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Practical addenda

Addendum 1: Health authorities' ADE reporting forms

In the Western world, many health authorities have introduced a national form for the voluntary reporting of ADEs by health professionals. Over the course of the years, some of these forms have also undergone modifications; however, the type of information requested has largely remained unchanged. Such forms always constitute a trade-off between all the information that one would like to obtain on an ADE case and the amount one presumes doctors can provide without all too much additional effort. The UK authorities, for instance, seem to favour volume rather than content of ADE reporting (presumably on the premise that cases can be followed up retrospectively if there appears to be a problem), whereas the USA form is more detailed.

IN CONFIDENCE — COMMITTEE ON SAFETY OF MEDICINES
REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

(For advice on reporting reactions see *Adverse Reactions to Drugs* section of BNF)

PATIENT'S DETAILS SURNAME _____ OTHER NAMES _____
DATE OF BIRTH (OR AGE) _____ **SEX:** M ☐ F ☐ **WEIGHT (kg)** _____
Hospital if relevant _____ **Hospital Number** _____ **Consultant in charge/GP Principal** _____

SUSPECTED DRUG (Give brand name of drug and batch number if known) _____
DATE STARTED _____ **DATE STOPPED** _____
ROUTE _____ **DAILY DOSE** _____
THERAPEUTIC INDICATION _____

SUSPECTED REACTIONS
_____
_____
DATE REACTION STARTED _____ **DATE REACTION ENDED** _____
OUTCOME (e.g. fatal, recovered, continuing) _____

REPORTING DOCTOR
Name _____
Address _____
_____
_____
_____
Telephone _____ **Specialty** _____
Signature **Date**

SEND TO CSM, FREEPOST, London SW8 5BR
OR if you are in one of the following NHS regions:
TO CSM Mersey, FREEPOST, Liverpool L3 3AB
OR CSM West Midlands, FREEPOST, Birmingham B15 1BR
OR CSM Northern, FREEPOST 1085, Newcastle upon Tyne NE1 1BR
OR CSM Wales, FREEPOST, Cardiff CF4 1ZZ

If you would like information about other reports associated with the suspected drug, tick here ☐

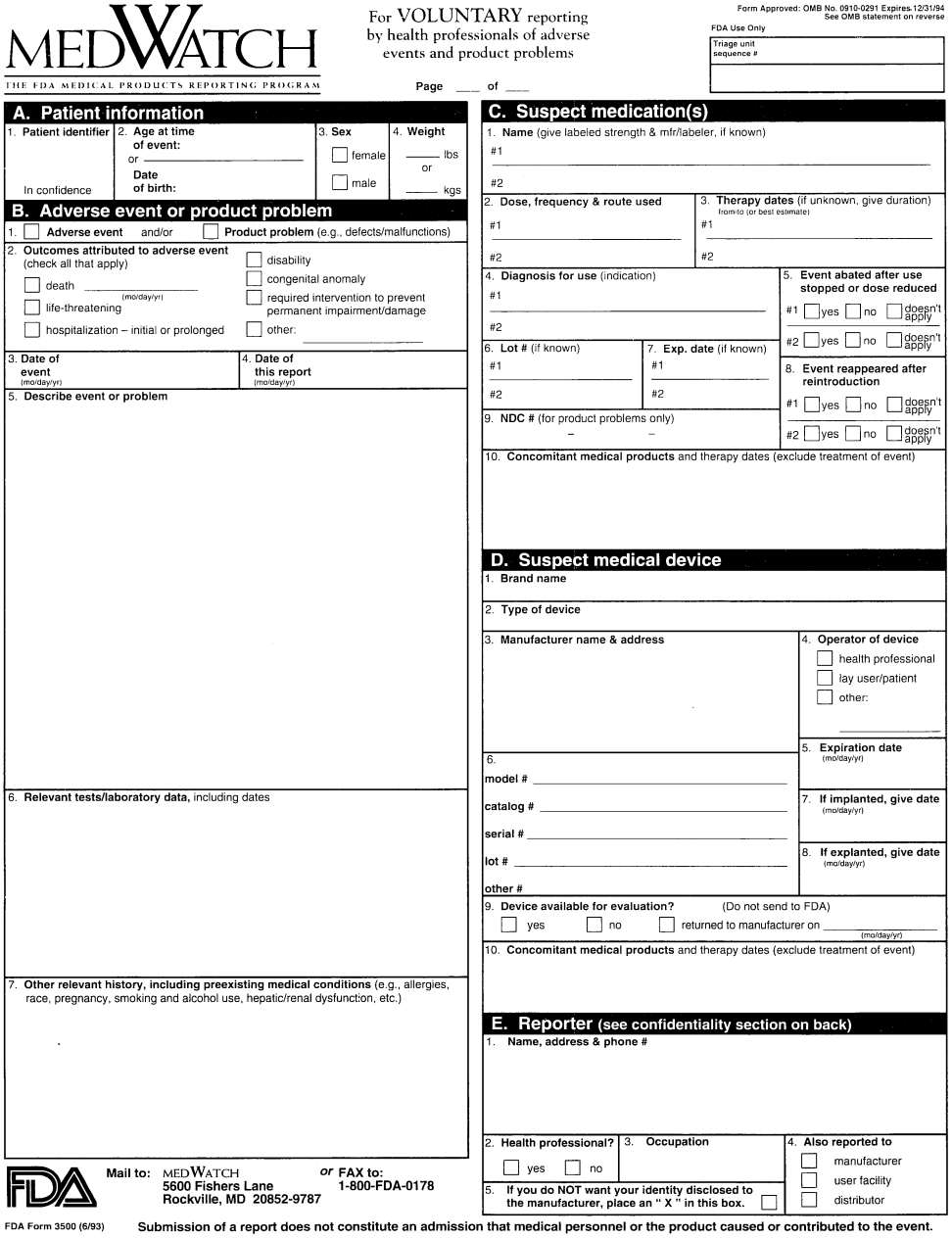
PTO

Fig. 1. The UK reporting form.

SSDI 0924-6479(94)00029-6

This Addendum gives the following two examples:

— The UK form (Fig. 1), widely known as "the yellow card". The UK was the first country to introduce this type of form. At present, it is made available to



MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence #

A. Patient information
1. Patient identifier (In confidence)
2. Age at time of event: or Date of birth:
3. Sex: female / male
4. Weight: ___ lbs or ___ kgs

B. Adverse event or product problem
1. Adverse event and/or Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
death (mo/day/yr)
life-threatening
hospitalization – initial or prolonged
disability
congenital anomaly
required intervention to prevent permanent impairment/damage
other:
3. Date of event (mo/day/yr)
4. Date of this report (mo/day/yr)
5. Describe event or problem
6. Relevant tests/laboratory data, including dates
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)
1. Name (give labeled strength & mfr/labeler, if known) #1 #2
2. Dose, frequency & route used #1 #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 #2
4. Diagnosis for use (indication) #1 #2
5. Event abated after use stopped or dose reduced #1 yes no doesn't apply #2 yes no doesn't apply
6. Lot # (if known) #1 #2
7. Exp. date (if known) #1 #2
8. Event reappeared after reintroduction #1 yes no doesn't apply #2 yes no doesn't apply
9. NDC # (for product problems only) – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device
1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device: health professional / lay user/patient / other:
5. Expiration date (mo/day/yr)
6. model # catalog # serial # lot # other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA) yes no returned to manufacturer on (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)
1. Name, address & phone #
2. Health professional? yes no
3. Occupation
4. Also reported to: manufacturer / user facility / distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box.

FDA
Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Fig. 2. The USA reporting form.

doctors via vehicles such as the BNF (British National Formulary), the Data Sheet Compendium and prescription pads. Many countries copied at least the yellow colour of the British form when they introduced their own national "brand".

— The FDA form whose lay-out was recently (1993) significantly revised to also encompass adverse effects of medical products other than medicines. This revised form has been intensively advertised in the context of a targeted "MedWatch" programme and also carries "MedWatch" at the top.