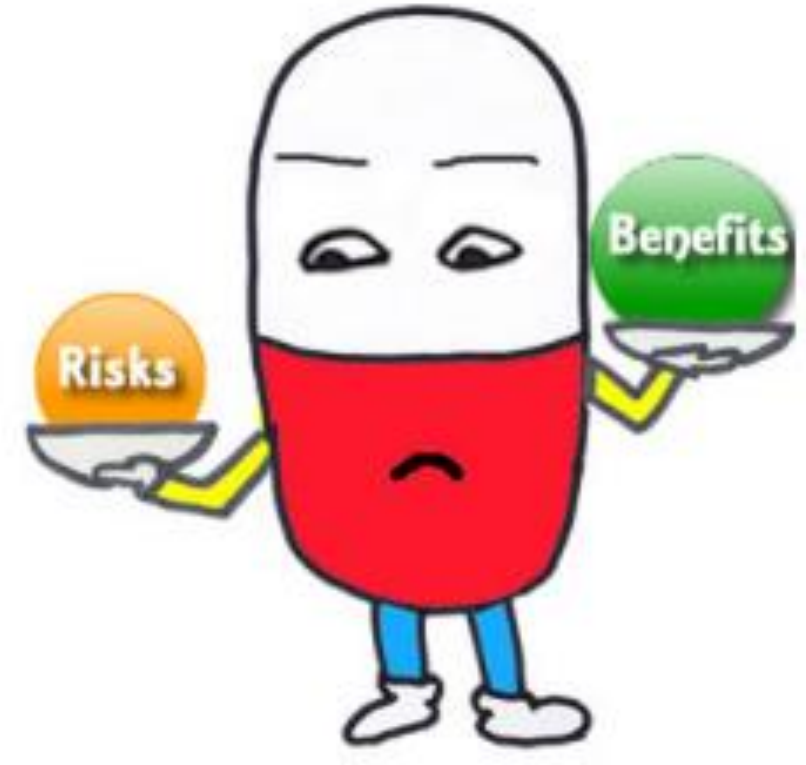
The Safe Use of Medicines

Malta Medicines Authority
Post-Licensing Directorate
23/03/2023

All Medicines have benefits (intended effects) but also have risks (side effects)



Historic Background

Development of Drug Regulation and ADR Reporting Systems

The Thalidomide tragedy

- Thalidomide is a drug that was marketed for treatment for morning sickness in pregnant women in the late 50s and early 60s.
- This drug caused babies to be born with a range of disabilities (birth defects).
- Out of this came stricter regulations for approving new drugs and systems for reporting of side effects

First Law & Regulations relating to proprietary medicinal products

- **Council Directive 65/65/EEC (1965)**
- **Medicines Act in Briton (1968)**

World Health Assembly resolution lead to the (WHO) Programme for International Drug Monitoring of 1968

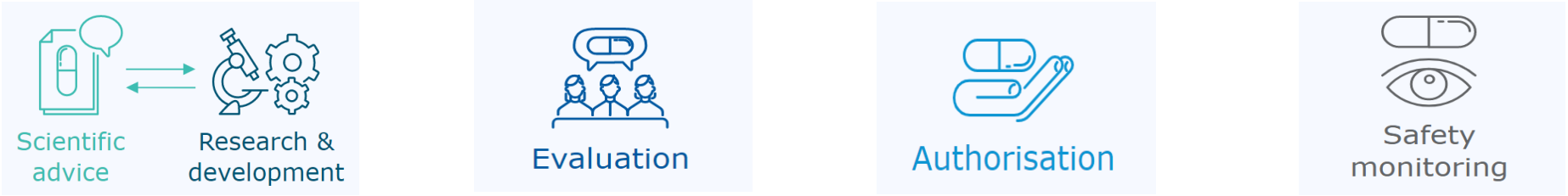
Today

Laws in Place.

All medicinal product require a **Marketing Authorisation prior to being marketed.**

This involves the independent assessments of **Quality, Safety & Efficacy** by regulators after the company carries out many pre-clinical studies and clinical trials.

Lifecycle of a medicinal product



Before a medicine is authorised for use, evidence of its safety and efficacy is derived from **clinical trials results.**

In spite of the system in place not all hazards may be established before a medicinal product is first marketed

It is acknowledged that safety information at the time of first marketing has uncertainties because:

- Animal testing is insufficiently predictive of human safety
- Data from clinical trials is limited by trial size, duration and controlled environment
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available and will only be evident once the drug has been used within wider population groups.

Hence….

Regulators and marketing authorisation holders (Companies) MUST maintain vigilance for safety issues that emerge with widespread real world use of a medicinal product

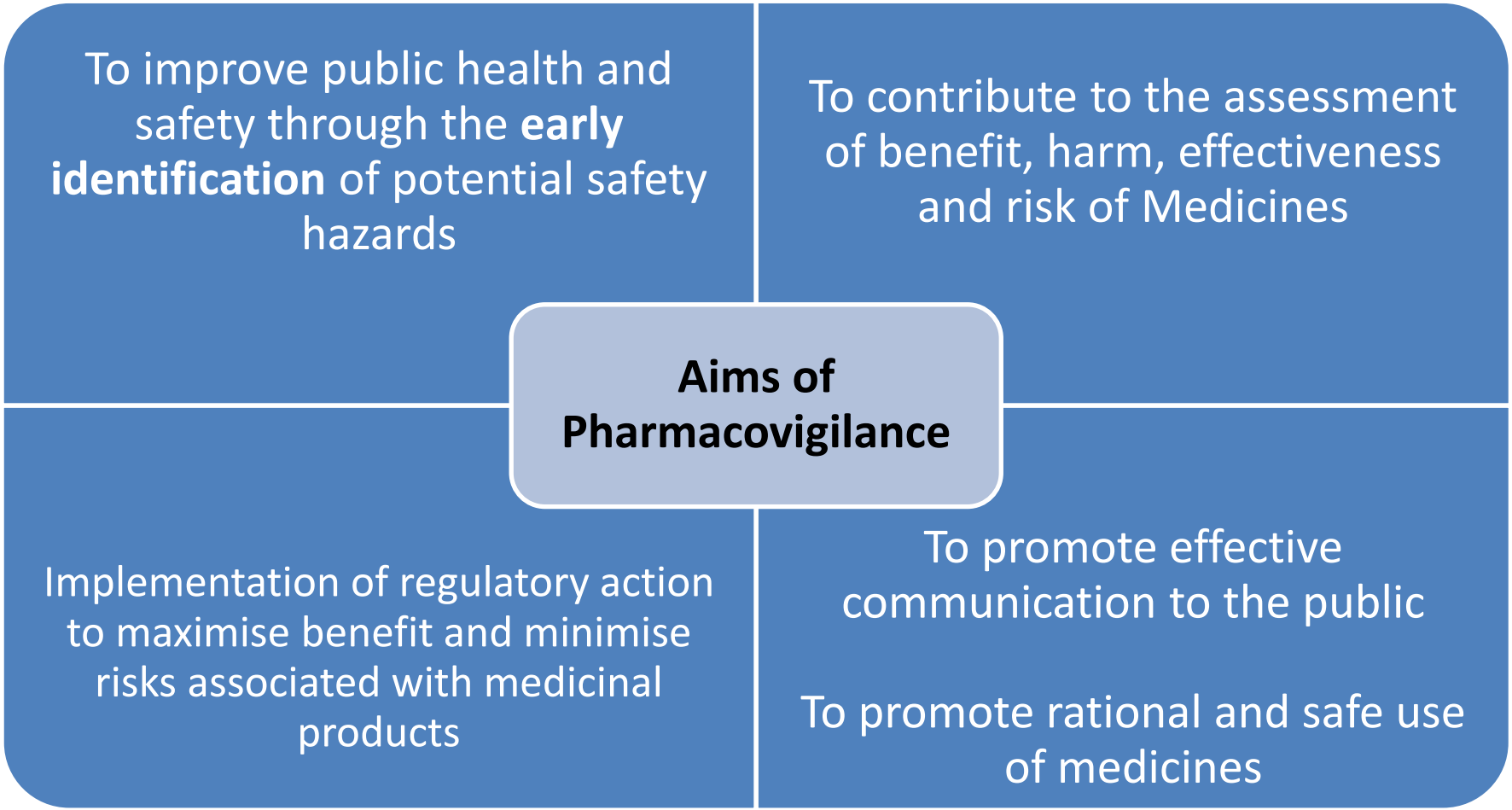
-Pharmacovigilance-

What is Pharmacovigilance?

- **Pharma** – indicates that the word refers to the pharmaceutical industry
- **Vigilance** – concerns the evaluation and control for any possible new safety concerns with medicines

Pharmacovigilance

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. (WHO 2002)


To improve public health and safety through the **early identification** of potential safety hazards
To contribute to the assessment of benefit, harm, effectiveness and risk of Medicines
Aims of Pharmacovigilance
Implementation of regulatory action to maximise benefit and minimise risks associated with medicinal products
To promote effective communication to the public
To promote rational and safe use of medicines

How is the safety of a medicine ensured once it has been put on the market?

- Once a medicine has been authorised for use in the EU, the EMA, EU Member States and MAHs (the companies), continuously monitor its safety and regulatory action is taken when needed [when the benefit – risk balance changes due to new information].
- In Malta, the MMA is responsible for co-ordination of the national PV system and to monitor the safety of medicinal products and medical devices on the local market.
- The European Medicines Agency (EMA) coordinates the EU PV system and provides important services (e.g., EudraVigilance), hosts the PRAC committee and support PV in the EU (single market).

Did you know?

Keeping MEDICINES safe

Experts from all over Europe and representatives of patients and healthcare professionals meet every month to discuss and analyse the latest information on the safety of medicines.

An agency of the European Union

PRAC - Pharmacovigilance Risk Assessment Committee

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- The PRAC is based at the EMA.
- It is responsible for all matters related to pharmacovigilance at an EU level.
- EMA publishes the agendas, minutes and highlights of the PRAC's plenary meetings to allow transparency of the decision-making process.
- There is one member and one alternate representing patients organisations

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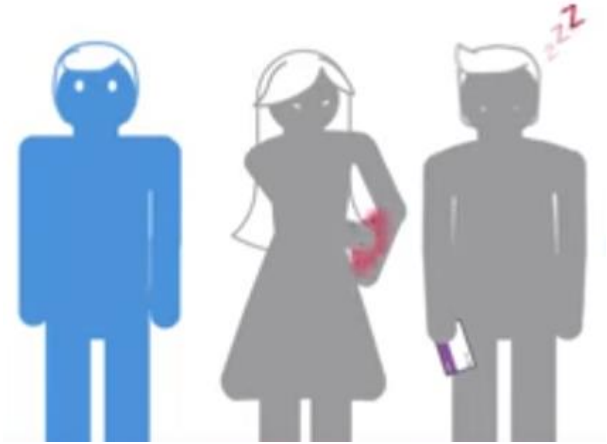


There are several factors which may determine whether a patient may experience a side effect or not:

- Age
- The concomitant use of other medicines
- The concomitant use of vitamins or dietary substances
- Concomitant disease or medical conditions such as immune deficiency, liver disease or kidney disease

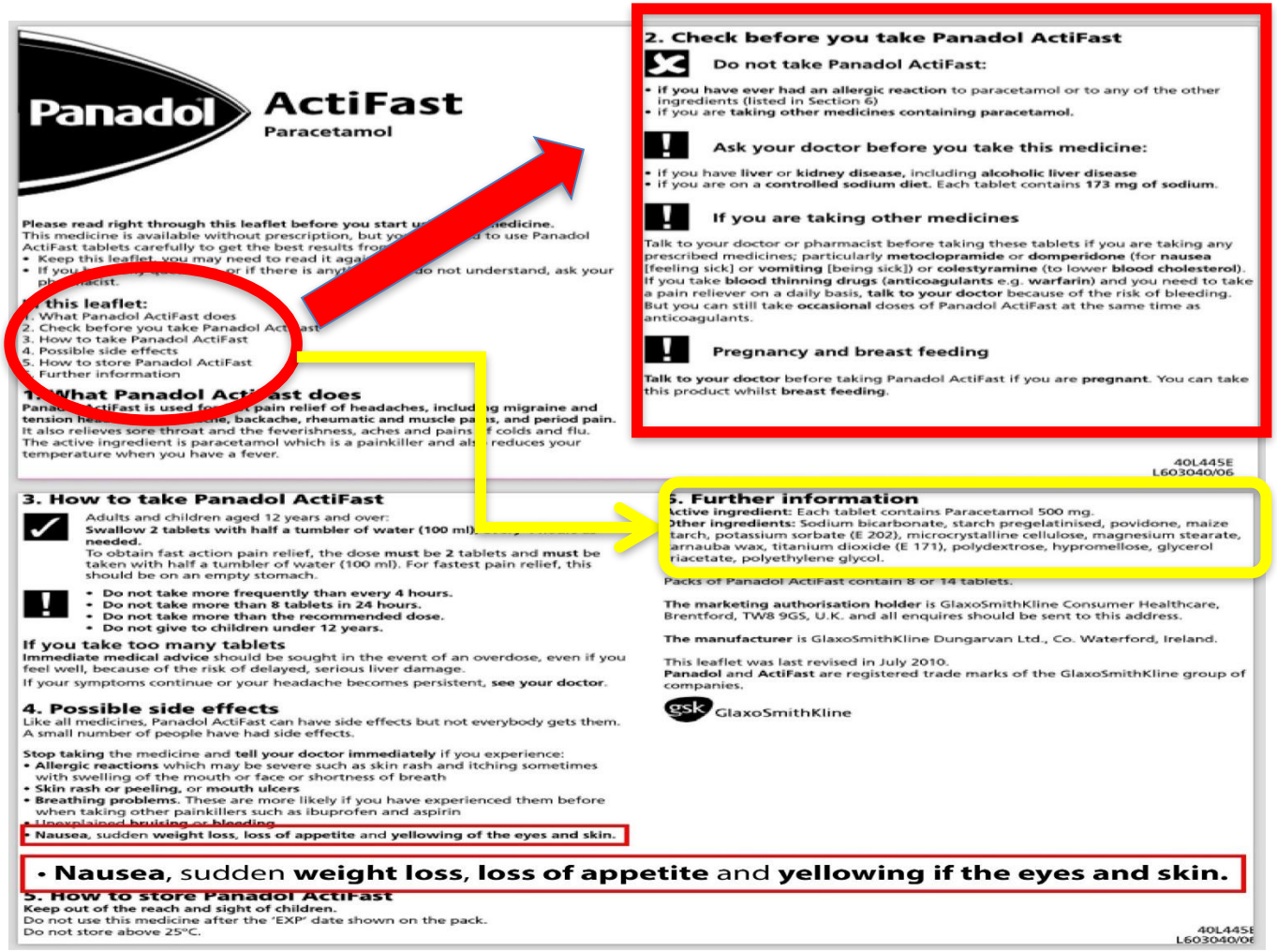
Common adverse events include, nausea, dry mouth, tiredness, headache etc.

Adverse events may be classified as serious or non-serious.

How can we use medicines safely?

Patient Information Leaflet (PIL)

May be found on the inside of the medicinal pack or attached to the pack itself.



Panadol ActiFast
Paracetamol

Please read right through this leaflet before you start u… medicine.
This medicine is available without prescription, but yo… to use Panadol ActiFast tablets carefully to get the best results fro…
- Keep this leaflet, you may need to read it aga…
- If you … or if there is any… do not understand, ask your pharmacist.

In this leaflet:
1. What Panadol ActiFast does
2. Check before you take Panadol Act…
3. How to take Panadol ActiFast
4. Possible side effects
5. How to store Panadol ActiFast
6. Further information

1. What Panadol Act…ast does
Panad… ActiFast is used fo… pain relief of headaches, includ… migraine and tension hea… ache, backache, rheumatic and muscle pa…, and period pain.
It also relieves sore throat and the feverishness, aches and pains … colds and flu.
The active ingredient is paracetamol which is a painkiller and als… reduces your temperature when you have a fever.

2. Check before you take Panadol ActiFast

Do not take Panadol ActiFast:
- If you have ever had an allergic reaction to paracetamol or to any of the other ingredients (listed in Section 6)
- If you are taking other medicines containing paracetamol.

Ask your doctor before you take this medicine:
- If you have liver or kidney disease, including alcoholic liver disease
- If you are on a controlled sodium diet. Each tablet contains 173 mg of sodium.

If you are taking other medicines
Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]) or colestyramine (to lower blood cholesterol). If you take blood thinning drugs (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. But you can still take occasional doses of Panadol ActiFast at the same time as anticoagulants.

Pregnancy and breast feeding
Talk to your doctor before taking Panadol ActiFast if you are pregnant. You can take this product whilst breast feeding.

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3. How to take Panadol ActiFast
Adults and children aged 12 years and over:
Swallow 2 tablets with half a tumbler of water (100 ml) … needed.
To obtain fast action pain relief, the dose must be 2 tablets and must be taken with half a tumbler of water (100 ml). For fastest pain relief, this should be on an empty stomach.
- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours.
- Do not take more than the recommended dose.
- Do not give to children under 12 years.

If you take too many tablets
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.
If your symptoms continue or your headache becomes persistent, see your doctor.

4. Possible side effects
Like all medicines, Panadol ActiFast can have side effects but not everybody gets them. A small number of people have had side effects.
Stop taking the medicine and tell your doctor immediately if you experience:
- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- Skin rash or peeling, or mouth ulcers
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

5. Further information
Active ingredient: Each tablet contains Paracetamol 500 mg.
Other ingredients: Sodium bicarbonate, starch pregelatinised, povidone, maize starch, potassium sorbate (E 202), microcrystalline cellulose, magnesium stearate, carnauba wax, titanium dioxide (E 171), polydextrose, hypromellose, glycerol triacetate, polyethylene glycol.
Packs of Panadol ActiFast contain 8 or 14 tablets.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquires should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Co. Waterford, Ireland.

This leaflet was last revised in July 2010.
Panadol and ActiFast are registered trade marks of the GlaxoSmithKline group of companies.

GlaxoSmithKline

• Nausea, sudden weight loss, loss of appetite and yellowing if the eyes and skin.

5. How to store Panadol ActiFast
Keep out of the reach and sight of children.
Do not use this medicine after the 'EXP' date shown on the pack.
Do not store above 25°C.

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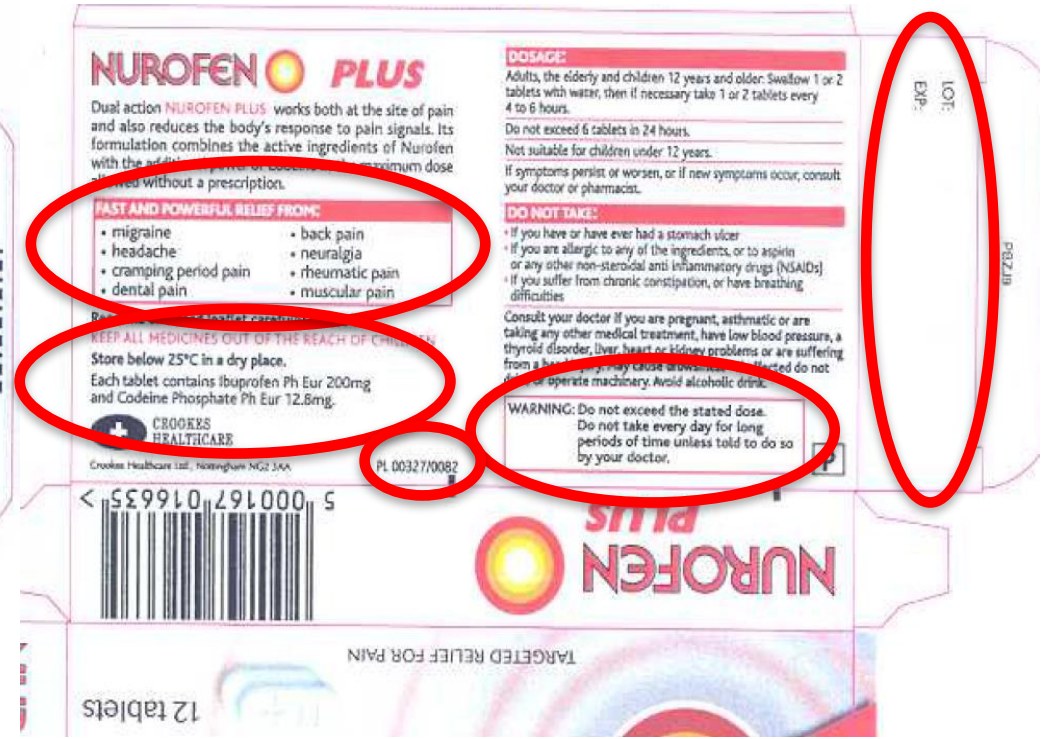
Common Sections in a PIL include:

- Indication (why a medicinal product is used)
- Posology and administration (how the medicine is dosed and administered)
- Possible side effects
- Storage instructions



Braille


Dispersible Aspirin
75 mg Tablets
For Oral Administration
75
mg

Primary Packaging system

Routine Pharmacovigilance

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Product Information	ADR reporting & Signal Management	Risk Management Plan	Periodic Safety Update Reports
•SmPC & PIL describe indications, contraindications, warnings, precautions, adverse events and give advice on storage, administration and correct use	•System to capture spontaneous reports from patients and HCP •Data Capture Aids for specific side effects •Literature Monitoring •Aggregate review of cases to detect statistically disproportionately reported product-adverse event pairs	•Describes the medicines safety profile [Identified Risks / Potential Risks / Missing Information] •Describes how risks will be prevented or minimised in patients •Outlines plans for studies and other activities to gain more knowledge about the safety and efficacy of the vaccine •Describe measuring the effectiveness of risk-minimisation measures	•Pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product / vaccine •Submission by marketing authorisation holders at defined time points during the post-authorisation phase

Additional PhV and aRMMs

Examples of additional PhV activities include: additional studies (to continue to study the safety of the medicines after marketing) and aRMMs

Additional Risk minimisation measures (aRMMs) are educational materials that are given to healthcare professionals and/or to patients with the aim of explaining the risk associated with the use of a medicinal product and the ways in which this risk can be minimised.

Not all medicines have additional risk minimisation measures. During the lifecycle of a medicinal product, there may be more than one risk minimisation measure associated with a particular medicine as more safety data is gathered from pharmacovigilance.

Risk Minimisation Measures

These may include:

- Patient Reminder cards
- Educational Material for patients and prescribers (brochures, training programmes, instructions for use and handling of medicinal product)
- DHPC – used to directly inform healthcare professionals about new, important safety information about a medicinal product
- PPP – Pregnancy Prevention Programme is a form of pregnancy-specific risk minimisation measure (e.g. for retiniods, valproate, methotrexate)
- PPPs are implemented where the product has the potential for:
  - A teratogenic effect
  - An adverse effect on the (neuro-) development of the child through exposure in-utero.

aRMMs examples

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Patient and Caregiver Guide

Important things to remember about your MAYZENT® (siponimod) treatment

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

If you have any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

aRMMs examples (an example of RMM in Maltese Language)

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Qabel ma tibda MAYZENT®

MAYZENT® m'għandux jintuża minn nisa tqal jew minn nisa li jistgħu joħorġu tqal li mhux qed jużaw kontraċezzjoni effettiva.

Qabel ma jinbeda t-trattament, irid isir test tat-tqala lil nisa li jistgħu joħorġu tqal, u kull riżultat negattiv għandu jkun iċċertifikat minn tabib.

Tkellem mat-tabib tiegħek dwar metodi affidabbli biex ma toħroġx tqila li għandek tuża waqt it-trattament u għal mill-inqas għaxart ijiem wara li tkun waqqaft it-trattament b'siponimod.

Jekk jogħġbok aqra l-fuljett ta' tagħrif dwar MAYZENT® inkluż fil-pakkett.

aRMMs examples (aRMMs examples (an example of RMM in Maltese Language)

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Qabel it-tnedija tat-trattament b'Gilenya

Tqala –Gilenya huwa teratoġeniku. Nisa li jistgħu joħorġ tqal (inkluż tfajliet adoloxxenti) għandhom ikunu mgħarrfa mit-tabib tagħhom dwar ir-riskji serji li għandu Gilenya għall-fetu, irid ikollhom test tat-tqala negattiv (ivverifikat minn professjonist mill-qasam tal-kura tas-saħħa), u għandhom jieħdu kontraċezzjoni effettiva qabel ma jinbeda t-trattament b'Gilenya.

Kanċer relatat mal-virus tal-papilloma umana (HPV) – It-tabib tiegħek se jevalwa jekk għandekx bżonn tagħmel screening għall-kanċer (inkluż test tal-Pap) u jekk għandekx titlaqqam kontra l-HPV.

Funzjoni tal-fwied – Gilenya jista' jwassal għal riżultati mhux normali fit-testijiet tal-funzjoni tal-fwied. Se jkollok bżonn tagħmel test tad-demm qabel ma jinbeda t-trattament b'Gilenya.

Aċċessjonijiet – Matul it-trattament jistgħu jseħħu aċċessjonijiet. Għarraf lit-tabib tiegħek jekk inti jew xi qarib għandkom storja ta' epilessija.

aRMMs examples (Highlighting Certain Side Effects)

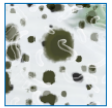
Your guide to therapy with Beovu® (brolucizumab) ▼

For the treatment of neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME)

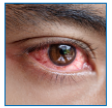
What to expect after treatment (cont)

Seek immediate medical help if you experience any of the following:

A sudden decrease or change in your vision



New or increased number of floaters (small particles in vision)



Overall redness of the eye

New or persistent eye pain or worsening eye discomfort

Flashes of light or increased sensitivity to light (discomfort from bright lights)

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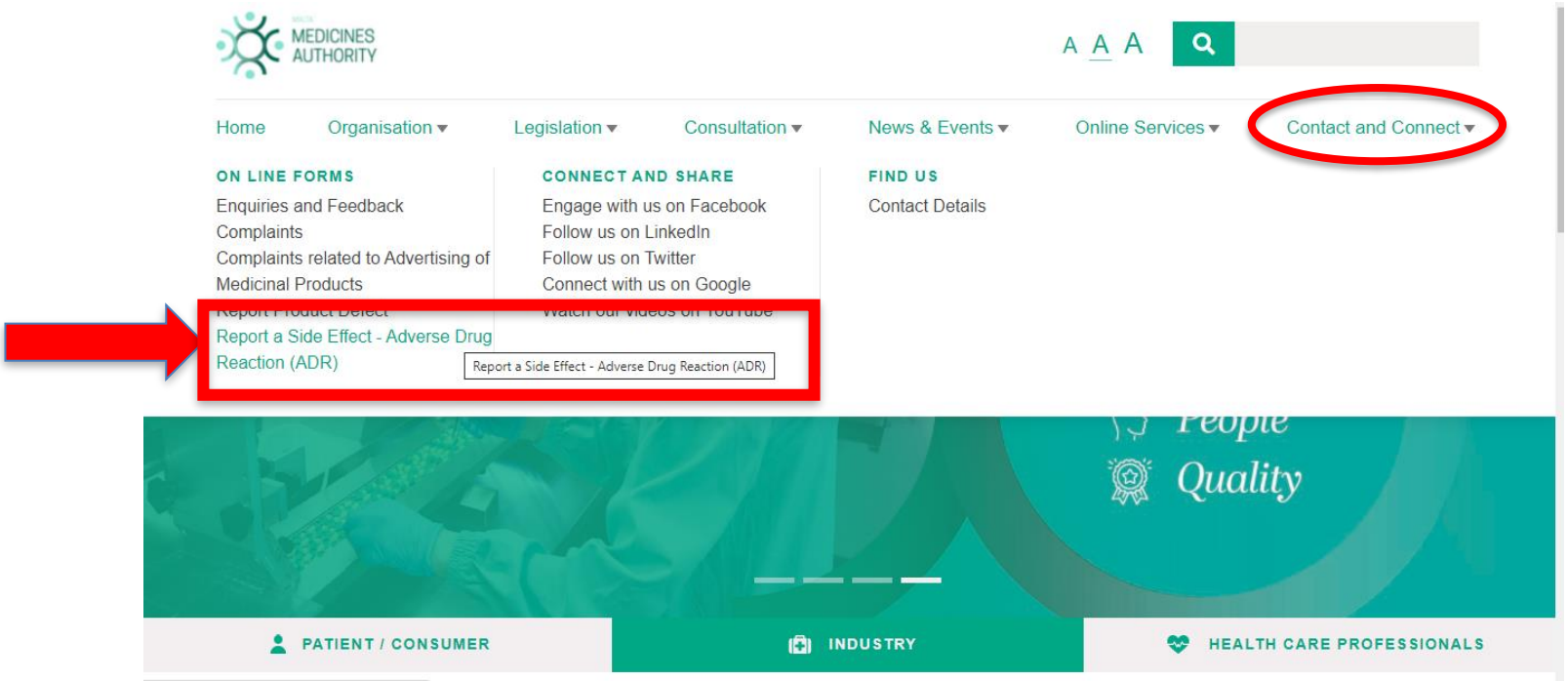
How to report side effects:

https://www.youtube.com/watch?v=kyQzikP86NM

Online reporting for patients

http://medicinesauthority.gov.mt



MEDICINES AUTHORITY

Home | Organisation | Legislation | Consultation | News & Events | Online Services | Contact and Connect

PATIENT / CONSUMER | INDUSTRY | HEALTH CARE PROFESSIONALS

Home / Adverse Drug Reaction

Adverse Drug Reaction

Useful Links

- Medical Devices
- Pharmacy Roster
- eHealth
- Government of Malta
- Heads of Medicines Agency
- Innovative Medicines

In Malta, both patients and consumers as well as healthcare professionals (HCPs) can report side effects that are experienced while taking a medicine.

For HCPs; The Adverse Drug Reactions (ADR) reporting form (for use by Healthcare Professionals) is avialable **here**

Useful Links

- Medical Devices
- Pharmacy Roster
- eHealth
- Government of Malta
- Heads of Medicines Agency
- Innovative Medicines Initiative
- European Medicines Agency

Activities

OR

HCPs may fill in the ADR form in ink, scan and then send via email to **postlicensing.medicinesauthority@gov.mt**

OR

HCPs can send the ADRs to the Marketing Authorisation Holder on the address that can be found on the medicine's package(in such cases do not send the same report to the Medicines Authority to avoid creation of dublicate reports).

For Patient and consumers; Patients and consumers should use the **online side effect report form** which is sent directly to the Medicines Authority

Form Details

Home » Forms » Form Details

Step 1 | Step 2

- Patient Initials *
- Gender
  - Male
  - Female
- Age (at time of reaction)
- Weight (in kg)
- Ethnicity
- Area in which you live
- Contact Email *

Step 1 | Step 2

- SUSPECT MEDICINES DETAILS

Name of the medicine (as this appears on the box)	Active ingredient	Dose	Prescribed for	Date started(dd-mm-yyyy)	Date stopped (dd-mm-yyyy)

Add Row

- OTHER MEDICINES DETAILS (including over-the-counter and herbal products)

Name of the medicine (as this appears on the box)	Active ingredient	Dose	Prescribed for	Date started(dd-mm-yyyy)	Date stopped (dd-mm-yyyy)

Add Row

- SIDE-EFFECT DETAILS

Describe the side effect	Date started(dd-mm-yyyy)	Date stopped (dd-mm-yyyy)

Add Row

- How serious do you consider this side effect?

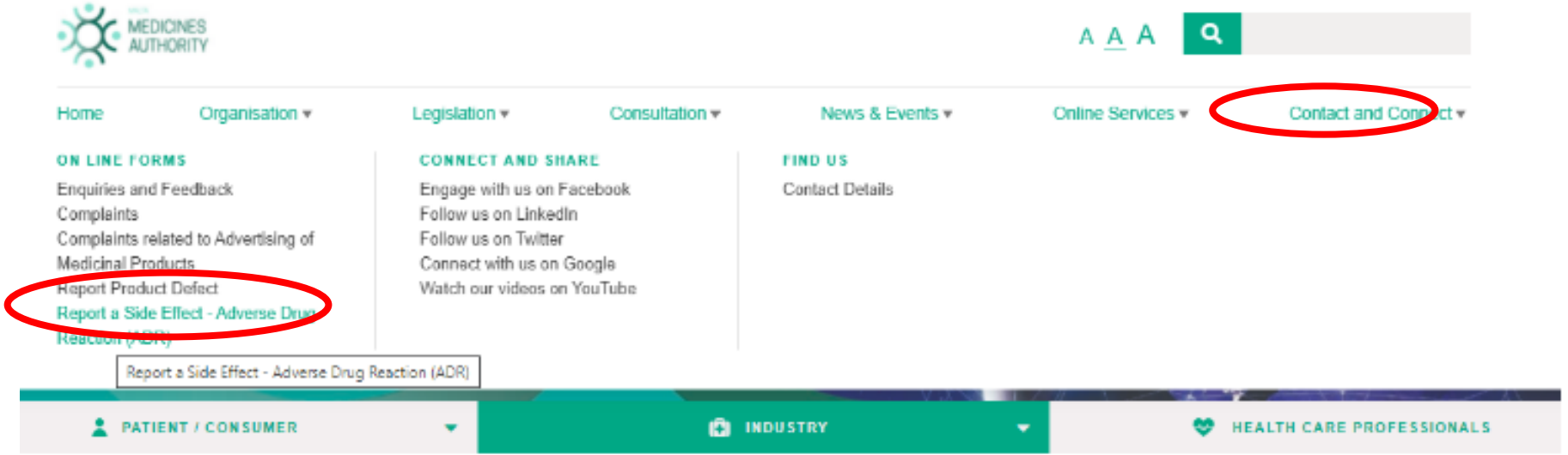
	How serious do you consider each ADR?						
	Fatal	Life Threatening	Caused or prolonged hospitalisation	Birth defect	Caused disability	Other medically significant condition	Not serious
Side Effect 1	○	○	○	○	○	○	○
Side Effect 2	○	○	○	○	○	○	○

How should HCPs report adverse drug reactions to the Medicines Authority

HCPs should use MMA ADR Paper Form
(online webportal is for patients)

Accessible from Homepage > Contact and Connect > Online forms > Report a Side Effect

https://medicinesauthority.gov.mt/adrportal?l=1

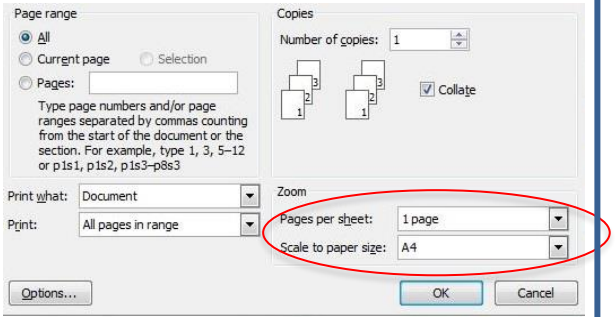


HCPs ADR reporting

The form is downloadable from the MMA website

A Note on Printing

Print to Scale A4



If difficulties are encountered, contact the MMA. Self-addressed paper Forms may be supplied.

Adverse Drug Reaction

MALTA MEDICINES AUTHORITY

Useful Links
Pharmacy Roster
eHealth
Government of Malta
Heads of Medicines Agency
Innovative Medicines Initiative
European Medicines Agency

Activities

In Malta, both patients and consumers as well as healthcare professionals (HCPs) can report side effects that are experienced while taking a medicine.

For HCPs; The Adverse Drug Reactions (ADR) reporting form (for use by Healthcare Professionals) is avialable **here**

Ways HCPs can report: HCPs may fill in the ADR form electronically using MS Word and send via email to **postlicensing.medicinesauthority@gov.mt**

OR

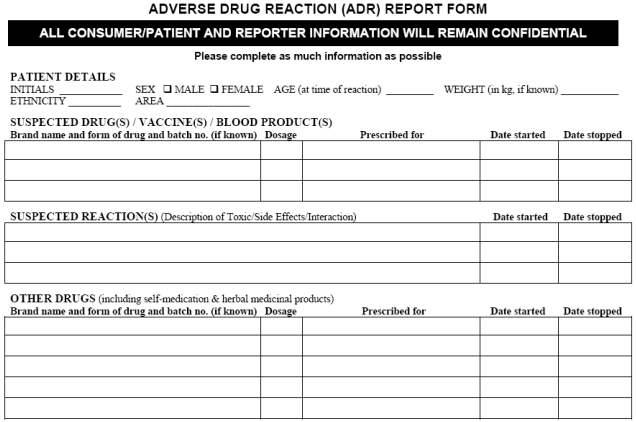
HCPs may fill in the ADR form in ink, scan and then send via email to **postlicensing.medicinesauthority@gov.mt**

OR

HCPs can send the ADRs to the Marketing Authorisation Holder on the address that can be found on the medicine's package(in such cases do not send the same report to the Medicines Authority to avoid creation of dublicate reports).

For Patient and consumers; Patients and consumers should use the **online side effect report form** which is sent directly to the Medicines Authority

The ADR Form for HCPs



ADVERSE DRUG REACTION (ADR) REPORT FORM

ALL CONSUMER/PATIENT AND REPORTER INFORMATION WILL REMAIN CONFIDENTIAL

Please complete as much information as possible

PATIENT DETAILS

INITIALS _____ SEX ❑ MALE ❑ FEMALE AGE (at time of reaction) _____ WEIGHT (in kg, if known) _____

ETHNICITY _____ AREA _____

SUSPECTED DRUG(S) / VACCINE(S) / BLOOD PRODUCT(S)

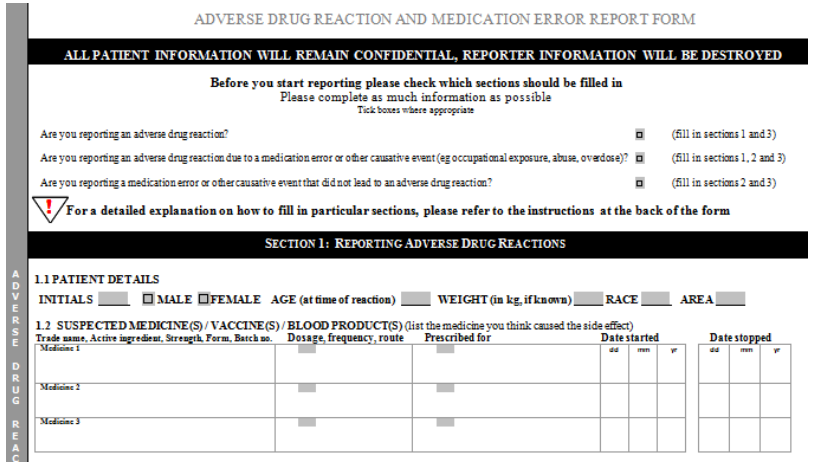
Brand name and form of drug and batch no. (if known)	Dosage	Prescribed for	Date started	Date stopped

SUSPECTED REACTION(S) (Description of Toxic/Side Effects/Interaction)

	Date started	Date stopped

OTHER DRUGS (including self-medication & herbal medicinal products)

Brand name and form of drug and batch no. (if known)	Dosage	Prescribed for	Date started	Date stopped



ADVERSE DRUG REACTION AND MEDICATION ERROR REPORT FORM

ALL PATIENT INFORMATION WILL REMAIN CONFIDENTIAL, REPORTER INFORMATION WILL BE DESTROYED

Before you start reporting please check which sections should be filled in

Please complete as much information as possible

Tick boxes where appropriate

Are you reporting an adverse drug reaction? ☐ (fill in sections 1 and 3)

Are you reporting an adverse drug reaction due to a medication error or other causative event (eg occupational exposure, abuse, overdose)? ☐ (fill in sections 1, 2 and 3)

Are you reporting a medication error or other causative event that did not lead to an adverse drug reaction? ☐ (fill in sections 2 and 3)

For a detailed explanation on how to fill in particular sections, please refer to the instructions at the back of the form

SECTION 1: REPORTING ADVERSE DRUG REACTIONS

ADVERSE DRUG REAC

1.1 PATIENT DETAILS

INITIALS ____ ☐ **MALE** ☐ **FEMALE** **AGE (at time of reaction)** ____ **WEIGHT (in kg, if known)** ____ **RACE** ____ **AREA** ____

1.2 SUSPECTED MEDICINE(S) / VACCINE(S) / BLOOD PRODUCT(S) (list the medicine you think caused the side effect)

Trade name, Active ingredient, Strength, Form, Batch no.	Dosage, frequency, route	Prescribed for	Date started dd	Date started mm	Date started yr	Date stopped dd	Date stopped mm	Date stopped yr
Medicine 1								
Medicine 2								
Medicine 3								

Current ADR form

- Redesigned and launched in 2013
- Combines ADR and ME reporting into one form
- Measures to promote data quality; Granular Data Fields, Information sheet and Decision Tree

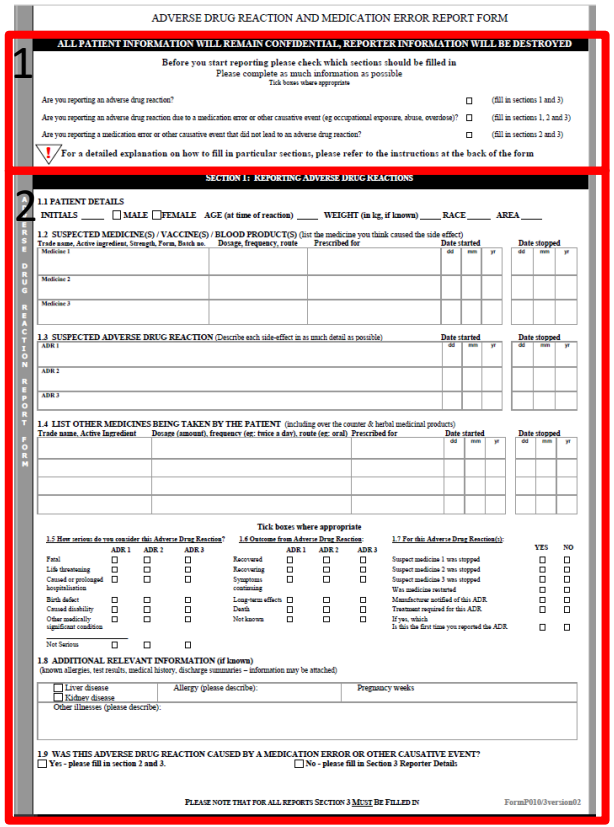
Tanti A, Serracino-Inglott A, Borg JJ. Designing a national combined reporting form for adverse drug reactions and medication errors. East Mediterr Health J. 2015; 21(4):246-55.

Understanding the Layout: HCP ADR reporting Form

Paper Form

Main Sections

- Decision Tree (1)
- Section 1: Reporting Adverse Drug Reactions (2)
- Section 2: Medication Error Reporting (3)
- Section 3: Reporter Details (4)
- Instruction Sheet Overleaf



How to Report: For HCPS

PRINT, FILL IN AND SEND BY POST TO

Medicines Authority
Sir Temi Żammit Buildings,
Malta Life Sciences Park,
San Ġwann SĠN 3000
Malta

OR

FILL IN WORD AND EMAIL TO
FILL IN INK, SCAN AND EMAIL TO

postlicensing.medicinesauthority@gov.mt

OR

Send to the Marketing Authorisation holder of that product

Details on the MAH may be found on the PIL inside every box

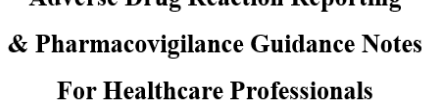
Do Not send the same report to the MAH and to the Malta Medicines Authority as this will create duplicates

Additional Resources for HCPs

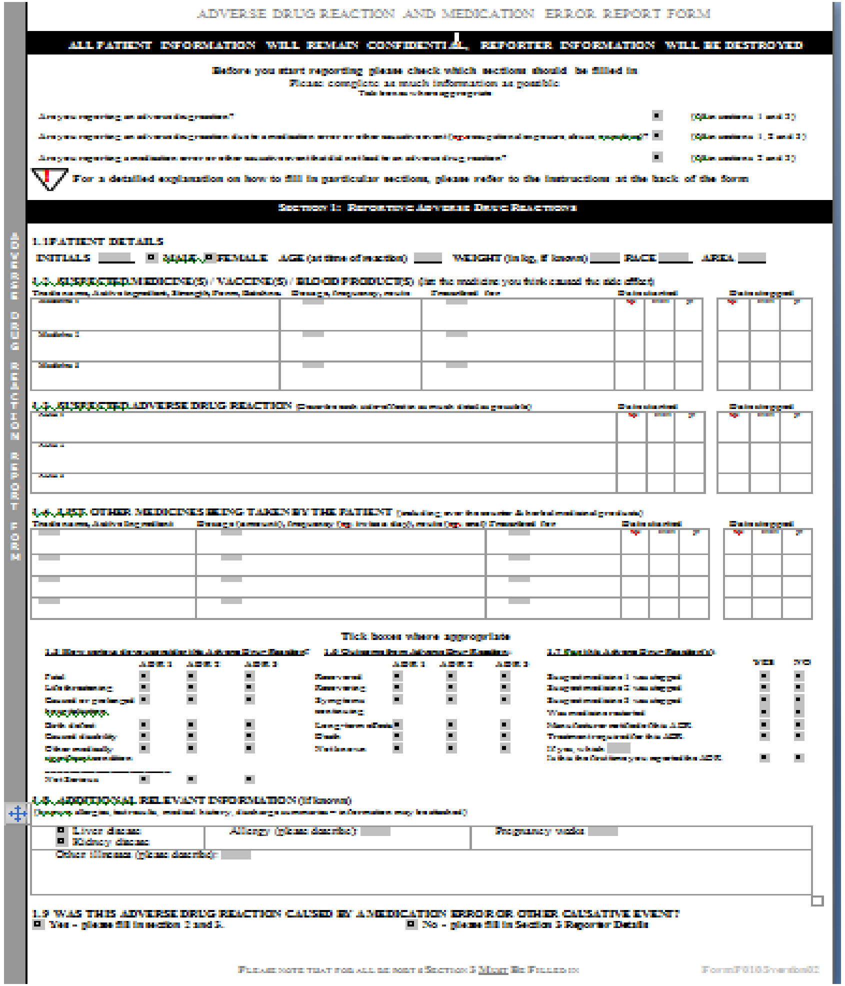
HCPs may refer to the:

Adverse Drug Reaction Reporting & Pharmacovigilance Guidance Notes for Healthcare Professionals for further background and instruction on how to report ADRs.

The ADR form for HCPs also contains a detailed step by step instruction sheet overleaf.



www.medicinesauthority.gov.mt/adversedrugreactions



ADVERSE DRUG REACTION AND MEDICATION ERROR REPORT FORM

ALL PATIENT INFORMATION WILL REMAIN CONFIDENTIAL, REPORTER INFORMATION WILL BE DESTROYED

Before you start reporting please check which sections should be filled in

Please complete as much information as possible

For a detailed explanation on how to fill in particular sections, please refer to the instructions at the back of the form

SECTION 1: REPORTING ADVERSE DRUG REACTIONS

1.1 PATIENT DETAILS

INITIALS MALE FEMALE AGE (at time of reaction) WEIGHT (in kg, if known) RACE AREA

1.2 SUSPECTED MEDICINE(S) / VACCINE(S) / BLOOD PRODUCT(S)

1.3 SUSPECTED ADVERSE DRUG REACTION

1.4 OTHER MEDICINES BEING TAKEN BY THE PATIENT

Tick boxes where appropriate

1.8 ADDITIONAL RELEVANT INFORMATION (if known)

Liver disease

Kidney disease

Allergy (please describe)

Pregnancy weeks

Other illnesses (please describe)

1.9 WAS THIS ADVERSE DRUG REACTION CAUSED BY A MEDICATION ERROR OR OTHER CAUSATIVE EVENT?

Yes - please fill in section 2 and 3.

No - please fill in Section 3 Reporter Details

PLEASE NOTE THAT FOR ALL REPORTS SECTION 3 MUST BE FILLED IN

MALTA MEDICINES AUTHORITY

Patients may also report a side effect through a healthcare professional of their choice.

Confidentiality

Any information including attachment/s related to the identities of the reporter and patient **will be kept confidential**

Minimum requirements for a valid report

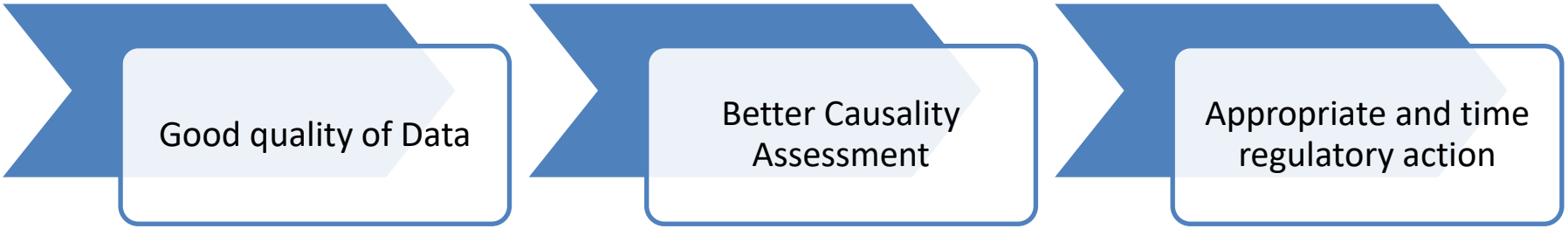
MALTA MEDICINES AUTHORITY

For a valid report, 4 DATA ELEMENTS are necessary

Promoting Good Data Quality in ADR reports

MALTA MEDICINES AUTHORITY

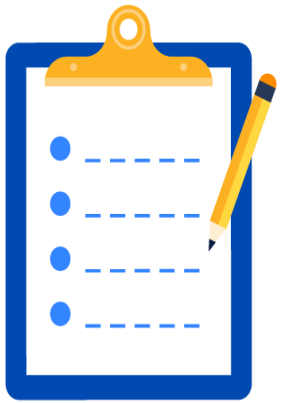
The quality of ADR reports is very important when carrying out **casualty assessment** and taking decisions on regulatory actions in a timely way



Casualty assessment = the assessment of the likelihood that a drug has caused the ADR

Information to be included in the ADR report

- Patient details (name, age, gender)
- Details on the medicine which is suspected of causing a side effect (medicinal name, dose, indication, date of start of treatment, end date of treatment (where applicable)),
- Information about the side effect (start/stop date of event where applicable)
- Concomitant medications
- Concomitant disease or medical conditions



What makes a report one of good quality?

- Be as **accurate** as possible; avoid vague descriptions (e.g. feeling upset/fussy) and ambiguous terms – (e.g. congestion: nasal congestion or congestion of liver sinus? Pain: where?). Avoid the use of abbreviations.
- Be as **specific** as possible when reporting start and end dates of for e.g. medicinal treatment duration, adverse event.
- Give relevant patient details e.g. past medical history, concomitant medication and outcome of event e.g. did the patient recover from the adverse event?
- When indicating laboratory data report units and range e.g. Blood glucose 4 mmol/L (range: 3.9-7.1 mmol/L).

What happens to my side effects report?

Keeping MEDICINES safe

If side effects are unusual a flag is raised and EU experts take an even closer look. This can lead to a change in how the medicine is prescribed.

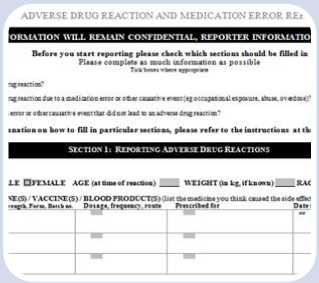
You can play a role in making medicines safer by reporting side effects directly to your national medicines authority.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

An agency of the European Union

EU system of Adverse Drug Reactions

MALTA MEDICINES AUTHORITY


ADVERSE DRUG REACTION AND MEDICATION ERROR RE

ORMATION WILL REMAIN CONFIDENTIAL, REPORTER INFORMATIO

Before you start reporting please check which sections should be filled in
Please complete as much information as possible
Tick boxes where appropriate

ng reaction?

ng reaction due to a medication error or other causative event (eg occupational exposure, abuse, overdose)?

error or other causative event that did not lead to an adverse drug reaction?

uation on how to fill in particular sections, please refer to the instructions at th

SECTION 1: REPORTING ADVERSE DRUG REACTIONS

LE ☐FEMALE AGE (at time of reaction) WEIGHT (in kg, if known) RAC

VE(S) / VACCINE(S) / BLOOD PRODUCT(S) (List the medicine you think caused the side effec
rength, Form, Batch no. Dosage, frequency, route Prescribed for Date

Spontaneous Reports (from HCPs and Consumers)

Reported to

NCAs or MAHs

Transmitted to

EudraVigilance (EU-wide database of ADR reports)

Signals Raised

Review by PRAC CHMP adoption Decision by EC

Results in

Regulatory Action (Update of PIL) & communication

The Malta Medicines Authority's Role in Safety Monitoring

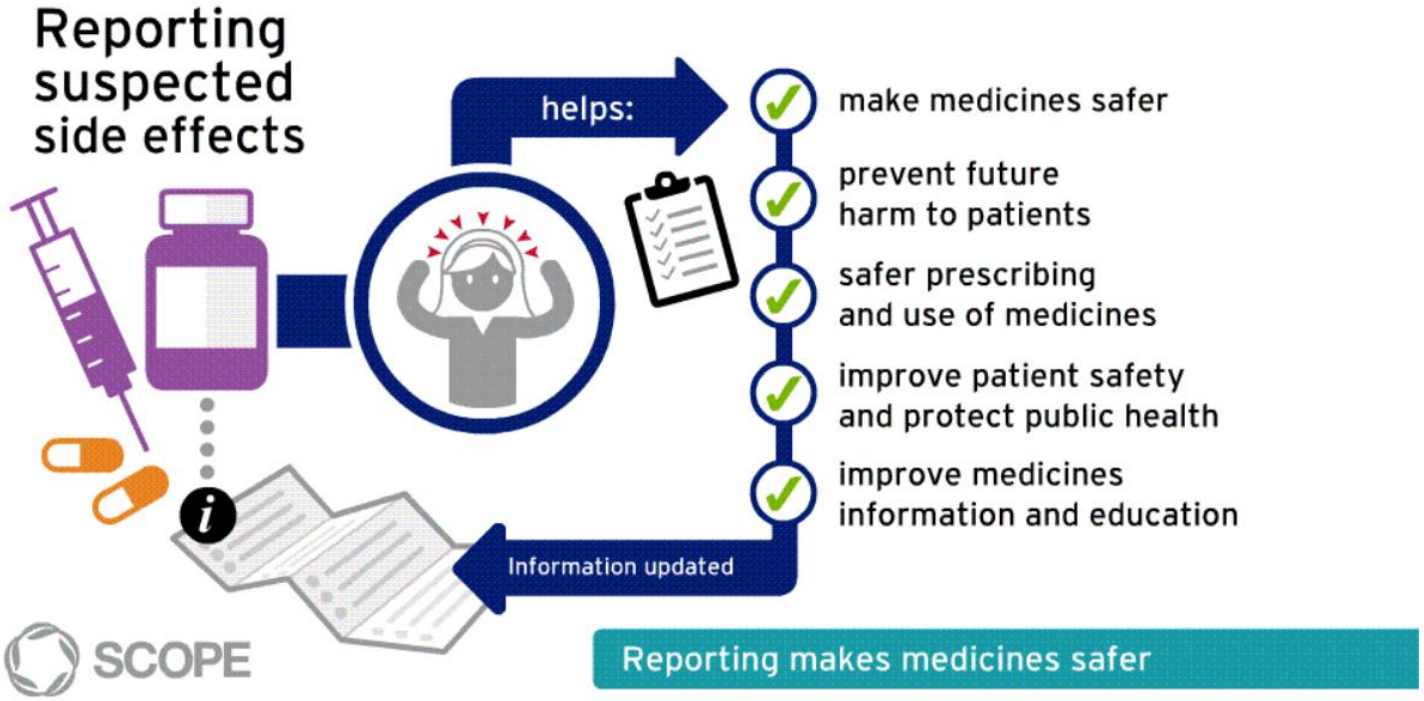
The MMA monitors the safety of medicinal products in Malta and supports the safe and rational use of medicines through the provision of objective and unbiased information.

Key activities

- Managing ADRs (Acknowledgement / Validation / Causality / Databasing / Transmission to EV)
- Raise potential safety signals to the PRAC
- Participate in EU Decision Making on Regulatory Actions at the level of the EMA
- Communicate on Safety Issues (via DHPCs and Safety Circulars)
- Approve Risk Minimisation Measures and ensure their implementation

Why should we report side effects?

MALTA MEDICINES AUTHORITY



MedSafetyWeek and World Antimicrobial Awareness Week (Nov 2022)

The MMA participated and promoted two social media campaigns:

1. The **#MedSafetyWeek** was aimed at increasing awareness on the importance of monitoring of side effects and encouraging the reporting of side effects by both healthcare professionals and patients.
2. The **World Antimicrobial Awareness Week** was aimed at improving understanding of Antimicrobial Resistance (AMR) and push for the adoption of best practices by policymakers, healthcare professionals and institutions, as well as by the public.

https://www.facebook.com/medicinesmalta/

Additional queries may be sent to postlicensing.medicinesauthority@gov.mt