



WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ

INDEXED

RESEARCH PROJECT FOR INTERNATIONAL DRUG MONITORING



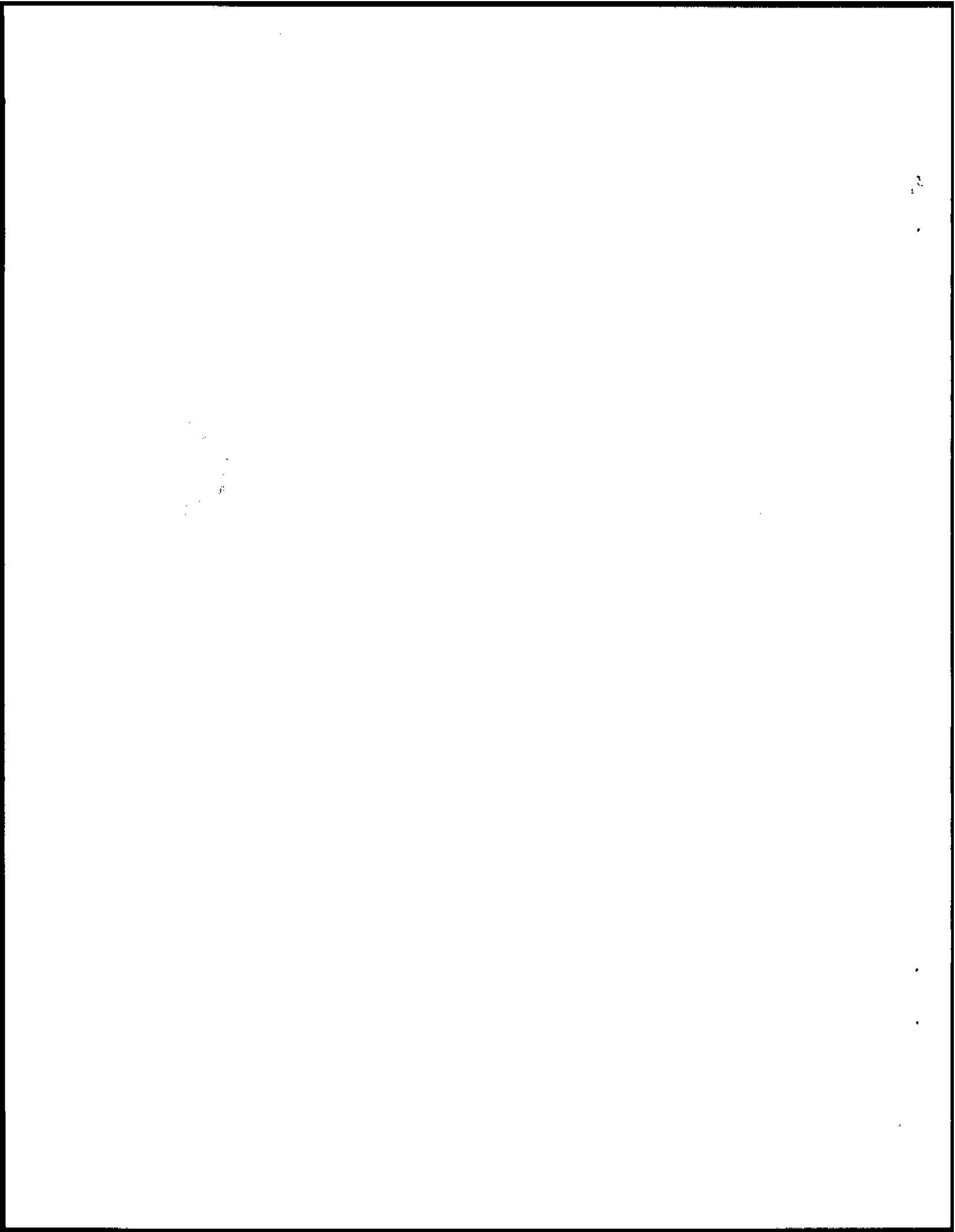
GUIDE TO PARTICIPATING COUNTRIES

1971 EDITION

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INTRODUCTION

The new edition of the Guide has been developed on the basis of several discussions with the Representatives from National Monitoring Centres and reflects the experience gained by the Research Project during its earlier stages of operation.

As information given in the first two pages of the first edition¹ is still valid as outlining the internationally accepted principles of the Pilot Project and the views of the preceding scientific groups, portions of that text are retained even though some items are being or have already been implemented.

In this edition, relevant changes of practical technical value commence from paragraph What to Report, page 3.

The Nineteenth and Twentieth World Health Assemblies^{2,3} requested that a Pilot Research Project for International Drug Monitoring be initiated by means of compilation and analysis of individual reports of suspected adverse reactions to drugs⁴.

The Twenty-third World Health Assembly in May 1970 reviewed the results of the pilot phase of the Project and recommended its development into a primary operational phase aimed at the establishment of an international system for monitoring adverse reactions to drugs⁵. The Director-General's report⁶ to the Twenty-third World Health Assembly stated as follows:

"45. The Project would now move into a primary operational phase, the objectives of which would be as follows:

- (a) further develop and adjust the methodology evolved during the pilot phase for an operational international system of monitoring adverse reactions to drugs utilizing case reports submitted by national centres;
- (b) undertake the recording and analysis of submitted data and their feed-back to national centres on an operational basis in order to determine suitability and usefulness of data presentation;

¹ Determined at a meeting of Representatives of Drug Monitoring Centres held in Washington, D.C., June 1966

² Resolution WHA19.35

³ Resolution WHA20.51

⁴ Off. Rec. Wld Hlth Org. 148, Annex 11

⁵ Resolution WHA23.13

⁶ Off. Rec. Wld Hlth Org. 184, Annex 8

- (c) provide facilities for searches by WHO and the national centres of stored data;
- (d) study the mechanisms by which reports from additional drug monitoring centres can be included in the operation; and
- (e) study the contribution of an international drug monitoring system to national programmes for drug efficacy and safety, research in therapeutics and pharmacology.

46. The WHO Centre has already made considerable progress in the development of drug reference lists and of recording systems for drugs and adverse reactions. During the primary operational phase, these methodologies, together with additional computer programmes for routine analyses, alerting signals, and special file searches, can be expanded and adapted to meet the requirements of a fully operational phase.

47. It is anticipated that additional national drug monitoring centres may be in a position to contribute reports to the WHO Centre in the future. Increasing benefits are likely to accrue from the availability of information on the adverse effects of drugs from a wide range of countries.

48. Once the WHO Centre is in the primary operational phase, all countries, including those not participating directly, would be able to benefit. By augmenting drug safety evaluation in countries with national monitoring systems, more meaningful information on drug hazards could be provided by WHO to all its Member States. The speedier accumulation of evidence that warns all countries of a particular drug hazard, and the facilities for effective interchange of information on a range of important and perpetually changing problems, should assist all countries to reduce their drug-induced illnesses and deaths.

49. Provision would be made for detailed studies of technical development, including the value to national centres of information disseminated during the primary operational phase. A comprehensive programme assessment should be undertaken, preferably no later than three years after entering the primary operational phase, and provide recommendations for the development of a fully operational system capable of receiving, analysing and disseminating meaningful information on adverse reactions to drugs to Member countries."

In addition to the above it may be useful to reiterate several guidelines to the Project's activities based on specific recommendations of the Scientific Group on International Drug Monitoring, November 1965⁷.

"Monitoring of adverse reactions to drugs should be initiated on an international scale, in the form of a Pilot Research Project and as a collaborative effort of countries in a position to participate.

This Pilot Research Project should be implemented forthwith, and should be subject to the authority of WHO.

National drug monitoring centres participating in the Project will maintain facilities for collecting relevant information and transmitting it to a WHO Monitoring Centre.

Any national action resulting from national or international monitoring activities will remain the responsibility of the participating countries.

⁷ Scientific Group on Monitoring Adverse Reactions, Geneva, 22-28 November 1964 (PA/8.65)

Although during the initial research phase there would be no general dissemination of information, evidence of a serious drug hazard obtained from the WHO Drug Monitoring Project should bring about appropriate action by a participating country, thus ensuring that all WHO Member States are informed under the terms of resolution WHA16.36.

If the WHO Centre finds unequivocal evidence of a serious drug hazard that demands action with extreme urgency, the Director-General should naturally have authority to advise WHO Member States immediately at his discretion.

WHO should encourage training of specialist staff and exchange of ideas and experience for the further development of drug monitoring.

Attention should be given to the possibility that, from analysis of the stored data, leads will emerge which should stimulate research of a more fundamental character."

Participants in the Project are designated centres located in Member countries that already have national monitoring systems, and that are prepared to comply with the principles and technical requirements of this Research Project. In each such country, the monitoring organization will be designated a participating national centre and will be in communication with the WHO Centre located in Geneva.

The internal recording system is based on English, and therefore for the present reports should be submitted in that language. However, one aspect of the research will be a study of problems connected with data recording in other languages.

Guidelines for reporting

The instructions that follow are intended to aid participating centres in the preparation of reports of suspected adverse reactions under the agreed reporting format.

What to report

Each participating centre should transmit to the WHO Centre reports of individual cases of suspected adverse reactions to drugs as soon as is practicable, after scrutiny at the national centre for elimination of gross errors. For the purposes of the Project:

A drug is defined as any substance administered to man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function⁸.

An adverse reaction to a drug is defined as one which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function⁸.

This definition excludes accidental or felonious excessive dosage or maladministration.

All adverse reactions are of interest, ranging from well-known "side effects" to those reactions in which the reporting physician only suspects a drug as the etiological agent.

⁸ Scientific Group on Monitoring Adverse Reactions, Geneva, 22-28 November 1964 (PA/8.65)

Address

Reports from a national centre should be mailed at twice-monthly intervals to the Senior Project Officer, Research Project for International Drug Monitoring, World Health Organization, 1211 Geneva 27, Switzerland.

How to report

Each national centre is asked to transcribe information in English on each case reported on to the revised form "Report of Suspected Drug Reaction, WHO/RDM C-3, June 1971" (attached). Type-written reports are preferable. Only the original report is to be sent to the WHO Centre; the second copy may be retained for the national centre's files. Supplies of forms may be obtained from the Drug Monitoring Unit, WHO, Geneva.

The WHO Centre is also prepared to receive reports submitted on magnetic tape, but the technical details of this approach should be discussed with the WHO Centre well before sending such reports.

Basic information

Certain basic information on each case is fundamental to the Research Project, and all reports submitted should carry this information as far as is practicable. This includes the country code, country case identification number, report sequence and data source, date of birth, sex, the adverse reaction(s), drug name(s), indication whether a drug is "suspected" or "other", disorder or reason for use of drug, and outcome.

Any additional information either in the initial report or follow-up reports would be most appreciated.

INSTRUCTIONS FOR COMPLETING THE DMO/RDM FORM, C-3, JUNE 1971

This form is used both by the national centre for completing Reports of Suspected Drug Reactions for the WHO Project and by the WHO Project for coding and further processing prior to computerization. The form is divided into four "cards" for purposes of key-punching, identified in the left margin. In the instructions that follow, frequent reference is made to the card number and positions within that card. A careful study of this guide is necessary to attain maximum accuracy and your co-operation is earnestly sought in adhering as much as possible to the instructions that follow. The speed of computerizing reports received, so essential for achieving the WHO Centre's objectives, depends largely on the accuracy and extent to which the instructions are followed.

GENERAL

1. Preferably, a typewriter should be used for filling in this form.
2. Shaded areas are to be filled in only by the WHO Centre.
3. The figure zero is coded \emptyset . The letter "O" is coded O.
4. The number one is coded 1. The letter "I" is coded I.
5. CAPITAL LETTERS are to be used throughout.
6. Coding fields are to be left blank if data have not been recorded (do not insert "N.R.", "Not Reported", "Unknown", etc.).
7. Do not submit reports where the period between the date of onset of reaction and the current date is more than two years.
8. Wherever space for the date is provided, zeros (\emptyset) should be added to complete the 6-digit field. For 6 July 1970, code $\emptyset 6 \emptyset 7 7 \emptyset$; if only the month and year are given, code $\emptyset \emptyset \emptyset 7 7 \emptyset$; if only the year, code $\emptyset \emptyset \emptyset \emptyset 7 \emptyset$.

CARD 1

POSITIONS

1-3

COUNTRY

The country code is to be filled in according to the following list:

Australia	AUL
Canada	CAN
Czechoslovakia	CZS
Denmark	DEN
Germany, Federal Republic of	GER
Ireland, Republic of	IRE
Netherlands	NEL
Norway	NOR
New Zealand	NZL
Sweden	SWE
United Kingdom of Great Britain and Northern Ireland ..	UKB
United States of America	USA

CARD 1 (continued)

POSITIONS

4-20

COUNTRY CASE IDENTIFICATION NO.

Each case must have a unique identification code of not more than 17 positions. Dashes, strokes, spaces, etc. are acceptable in this field. The same identification or code must be used on any subsequent report relating to the same case.

21-22

REPORT SEQUENCE

The first report on a case will be termed an initial report, and should be coded $\phi 1$. Any further information and any corrections to the initial report should be submitted later on additional forms and numbered consecutively $\phi 2, \phi 3, \phi 4$, etc. in this section, and should retain the identification data (Card 1, pos. 1-3 and 4-20) together with all relevant data from the initial report.

23

DATA SOURCE

The source of the data is to be marked here according to the table below:

SOURCE		REPORTS	
		Regular*	Special**
Hospital		A	B
Non-hospital	General practitioner or a non-hospital doctor	G	H
	Specialist doctor	K	L
	Dentist	M	N
	Non-doctor or dentist	T	U

* Regular - routine national monitoring system

** Special - where a report originated from a clinical trial, special study, manufacturer's report, etc.

24-29

DATE OF BIRTH

Date of birth is to be recorded in the order: day, month and year, as completely as known. Zeros (ϕ) should be added to complete the 6-digit field. For 6 July 1970, code $\phi 6\phi 77\phi$; if only the month and year are given, code $\phi\phi\phi 77\phi$; if only the year, code $\phi\phi\phi\phi 7\phi$.

CARD 1 (continued)

POSITIONS

30-31

AGE

If the age is given in years, 01-99 may be inserted in this space. If the age is given in months, weeks or days, record it as closely as possible to the last completed time period. If 100 or more, code 99. For 1-9 years, code 01-09. For less than one year, code according to the following:

11 months = 1M	7 weeks = 7W	6 days = 6D
10 " = 0M	6 " = 6W	5 " = 5D
9 " = 9M	5 " = 5W	4 " = 4D
8 " = 8M	4 " = 4W	3 " = 3D
7 " = 7M	3 " = 3W	2 " = 2D
6 " = 6M	2 " = 2W	1 " = 1D
5 " = 5M	1 " = 1W	>1 " = 00
4 " = 4M		
3 " = 3M		
2 " = 2M		

For less than 2 months, code weeks; for less than 1 week, code days.

It should be noted that if the age is 12 months the code, written in pos. 30-31, is 01 (i.e. 1 year), if 11 months the code is 1M, if 10 months the code is 0M, and if 1 month the code is 4W.

32

SEX

Use either M for Male, or F for Female.

33-35

HEIGHT

Height is to be recorded in centimetres to the nearest centimetre (no fractions). Add zeros (0) in front of numbers less than 100 (e.g. 075).

36-38

WEIGHT

Weight is to be recorded in kilograms to the nearest kilogram (no fractions). Add zeros (0) in front of numbers less than 100 (e.g. 008).

39-51

ETHNIC ORIGIN

Ethnic origin is recorded mainly according to the reported terminology, and further additions will be considered as they arise.

CARD 1 (continued)

POSITIONS

39-51
(continued)

ETHNIC ORIGIN (continued)

AFRICAN NEGRO	INDIC
ALPINE	IRISH
AM INDIAN	JEWISH
AM NEGRO	LAPP
ASIAN	MAORI
AUSTRALOID	MEDITERRANEAN
ESKIMO	NE EUROPEAN
EUROPEAN	NW EUROPEAN

52-57

DATE OF ONSET OF REACTION

The date when the adverse reaction started is to be recorded in the order: day, month and year. Zeros (0) should be added to complete the 6-digit field. For 6 July 1970, code 060770; if only the month and year are given, code 000770; if only the year, code 000070.

If the period between the date of onset of reaction and the current date is more than 2 years, the report is not processed.

58-79

These positions must be left blank.

CARD 2

POSITIONS

1-33
35-67

ADVERSE REACTION DESCRIPTION IF AVAILABLE

Enter a description of any symptom, disease or condition suspected to be an adverse drug reaction. Where practicable, follow as closely as possible the text of the reporting physician. Underline all terms that describe relevant signs or symptoms.

If necessary, the description may continue in the space for Additional Information (Card 4, bottom of the form). Please state if medical records are available. It is earnestly requested that the DMO/RDM adverse reaction preferred term(s) from the latest edition of the Adverse Reaction Terminology be recorded in the special boxes provided using the WHITE AREA only. If a suitably matching term cannot be found in the DMO/RDM Adverse Reaction Terminology, this should be indicated in the report. If more than six terms are to be coded, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

Death reported as an adverse reaction should be recorded in this space as well as in Outcome, Card 4, pos. 33. When death is reported to be due to other causes and only coincidental to the adverse reaction, it is coded only in Outcome, Card 4, pos. 33.

CARD 2 (continued)

POSITIONS

- 34 and 68 These positions are used for "follow-up" reports only. Code "x" in position(s) 34 and/or 68 when the same reaction(s) is experienced to the same drug(s), use ~~02-09~~ report sequence, repeat identification data (Card 1, positions 1-3 and 4-20) together with all relevant data from the initial report.
- 69-70 To be left blank.

CARD 3

POSITIONS

1-39

DRUGS

Use white space only; the shaded area below must be left blank. Only one drug may be inserted per line. If, for instance, the same drug was administered on two occasions or in a different form or regimen, separate lines must be used for each change in form, dosage regimen, etc. Repeat all unchanged data from the previous line (drug name, etc.), add the variables and code 1, 2 or 3, etc. in position 70 of Card 3. Ditto marks may not be used. If more than 5 drug lines are to be coded, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

Drug names should be reported in the following order of preference:

- (1) trade or proprietary name (spelling should follow the official or selected drug list of the country);
- (2) international nonproprietary name;
- (3) national nonproprietary name;
- (4) chemical name (structural formula).

For trade names and nonproprietary names that are not in the official or selected drug list, active ingredient(s), manufacturer and therapeutic use are to be indicated in the area for Additional Information at the bottom of the form.

Drugs administered after the onset of the adverse reaction, e.g. drugs used to treat the adverse reaction should not be included in this area unless they are suspected as aggravating the initial reaction. If such a drug(s) then produces a different adverse reaction, use additional C-3 form(s) and repeat identification data (Card 1, positions 1-3 and 4-20) and code the appropriate report sequence, ~~02-09~~ (Card 1, positions 21-22).

CARD 3 (continued)

POSITIONS

40

S OR O (SUSPECTED OR OTHER DRUGS)

Use the white space only. The drug(s) suspected of producing the adverse reaction reported should be indicated by "S" and any other drug(s) given prior to the onset of the reaction but not suspected should be marked "O". This information should always be given.

41-43

DRUG FORM

Use the white space only. The codes listed below are used by the WHO Centre. These codes should be used as far as is practicable.

When the Drug Form is recorded, the Route must also be filled in and the two combined must conform to the Quality Control checking table on page 15.

<u>Drug Form</u>	<u>Codes</u>
Aerosol	AER
Cachet	CTS
Capsule (excludes sustained release capsule, see SRC)	CAP
Chewable tablet	CTB
Drops (excludes eye, ear or nasal drops, see EDR, EED and NDR)	DRO
Dusting powder	DPO
Ear drops	EDR
Enema	ENM
Enteric coated tablet	ENT
External (if route known but form not given)	EXT
Eye drops (includes eye drops and eye lotion only)	EED
Eye ointment	EOI
Granules	GRA
Implant	IMP
Infusion	INF
Inhalant (includes volatile anaesthetics, vitellae, spray for inhalation)	INH
Injection (includes microcrystal inj.)	INJ
Insufflation	INS
Jelly	JEL
Liquid (topically applied)	LIQ
Lotion (excludes eye lotion - see EED)	LOT
Lozenge	LOZ
Mouthwash	MWH
Nasal drops	NDR
Ointment (includes cream & liniment)	OIN
Per oral (if route known but form not given)	POR
Pill (includes only the spherically-shaped form, not tablet)	PIL
Powder (excludes dusting powder, see DPO)	POW
Shampoo	SHP
Solution (includes all <u>per orally</u> administered liquid drug forms; excludes drops and syrup, see DRO and SYR)	SOL
Spincap	SPC

CARD 3 (continued)

POSITIONS

44-45

DRUG FORM (continued)

(continued)

<u>Drug Form</u>	<u>Codes</u>
Spray (excludes spray for inhalation and aerosol)	SPR
Suppository	SUP
Sustained release capsule	SRC
Sustained release tablet	SRT
Syrup	SYR
Tablet (includes regularly coated tablet, dragee and vaginal tablet but not sustained release tablet - see SRT)	TAB

44-46

DOSAGE REGIMEN

Use the white space only. The dosage regimen is to be indicated in metric units, appropriate International Units or coded DF (Dosage Form, as in the case of Multiple-Ingredient Drugs).

This is followed by units of time, e.g. day, week, month, etc. All divided doses should be changed into daily, weekly, monthly or yearly dosages as appropriate.

44-46

Numbers indicating the amount of drug should be recorded right justified. A decimal point may be used in positions 44 or 45. All amounts when reported in such a way as to occupy 4 or more coding positions (including the decimal point) should be converted where appropriate to a different unit scale so as to fit into the 3 available positions, e.g.:

0.125 KG = 125 GM
0.005 GM = 5 MG
0.175 MG = 175 RG

(See also Table I, page 13)

CARD 3 (continued)

POSITIONS

47-48

<u>Unit</u>	<u>Codes</u>
Dosage Form *	DF
Grams	GM
International Units - less than 1000	UI
International Units - in thousands	KU
International Units - in millions	MU
Kilograms	KG
Litres	LT
Micrograms	RG
Millicuries	MC
Milligrams	MG
Millilitres	ML
Percent. (Topical only)	PC

* DF is to be recorded when no other unit is given. This pertains to all multiple-ingredient drugs where drug form and route are filled in, also to single-ingredient drugs where no metric or International Units are given.

When neither form nor route are given, DF should not be recorded, and positions 44-48 should be left blank. (See Table I, page 13).

49

<u>Frequency</u>	<u>Codes</u>
Cyclical (for oral contraceptives only)	C
Daily	D
Monthly	M
PRN (as necessary)	N
Total	T
Weekly	W
Yearly	Y
Number of times used	Numeric 1-9

(See Table I, page 13)

CARD 5 (continued)

POSITIONS

49

TABLE I. EXAMPLES ON CODING OF DOSAGE REGIMEN

(continued)

If reported as:			Positions 44-49 - code:					
Amount	Unit	Frequency	Amount			Unit		Time
			44	45	46	47	48	49
	Cyclical	Cyclical						C
5	Dosage form such as INJ. TAB. CAP. SUP. etc.	Daily			5	D	F	D
1	Dosage form ...	Once			1	D	F	I
10	Dosage form ...	Total		1	∅	D	F	T
100	Grams	Daily	1	∅	∅	G	M	D
55	International Units	Once		5	5	U	T	I
1	Kilogram	Yearly			1	K	G	Y
2	Litres	Monthly			2	L	T	M
0.5	Microgram	Daily	∅	.	5	R	G	D
500	Milligrams	Daily	5	∅	∅	M	G	D
.25	Milligrams	As necessary	.	2	5	M	G	N
90	Millilitres	Five times		9	∅	M	L	5
1.8	Million International Units	Daily	1	.	8	M	U	D
50	Thousand International Units	Weekly		5	∅	K	U	W
5	Topical percent	Daily			5	P	C	D

50-51

ROUTE

Use white space only. The route by which the drug was administered is to be entered. At present the following codes are used by the WHO Centre.

When the route is recorded, the dosage form must also be filled in and the two combined must conform to the Quality Control checking table on page 15.

CARD 3 (continued)

POSITIONS

50-51

(continued)

ROUTE (continued)

<u>Route</u>	<u>Codes</u>
Buccal (includes gargles)	BU
Conjunctival	CO
Dental (includes injection)	DE
Implant	RF
Inhalation	IH
Insufflation	RF
Intra-arterial	IA
Intra-articular	IR
Intradermal	ID
Intramuscular	IM
Intranasal	IN
Intraperitoneal	IP
Intrapleural	IL
Intrathecal	IT
Intratracheal	TR
Intrauterine	IU
Intravenous	IV
Per oral	PO
Per rectal	PR
Subcutaneous	SC
Sublingual	SL
Systemic (if route is not specified)	SY
Topical (external - skin)	TO
Vaginal	VA

DRUG ADMINISTRATION

Use the white space only. Full dates of drug administration - Began and Terminated dates are preferred. However, where dates are unavailable, duration of drug treatment is acceptable.

If duration in time periods (days or weeks, etc.) is reported with either the began or terminated date, the missing date should be calculated and recorded in the appropriate space.

Wherever space for the date is provided, zeros (0) should be added to complete the 6-digit field. For 6 July 1970, code 060770; if only the month and year are given, code 000770; if only the year, code 000070.

If drug administration is for a period of one day, e.g. 6 July 1970, code BEGAN 060770 and TERMINATED 060770.

CARD 3 (continued)

POSITIONS

52-57

BEGAN

Record the date drug treatment began. If a drug treatment began more than 10 years ago, insert a diagonal stroke "/" in position 52 and omit the day of the month on which treatment started; code the month and year in the usual way.

58-63

TERMINATED

Record the date drug treatment terminated. If the drug treatment was continued code CONTIN. For long-term administration of unknown duration code L TERM and for short-term administration code S TERM.

63

DURATION

If duration of drug treatment is given only in time periods:

Code D for days
W for weeks
M for months
Y for years

in position 63, preceded by the number of days, weeks, etc. reported, in the appropriate number of positions immediately to the left.

64

PREVIOUS ADMINISTRATION

Use the white space only. Code Y if the drug had previously been administered, or N if it had not been given before.

65-69

DISORDER OR REASON FOR USE OF DRUG

Use the white space only. Indicate the disease, condition or reason for which the drug was administered. If more than one indication, use separate lines for each and code 1, 2 or 3, etc. in position 70 of Card 3 (see 3rd paragraph, page 9). It is preferred that 4-digit numbers from the 8th revision of the International Classification of Diseases 1965 be used to indicate the underlying diseases, condition, etc. for which the drug was given.

ICD numbers to the left of the "point" must be zero filled to 3 numerics, e.g. Pulmonary tuberculosis is 011 and not 11. The "point" is indicated in the C-3 form by a heavy bar between positions 68 and 69 and should not be coded by a period ".".

Code trauma from the N series. If this is not possible code the agent producing trauma from the E series. If the drug indication is for diagnostic or prophylactic procedures (except oral contraceptives) code from the Y series.

CARD 3 (continued)

POSITIONS

65-69

DISORDER OR REASON FOR USE OF DRUG (continued)

(continued)

The following codes may be used:

Positions

	65	66	67	68	69
Surgery (an ICD number following the letter code may be used to indicate the reason for surgery) ..	S				
Contraception (drugs only)	P				
Premedication	M				
Diagnostic X-Ray (procedure not specified)	Y				
Pain			-	1	

70

Code 1, 2 or 3, etc. for a drug name repeated to accomodate variables (see 3rd paragraph, page 9) and "Disorder or Reason for Use of Drug" above.

This number is used only to link drug information within a single drug reaction report.

CARD 4

POSITIONS

1-4

OTHER CONCURRENT THERAPIES

Use the white space only. Codes should be taken from the list below.

Positions for two "Other Concurrent Therapies" are provided; if more than two are required, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

If other "Other Concurrent Therapies" than those listed below are reported, they may be recorded in open text in this space.

	<u>Codes</u>
Therapeutic X-Ray	Ø1
Transfusion	Ø2
Surgery	Ø3
Lumbar puncture	Ø4
Physiotherapy	Ø5
Bed rest	Ø6
Psychotherapy	Ø7
Diet	Ø8

CARD 4 (continued)

POSITIONS

1-4
(continued)

OTHER CONCURRENT THERAPIES (continued)

	<u>Codes</u>
Est (Electroshock therapy)	9
Heart catheterization	10
Dressing/Bandage	13
Cystoscopy	14
Radio-active isotope treatment	15
Renal transplantation	16
Haemodialysis	17
Peritoneal dialysis	18

5 LABORATORY DATA RELEVANT TO ADVERSE REACTION

Code 1 - if data confirm the adverse reaction

Code 2 - if data are relevant to the adverse reaction, but do not confirm it.

6 OTHER LABORATORY DATA

Code 1 - if laboratory data relevant to the underlying disease conditions are reported.

Code 2 - if any other laboratory data are available.

7 DRUG REACTION HISTORY

All available information is to be recorded on previous reactions to the same or similar drugs and whether the patient has had the same or similar reactions to other drugs.

The following codes may be used in this area but are by no means exhaustive. If more than one position is needed use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

	<u>Code</u>
History of different adverse reaction to the suspected drug	A
No adverse reaction to previous administration of the suspected drug	B
Similar adverse reaction to suspected drug	C
Similar adverse reaction to another drug	D
Different adverse reaction to another drug	E
C + E	F
No history of any drug reaction (record only when so stated)	G
Complex drug reaction history, e.g. unlisted, or formed by combinations of above	H

CARD 4 (continued)

POSITIONS

8-22

OTHER CONDITIONS PRIOR TO ADVERSE REACTION

Use white space only. Any associated pathology existing prior to the onset of the reaction is to be entered here other than that recorded under "Disorder or Reason for Use of Drug". 4-digit number codes from the 8th revision of the International Classification of Diseases 1965 are preferred but open text is acceptable. Pregnancy may be coded 999.9. Space for 3 other conditions is provided. If more than 3, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

23-24

NUMBER OF PREGNANCIES

The total number of pregnancies is to be recorded here. If the gravidity is, for instance 12, the two positions in this space are used; if, however, the gravidity is 6, then the right-hand position (pos. 24) is used.

25-26

NUMBER OF LIVE BIRTHS

The total number of live births is to be recorded here. If the number is a single digit, the right-hand position (pos. 26) is to be used.

27-32

IF PREGNANT

If the patient was pregnant, the date of the start of her last menstruation is to be entered. Wherever space for the date is provided, zeros (0) should be added to complete the 6-digit field. For 6 July 1970, code 060770; if only the month and year are given, code 000770; if only the year, code 000070.

33

OUTCOME

This should be coded according to the list below. Please note that outcome codes A, B, F, or U, refer only to the reaction and not to the disease under treatment. If the patient died, "D" in this position signifies that this outcome was due either to the reaction or to other pre-existing causes. Death resulting from the suspected adverse reaction should be coded both in the space for the adverse reaction (Card 2), and also in this position. Death due to other causes and only coincidental to the adverse reaction should be coded only here.

	<u>Code</u>
Recovered without sequelae	A
Recovered with sequelae	B
Not yet recovered	F
Died	D
Unknown	U

CARD 4 (continued)

POSITIONS

34-39

DATE OF DEATH

Use white space only. Date of death should be coded in the order day, month, year, as follows: zeros (0) should be added to complete the 6-digit field. For 6 July 1970, code 060770; if only the month and year are given, code 000770; if only the year, code 000070.

40-43

CAUSE OF DEATH

Use white space only. It will be of help if the numbers in List A - 150 Causes for Tabulation of Morbidity, Mortality, page 439 of the 8th revision of the ICD 1965 - be used in coding causes of death and they should be entered in the right-hand positions here.

For numbers 1-137 inclusive omit prefix A;
For numbers 138-150 inclusive, code E for AE and N for AN;
For death due to anaphylactic shock, code 151;
For death reported to be a result of Surgery (post-operative) code 152.

If more than one cause of death, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

44-45

OTHER FACTORS

Use white space only.

Code from the following list any "other factors" that are reported. "Other factors" not listed should be written in open text in the space provided. For more than one "other factor" use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20).

	<u>Codes</u>
Occupation	01
Industrial	02
Household	03
Diet (non-therapeutic)	04
Smoking	05
Climate	06
Positive family history (hereditary predisposition) ...	07
Allergy history	08
Fair complexion (Red Hair, Ginger Hair)	09
Alcohol	14
Malnutrition	24

CARD 4 (continued)

POSITIONS

46-47

NATIONAL CENTRE COMMENTS

Comments on the suspected Drug Adverse Reaction report are requested and may be inserted in this section; the following list of codes may be used.

If more than one National Centre comment is to be coded, use additional C-3 forms and repeat identification data (Card 1, positions 1-3 and 4-20). National Centre comments not included in the list may be described in open text.

	<u>Codes</u>
Causality probable	01
Causality certain	02
Causality possible (not excluded)	03
Causality unlikely	04
Causality unusual	05
Causality serious	06
Manufacturer's error suspected	07
Causality unusual & serious	08
Rechallenge positive	09
Rechallenge negative	10

48-50 These positions must be left blank.

ADDITIONAL INFORMATION

- 51 If DRUG INTERACTION is suspected Code 1
- 52 This position must be left blank.
- 53 If EXISTING PATHOLOGY is considered to increase the possibility of
occurrence of the adverse reaction Code A
- 55 If HOSPITALIZATION is prolonged by the reaction Code 1
If admitted to hospital because of the reaction Code 2
If treated in hospital out-patient department only Code 3
- 56 If any MEDICATION is given to treat the adverse reaction Code 1
If no medication is given to treat the adverse reaction Code 2
- 57 If SUSPECTED DRUG IS STOPPED because of the adverse reaction Code 1
If suspected drug is continued at previous dose-level, in spite of the
reaction Code 2
If suspected drug is continued at reduced dose-level after the reaction .. Code 3
- 58-70 These positions must be left blank.

Further data on any other aspects of the report would be much appreciated and may be included here in open text or submitted on supplementary sheets, and attached to the C-3 form.