Diclofenac	Thrombocytopenia	No	Rheumatoid arthritis	Female	Recovered	Possible	75 mg	Oral	GP	65
	1988	M01AB05	Rewodina	GDR	Diclofenac	Purpura	No	Rheumatoid arthritis	Female	Recovered	Possible	75 mg	Oral	GP	65
	1988	M01AB05	Rewodina	GDR	Diclofenac	Heamaturia	No	Rheumatoid arthritis	Female	Recovered	Possible	75 mg	Oral	GP	65
95	1988	J01FA01	Lubomycin-b	Poland	Erythromycin	Hepatitis cholestatic	No	Diseases of sebaceous glands	Female	Recovered	Probable	800 mg	Oral	Hospital	18
	1988	J01FA01	Lubomycin-b	Poland	Erythromycin	Fever	No	Diseases of sebaceous glands	Female	Recovered	Probable	800 mg	Oral	Hospital	18
96	1988	C02DB01	Depressan	GDR	Dihydralazine	Thrombocytopenia	No	Hypertension	Male	Recovered	Probable	37 mg	Oral	Hospital	55

	1988	C02DB01	Depressan	GDR	Dihydralazine	Haematuria	No	Hypertension	Male	Recovered	Probable	37 mg	Oral	Hospital	55
	1988	C02DB01	Depressan	GDR	Dihydralazine	Purpura	No	Hypertension	Male	Recovered	Probable	37 mg	Oral	Hospital	55
	1988	C02DB01	Depressan	GDR	Dihydralazine	Melaena	No	Hypertension	Male	Recovered	Probable	37 m	Oral	Hospital	55
97	1988	C07FA05	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatitis	No	Hypertension	Female	Recovered	Certain	0.5 DF	Oral	Hospital	59
98	1988	J01FA01	Lubomycin-b	Poland	Erythromycin	Hepatitis cholestatic	No	Acne of sebaceous glands	Female	Recovered	Probable	800 mg	Oral	Hospital	23
99	1988	J01CE01	Jenacillin-a	GDR	Benzylpenicillin	Rash erythematous	No	Bronchopneumonia	Male	Recovered	Probable	800 kIU	IM	Hospital	2
100	1988	B01AA04	Falithrom	GDR	Phenprocoumon	Hepatitis	No	Venous embolism	Female	Recovered	Probable	3 mg	Oral	Hospital	37
101	1988	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Pruritus	No	Ulcerative colitis	Male	Recovered	Probable	3 g	Oral	Hospital	72
102	1988	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Hepatitis cholestatic	No	Respiratory infec-tion	Male	Recovered	Probable	4 DF	Oral	Hospital	41
103	1988	A02BX05	Pulvis stomachicus SR	GDR	Bismuth	Neuropathy	No	Ulcerative colitis	Male	Not recovered	Certain	36g	Oral	Hospital	48
	1988	A02BX05	Pulvis stomachicus SR	GDR	Bismuth	Ataxia	No	Ulcerative colitis	Male	Not recovered	Certain	36g	Oral	Hospital	48
104	1988	H03BB02	Methimazole	GDR	Thiamazole	Agranulocytosis	No	Toxic diffuse goiter	Female	Recovered	Certain	30 mg	Oral	Hospital	28
105	1988	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Flushing	No	Kidney infection	Female	Recovered	Probable	4 DF	Oral	GP	48
106	1988	N07BB01	Disulfiram	GDR	Disulfiram	Hepatitis	No	Alcohol dependence syndrome	Female	Recovered	Certain	250 mg	Oral	Hospital	26
107	1988	C02DB01	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatitis	No	Hypertension	Female	Not recovered	Certain	1.5 DF	Oral	Hospital	46
108	1988	C08CA05	Corinfar	GDR	Nifedipine	Pruritus	No	Hypertension	Female	Recovered	Certain	60 mg	Oral	GP	57
	1988	C08CA05	Corinfar	GDR	Nifedipine	Oedema legs	No	Hypertension	Female	Recovered	Certain	60 mg	Oral	GP	57
109	1998	A10BB01	Maninil	GDR	Glibenclamide	Anaemia haemolytic	No	Diabetes mellitus	Male	Recovered	Possible	3 mg	Oral	Hospital	64
110	1988	A03FA01	Cerucal	GDR	Metoclopramide	Extrapyramidal disorder	No	Gastritis	Female	Recovered	Certain	30 mg	Oral	SP	46
111	1988	N02BB04	Propyphenazone	GDR	Propyphenazone	Allergic reaction	No	Nasopharyngitis	Female	Recovered	Probable	200 mg	Rectal	Hospital	8
	1988	N02BB04	Propyphenazone	GDR	Propyphenazone	Bronchospasm	No	Nasopharyngitis	Female	Recovered	Probable	200 mg	Rectal	Hospital	8
	1988	N02BB04	Propyphenazone	GDR	Propyphenazone	Pruritus	No	Nasopharyngitis	Female	Recovered	Probable	200 mg	Rectal	Hospital	8
112	1988	J01FA01	Lubomycin-b	Poland	Erythromycin	Hepatocellular damage	No	Bronchiti	Male	Recovered	Certain	1.6 g	Oral	Hospital	8
113	1988	N03AG01	Convulsofin	GDR	Valproic acid	Pancreatitis	No	Epilepsy	Female	Recovered	Probable	80 gtt	Oral	Hospital	8
114	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazin	Pneumonia	No	Regional enteritis	Female	Not recovered	Probable	3 g	Oral	Hospital	34
	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazin	Glossitis	No	Regional enteritis	Female	Not recovered	Probable	3 g	Oral	Hospital	34
	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazin	Nausea	No	Regional enteritis	Female	Not recovered	Probable	3 g	Oral	Hospital	34
115	1989	J01AA02	Doxycycline	GDR	Doxycycline	Anaphylactic shock	No	NA	Female	Recovered	Probable	100 mg	IV	Hospital	20
116	1989	M01CC01	Penicillamine	CSSR	Penicillamine	Rash erythematous	No	NA	Female	Recovered	Certain	3 DF	Oral	Hospital	55
117	1989	NA	Patentblau v	BRD	Sulphan blue	Urticaria	No	Neoplasm of prostate	Male	Recovered	Probable	1 ml	SC	Hospital	64
118	1989	C02AB01	Dopegyt	Hungary	Methyldopa	Hepatitis	No	Hypertension	Female	Recovered	Probable	250 mg	Oral	Hospital	53
119	1989	C07FA05	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatitis	No	Hypertension	Female	Recovered	Certain	2 DF	Oral	Hospital	55

120	1989	C08CA05	Corinfar	GDR	Nifedipine	Oedema legs	No	Hypertension	Female	Not recovered	Probable	60 mg	Oral	GP	58
121	1989	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Male	Recovered	Probable	50 mg	Oral	Hospital	63
122	1989	H02AB06	Prednisolut	GDR	Prednisolon	Respiratory insufficiency	No	Asthma	Female	Recovered	Possible	50 mg	IV	Hospital	61
123	1989	N02BB02	Analgin	GDR	Metamizole/ lidocain	Anaphylactic shock	No	Respiratory infection	Female	Recovered	Probable	1.5 g	Oral	GP	35
124	1989	N03AF01	Finlepsin	GDR	Carbamazepine	Rash maculo-papular	No	Alcohol dependence syndrome	Male	Not recovered	Probable	400 mg	Oral	Hospital	21
	1989	N03AF01	Finlepsin	GDR	Carbamazepine	Rash follicular	No	Alcohol dependence syndrome	Male	Not recovered	Probable	400 mg	Oral	Hospital	21
125	1989	N02BB04	Propyphenazone	GDR	Propyphenazone	Allergic reaction	No	Respiratory infection	Male	Recovered	Probable	200 mg	Rectal	Hospital	8
	1989	N02BB04	Propyphenazone	GDR	Propyphenazone	Bronchospasm	No	Respiratory infection	Male	Recovered	Probable	200 mg	Rectal	Hospital	8
	1989	N02BB04	Propyphenazone	GDR	Propyphenazone	Rash erythematous	No	Respiratory infection	Male	Recovered	Probable	200 mg	Rectal	Hospital	8
	1989	N02BB04	Propyphenazone	GDR	Propyphenazone	Rhinitis	No	Respiratory infection	Male	Recovered	Probable	200 mg	Rectal	Hospital	8
126	1989	N05AA01	Propaphenin	GDR	Chlorpromazine	Hepatocellular damage	No	Constipation	Female	Not recovered	Probable	75 mg	Oral	Hospital	42
127	1989	J01CE01	Jenacillin	GDR	Benzylpenicillin	Dyspnoea	No	Skin disease	Male	NA	Certain	1 MIU	IM	GP	60
	1989	J01CE01	Jenacillin	GDR	Benzylpenicillin	Parasthesia	No	Skin disease	Male	NA	Certain	1 MIU	IM	GP	60
	1989	J01CE01	Jenacillin	GDR	Benzylpenicillin	Cyanosis	No	Skin disease	Male	NA	Certain	1 MIU	IM	GP	60
128	1989	C07FA05	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatocellular damage	No	Hypertension	Female	Not recovered	Probable	1 DF	Oral	Hospital	34
	1989	C07FA05	Obsilazin	GDR	Propranolol/ dihydralazin	Jaundice	No	Hypertension	Female	Not recovered	Probable	1 DF	Oral	Hospital	34
129	1989	D08AC02	Solutio Chlorhexidini SR	GDR	Chlorhexidine	Anaphylactic shock	No	Apical peridontitis	Male	Not recovered	Probable	5 ml	Dental	GP	20
130	1989	R03DA05	Aminophylline	GDR	Aminophylline	Phlebitis	No	Asthma	Male	Recovered	Probable	240 mg	IV	SP	54
131	1989	J01EE07	Berlocombin	GDR	Sulfamerazine/ trimethoprim	Nervousness	No	Acute sinusitis maxillary	Female	Recovered	Possible	4 DF	Oral	SP	74
132	1989	J01CE08	Pendysin	GDR	Benzathine benzylpenicillin	Anxiety	No	Erysipelas	Female	NA	Certain	1 DF	IM	Hospital	75
133	1989	J01AA02	Doxycycline	GDR	Doxycycline	Oesophagitis	No	Otitis media	Female	Recovered w. sequaelae	Probable	100 mg	Oral	GP	26
134	1988	N02BB02	Analgin	GDR	Metamizole/ lidocain	Agranulocytosis	No	Streptococcal sore throat	Female	Recovered	Possible	3 g	Oral	Hospital	14
135	1988	A02BA02	Zantic	GlaxoSmith Kline	Ranitidine	Hepatitis	No	Neoplasm of digestive system	Male	Recovered	Probable	2g	Oral	Hospital	42
136	1988	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Urticaria	No	Ulcerative colitis	Male	Recovered	Probable	3 g	Oral	Hospital	72
137	1989	B01AB01	Heparin	GDR	Heparin	Avascular necrosis of bone	No	Malignant neoplasm of rectum	Female	Not recovered	Certain	5 kIU	SC	Hospital	76
138	1989	N03AF01	Finlepsin	GDR	Carbamazepine	Rash maculo-papular	No	Epilepsy	Female	Recovered	Probable	3 DF	Oral	SP	28
	1989	N03AF01	Finlepsin	GDR	Carbamazepine	Pruritus	No	Epilepsy	Female	Recovered	Probable	3 DF	Oral	SP	28
139	1989	B01AB01	Heparin	GDR	Heparin	Avascular necrosis of bone	No	NA	Male	Not recovered	Probable	10 kIU	SC	Hospital	40
140	1989	C07FA05	Obsilazin	GDR	Propranolol/ dihydralazin	Hepatocellular damage	No	Hypertension	Female	Not recovered	Probable	3.5 DF	Oral	Hospital	55
141	1989	N03AB02	Phenytoin	GDR	Phenytoin	Dermatitis	No	Epilepsy	Male	Recovered	Probable	150 mg	Oral	Hospital	9
142	1989	C07AB13	Cordanum	GDR	Talinolol	Gastritis	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57
	1989	C07AB13	Cordanum	GDR	Talinolol	Blepharitis	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57

	1989	C07AB13	Cordanum	GDR	Talinolol	Conjunctivitis	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57
	1989	C07AB13	Cordanum	GDR	Talinolol	Lacrimation abnormal	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57
	1989	C07AB13	Cordanum	GDR	Talinolol	Rash erythematous	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57
	1989	C07AB13	Cordanum	GDR	Talinolol	Alopecia	No	Hypertension	Female	Not recovered	Probable	100 mg	Oral	GP	57
143	1989	V08AB05	Ultravist	Bayer	Iopromide	Thrombophlebitis	No	NA	Female	Recovered w. sequaelae	Certain	50 ml	IV	Hospital	48
	1989	V08AB05	Ultravist	Bayer	Iopromide	Embolism pulmonary	No	NA	Female	Recovered w. sequaelae	Certain	50 ml	IV	Hospital	48
144	1989	J01FA01	Etromycin	Orion	Erythromycin	Hepatocellular damage	No	NA	Male	Recovered	Certain	360 mg	Oral	Hospital	2
	1989	J01FA01	Etromycin	Orion	Erythromycin	Sgpt increased	No	NA	Male	Recovered	Certain	360 mg	Oral	Hospital	2
	1989	J01FA01	Etromycin	Orion	Erythromycin	Sgot increased	No	NA	Male	Recovered	Certain	360 mg	Oral	Hospital	2
145	1989	N05AH02	Leponex	Novartis	Clozapine	Agranulocytosis	No	Paranoid type schizophrenia	Female	Recovered	Probable	200 mg	Oral	Hospital	24
146	1989	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis cholestatic	No	Back disorder	Female	Recovered	Probable	10 ml	IM	Hospital	66
147	1989	M01AC01	Piroxicam	GDR	Piroxicam	Vision abnormal	No	Systemic lupus erythematous	Male	Recovered	Probable	20 mg	Oral	Hospital	43
	1989	M01AC01	Piroxicam	GDR	Piroxicam	Accommodation abnormal	No	Systemic lupus erythematous	Male	recovered	Probable	20 mg	Oral	Hospital	43
148	1989	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis	No	Hypertension	Male	Recovered	Probable	2 DF	Oral	SP	53
	1989	C02DB01	Depressan	GDR	Dihydralazine	Sgot increased	No	Hypertension	Male	recovered	Probable	2 DF	Oral	SP	53
	1989	C02DB01	Depressan	GDR	Dihydralazine	Sgpt increased	No	Hypertension	Male	recovered	Probable	2 DF	Oral	SP	53
149	1989	J01AA02	Doxycycline	GDR	Doxycycline	Vasculitis allergic	No	NA	Female	Recovered	Probable	0.1 g	Oral	Hospital	40
	1989	J01AA02	Doxycycline	GDR	Doxycycline	Fever	No	NA	Female	Recovered	Probable	0.1 g	Oral	Hospital	40
150	1989	A08A A	Sedafamem	GDR	Phendimetrazine	Psychosis	No	Obesity	Male	Recovered	Certain	2 DF	Oral	GP	40
151	1989	N03AG01	Convulsofin	GDR	Valproic acid	Thrombocytopenia	No	Epilepsy	Male	Recovered	Certain	3 DF	Oral	Hospital	12
152	1989	C02DB01	Depressan	GDR	Dihydralazine	Hepatitis cholestatic	No	Hypertension	Male	Recovered	Certain	75 mg	Oral	GP	55
153	1989	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis	No	Niple infection	Female	Recovered	Probable	250 mg	Oral	Hospital	25
	1989	M01AA06	Ketazon	CSSR	Kebuzone	Hepatitis	No	Gout	Female	Recovered	Probable	750 mg	Oral	Hospital	49
154	1989	B01AD01	Awelysin	GDR	Streptokinase	Hepatitis	No	Venous embolism	Male	Recovered	Probable	3 MIU	IV	Oral	NA
155	1989	B01AB01	Heparin	GDR	Heparin	Avascular necrosis of bone	No	NA	Female	Not recovered	Probable	10 kIU	SC	Hospital	29
156	1989	N02AC03	Tiretta analgica "p"	GDR	Codeine/ papaverin/ aminophenazone/ phenazone	Anaphylactic shock	No	Migraine	Female	Recovered	Probable	4 ml	IV	GP	26
157	1989	B01AD01	Awelysin	GDR	Streptokinase	Anaphylactic shock	No	Acute myocardial infection	Male	NA	Probable	0.2 MIU	IV	Hospital	47
158	1989	S03AA08	Berlicetin	GDR	Prednisolone/ chloramphenicol	Otitis externa	No	Ear disorder	Female	Recovered	Certain	1 ml	Top.	SP	50
159	1989	S03AA08	Berlicetin	GDR	Prednisolone/ chloramphenicol	Otitis externa	No	Ear disorder	Male	Recovered	Certain	1 ml	Top.	SP	33
	1989	S03AA08	Berlicetin	GDR	Prednisolone/ chloramphenicol	Pruritus	No	Ear disorder	Male	Recovered	Certain	1 ml	Top.	SP	33
160	1989	N05AH02	Alemoxan	GDR	Clozapine	Agranulocytosis	No	Paranoid states	Female	Not recovered	Probable	200 mg	Oral	Hospital	38
	1989	N05AH02	Alemoxan	GDR	Clozapine	Rhinitis	No	Paranoid states	Female	Not recovered	Probable	200 mg	Oral	Hospital	38

	1989	N05AH02	Alemoxan	GDR	Clozapine	Bronchitis	No	Paranoid states	Female	Not recovered	Probable	200 mg	Oral	Hospital	38
	1989	N05AH02	Alemoxan	GDR	Clozapine	Rash pustular	No	Paranoid states	Female	Not recovered	Probable	200 mg	Oral	Hospital	38
161	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Rash erythematous	No	Ulcerative colitis	Male	Recovered	Probable	3.5 g	Oral	Hospital	52
	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Sgot increased	No	Ulcerative colitis	Male	Recovered	Probable	3.5 g	Oral	Hospital	52
	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Sgpt increased	No	Ulcerative colitis	Male	Recovered	Probable	3.5 g	Oral	Hospital	52
	1989	A07EC01	Sulfasalazin	Yugoslavia	Sulfasalazine	Leukocytosis	No	Ulcerative colitis	Male	Recovered	Probable	3.5 g	Oral	Hospital	52
162	1989	M01CB01	Tauredon	Byk Gulden	Aurothiomalate	Purpura	No	Rheumatoid arthritis	Female	Recovered	Certain	220 mg	IM	Hospital	73
	1989	M01CB01	Tauredon	Byk Gulden	Aurothiomalate	Trombocytopenia	No	Rheumatoid arthritis	Female	Recovered	Certain	220 mg	IM	Hospital	73
163	1989	N03AF01	Finlepsin	GDR	Carbamazepine	Hepatorenal syndrome	No	Convulsions	Male	Not recovered	Possible	1.5 DF	Oral	Hospital	4
164	1989	A02BA01	Altramet	GDR	Cimetidine	Gynaecomastia	No	Oesophagitis	Male	Recovered	Probable	1 g	Oral	Hospital	62
165	1989	J01GB03	Gentamicin	Bulgaria	Gentamicin	Deafness	No	Fracture of ribs	Male	Not recovered	Probable	120 mg	IV	Hospital	48
166	1990	J01CE01	Penicillin g	GDR	Benzylpenicillin	Anaphylactic shock	No	NA	Female	Recovered	Certain	5 ml	IV	Hospital	24
167	1990	N01AX04	Sombrevin	Hungary	Propanidid	Thrombophlebitis	No	Phlebitis	Female	Recovered w. sequaelae	Probable	NA	NA	Hospital	51
168	1990	N01AX04	Sombrevin	Hungary	Propanidid	Thrombophlebitis	No	Phlebitis	Female	Recovered	Probable	NA	NA	Hospital	38
169	1990	N01AX04	Sombrevin	Hungary	Propanidid	Thrombophlebitis	No	Phlebitis	Female	Recovered	Probable	NA	NA	Hospital	36
170	1990	B01AD01	Awelysin	GDR	Streptokinase	Dizziness	No	Phlebitis	Male	Recovered	Certain	1 MIU	IV	Hospital	66
	1990	B01AD01	Awelysin	GDR	Streptokinase	Flushing	No	Phlebitis	Male	Recovered	Certain	1 MIU	IV	Hospital	66
	1990	B01AD01	Awelysin	GDR	Streptokinase	Headache	No	Phlebitis	Male	Recovered	Certain	1 MIU	IV	Hospital	66
	1990	B01AD01	Awelysin	GDR	Streptokinase	Hypertension	No	Phlebitis	Male	Recovered	Certain	1 MIU	IV	Hospital	66
	1990	B01AD01	Awelysin	GDR	Streptokinase	Sweating increased	No	Phlebitis	Male	Recovered	Certain	1 MIU	IV	Hospital	66
171	1990	C08CA05	Corinfar	GDR	Nifedipine	Taste perversion	No	Hypertension	Male	Recovered	Probable	NA	NA	GP	49
172	1990	J04AB02	Rifampicin	Rumania	Rifampicin	Nausea	No	NA	Female	Recovered	Possible	NA	Oral	SP	41
	1990	J04AB02	Rifampicin	Rumania	Rifampicin	Purpura	No	NA	Female	Recovered	Possible	NA	Oral	SP	41
	1990	J04AB02	Rifampicin	Rumania	Rifampicin	Trombopenia	No	NA	Female	Recovered	Possible	NA	Oral	SP	41
173	1990	C02DB01	Depressan	GDR	Dihydralazine	Anxiety	No	Hypertension	Female	Recovered	Probable	25 mg	Oral	GP	34
	1990	C02DB01	Depressan	GDR	Dihydralazine	Depression	No	Hypertension	Female	Recovered	Probable	25 mg	Oral	GP	34
	1990	C02DB01	Depressan	GDR	Dihydralazine	Hypertension	No	Hypertension	Female	Recovered	Probable	25 mg	Oral	GP	34
	1990	C02DB01	Depressan	GDR	Dihydralazine	Vision abnormal	No	Hypertension	Female	Recovered	Probable	25 mg	Oral	GP	34
174	1990	B01AB01	Heparin	GDR	Heparin	Nausea	No	NA	Male	Recovered	Possible	15 kIU	SC	Hospital	83
	1990	B01AB01	Heparin	GDR	Heparin	Vision abnormal	No	NA	Male	Recovered	Possible	15 kIU	SC	Hospital	83
	1990	B01AB01	Heparin	GDR	Heparin	Vomiting	No	NA	Male	Recovered	Possible	15 kIU	SC	Hospital	83
175	1990	J04AB02	Rifampicin	Rumania	Rifampicin	Renal failure acute	No	NA	Male	Recovered	Possible	NA	Oral	SP	57

176	1990	J01FA01	Lubomycin-b	Poland	Erythromycin	Hepatitis cholestatic	No	NA	Female	NA	Probable	NA	Oral	Hospital	3
	1990	J01FA01	Lubomycin-b	Poland	Erythromycin	Hepatomegaly	No	NA	Female	NA	Probable	NA	Oral	Hospital	3
	1990	J01FA01	Lubomycin-b	Poland	Erythromycin	Sgot increased	No	NA	Female	NA	Probable	NA	Oral	Hospital	3
	1990	J01FA01	Lubomycin-b	Poland	Erythromycin	Sgpt increased	No	NA	Female	NA	Probable	NA	Oral	Hospital	3
177	1990	J01CE01	Jenacillin-a	GDR	Benzylpenicillin	Dizziness	No	Erysipelas	Male	Recovered	Probable	2 MIU	IM	Hospital	54
178	1990	N01AB01	Halan	GDR	Halothane	Hepatic function abnormal	No	NA	Male	Recovered	Certain	1 times	INH	Hospital	49
	1990	N01AB01	Halan	GDR	Halothane	Hepatitis	No	NA	Male	Recovered	Certain	1 times	INH	Hospital	49
	1990	N01AB01	Halan	GDR	Halothane	Eosinophilia	No	NA	Male	Recovered	Certain	1 times	INH	Hospital	49
	1990	N01AB01	Halan	GDR	Halothane	Prothrombin decreased	No	NA	Male	Recovered	Certain	1 times	INH	Hospital	49
179	1990	A12AA06	Calcium dobesilate	GDR	Calcium dobesilate	Injection site reaction	No	Abnormal blood chemistry	Female	Not recovered	Certain	20 ml	IV	Hospital	3 mo.
	1990	A12AA06	Calcium dobesilate	GDR	Calcium dobesilate	Calcinosis	No	Abnormal blood chemistry	Female	Not recovered	Certain	20 ml	IV	Hospital	3 mo.
180	1990	M03AC01	Pavulon	Organon Teknica	Pancuronium	Bradycardia	Yes	NA	Male	Died	Possible	mg	IC	Hospital	5 mo.
	1990	M03AC01	Pavulon	Organon Teknica	Pancuronium	Cardiac arrest	Yes	NA	Male	Died	Possible	.4 mg	IC	Hospital	5 mo.

Abbreviations

GP: general practitioner; SP: specialist physician; DF: defined formulation; mo.: months; IV: intravenous; IA: intraarteriel; IM: intramuscular; SC: subcutaneous; INH: inhalation; Top: topical; IC: intracardiac; BRD: Bundesrepublic Deutschland; CSSR: Czechoslovak Socialist Republic.

