



Association For Consumer Rights (Malta)

Pope Pius XII, Flat 4, Mountbatten Street, Blata l-Bajda
Hamrun HMR 1579, Malta

Tel no 356 21246982

Email: associationforconsumerrights@gmail.com

Resolution for ACR AGM 2017

Title of Resolution

Medicines and the Consumer-Patient

Name of individual submitting the resolution

ACR member Bianca Stivala, B.Sc. Pharm. Sci. (Hons.) (Melit.), M.Pharm.

Background Information

At present there are several concerns regarding medicines and the consumer, both with regards to retail medicines as well as those distributed by the public Pharmacy of Your Choice (POYC) Scheme. The scope of this resolution is to present current situations of concern and to provide recommendations to rectify them.

Justifications, reasons and current situations to be addressed

1. Printed material, such as packing and patient information leaflet (PIL), pertaining to certain products is not in English or Maltese
2. Font size of text of PIL is too small
3. Medicines are often dispensed without adequate patient counselling, leaving the consumer-patient with several question marks
4. Some POYC medicines are being dispensed in pre-packaged containers without PILs
5. POYC medicines being dispensed in pre-packaged containers look identical
6. Out-of-stock medicines
7. Medicines available are not always of the same brand

Proposals/Recommendations

1. All products are to have labelling and instructions available in English or Maltese. Medicinal products are no exception. The ACR should encourage the Medicines Authority and relevant stakeholders to ensure that all medicinal products made available locally carry appropriate labelling and PILs in English or Maltese. The said appropriate labelling is to be placed on the outer packaging and on the actual product, as in the case of medicine bottles. In cases where adhesive labelling would interfere with the use of the

medicine (as in the case of blister packs – attaching a sticker would make it physically impossible to take out the tablet) or where the inside item is too small (as in the case of ampoules) additional literature should be included. Besides fulfilling obligations to the consumer, appropriate labelling in English or Maltese is also necessary for healthcare professionals in case they would need to refer to the literature.

2. This issue is of particular concern, given that the geriatric population is a major consumer of medicines. In some cases the font size of the PIL is too small to be read comfortably, denying access to an important part of the medicine package. Two proposals are being put forward to rectify this shortcoming:
 - Suggesting to the local importer to produce a large text format of the PIL, to be made available upon request by pharmacies and consumers
 - Setting up of a telephone number/freephone where the PIL is read out automatically in English or Maltese. This service can either be set up by local importers for their respective brands of medicine, or by another institution which would take care of all medicines.
3. Information on how to take the medicine is given by the dispensing pharmacist, in line with the manufacturer's guidelines (listed on the PIL) and in case of prescriptions, according to the instructions listed on the prescription. In cases of conflict between the manufacturer's guidelines and instructions on the prescription, the pharmacist is duty-bound to clarify such issues with the prescriber. Setting up of standards in order to facilitate understanding of medicine administration by the consumer may be implemented in one of two ways:
 - [A printed form in English or Maltese](#) with checkboxes and space for notes to be filled in by the pharmacist's hand can be used. This is to be filled for each medicine dispensed and given to the patient along with the medicine.
 - Printed labels in English or Maltese containing advice on how to take medicines can be affixed to the medicine packages by the pharmacist immediately prior to dispensing.
4. Some medicines provided through POYC are distributed in sealed, white, plastic containers referred to as pre-packs. Such medicines are purchased in bulk and repackaged into these containers. Although this format is convenient for dispensing pharmacists, stock monitoring and storage purposes, one cannot say the same with regards to consumer affairs. These pre-packs carry a label with the POYC logo, generic name of medicine, lot number, quantity and expiry date. The POYC unit had distributed to all pharmacies one copy of the PIL of each pre-packaged medicine, for pharmacists to photocopy and distribute accordingly. Unfortunately this was never enforced, and pharmacists do not distribute copies of the PILs to patients due to time constraints and due to the absence of requests. The ACR should pressure the POYC unit to enforce this in a practical manner. Two proposals are put forward here:
 - A system can be rolled out whereby pharmacists distribute copies of these PILs every stipulated time period, whenever there is an update in the PIL and whenever there is a change in brand.

- The myhealth portal accessed using the eID can be updated to include a section on medicines. A downloadable copy of the PIL can be uploaded to this section in order for it to be easily accessed by patients using a computer.
5. Another shortcoming brought along by pre-packaged medicines is their appearance. As described before, these pre-packs take the form of white plastic containers which are at first glance identical, save for the content on the affixed label. This can cause confusion in cases where patients take more than one type of pre-packaged medicine, leading to issues such as non-compliance and incorrect administration of medicines. Additionally, this issue can cause the dispensing process to be time-consuming, as the pharmacist has to ensure that the patient (or proxy on behalf of the patient) has fully understood what medicines they are being given. The ACR should encourage the POYC unit to modify the labels affixed to the containers. The following is a list of suggested additions to the current contents on the label:
- A system of colour-coded labels for different pharmacological classes, for example red labels for heart medicine, blue labels for diabetes medicine, etc.
 - A colloquial expression pertaining to the medicine, also in Maltese, written for example *tal-pressjoni*, *tal-qalb*, *tal-pipi*, etc.
6. Out-of-stock medicine is an issue of major concern. Orders for medicines distributed via POYC are done by the Central Procurement and Supplies Unit (CPSU). The baseline of the ordering process of most items is past consumption patterns, with a time frame of 6-8 weeks delivery for normal procedures. In spite of all the efforts made to source medicinal products in adequate quantities and in good time, there are several shortcomings which may hinder this process, namely lack of availability from the manufacturer overseas, or a sudden increase in patient entitlements. The POYC unit is correctly enforcing checks on patient entitlements in order to ensure that the available stock is being dispensed according to entitlement, thus ensuring that correct distribution of stock. In cases where medicine is out-of-stock, patients have the option to purchase them, however they may not be willing to do so.

The ACR can propose a system whereby patients purchase the out-of-stock medicine to which they are entitled, and later reimburse them. This can also be extended to the entire free medicine system. Since there are various brands of the same medicine available on the retail market, the first step would be to gather the prices of all the brands available and draw up an average monetary figure. The patient would then be reimbursed the average monetary figure, regardless of which brand they purchased. In cases where they have purchased a medicine at a cheaper price than the average, they would be reimbursed the full price of the medicine.

7. There are several factors which determine the availability of brands, most notably availability (or lack of) from the manufacturer overseas, and the tender system adopted by the CPSU. Most medicines purchased by CPSU are generic medicines; these medicines are proven by their manufacturer to be therapeutically equivalent to the medicine produced by the original manufacturer. The patient should therefore be receiving the

same benefit regardless of the brand of the product. There are however cases where patients are allergic to, or can only tolerate specific brands.

- First and foremost, it is of utmost importance that the general public is given the right information, as their knowledge of what a generic medicine is will help them understand the reason why different brands appear from time to time and reassure them that it is safe for them to take.
- Another possible solution to this is to make available several brands of the same medicine at a given time. The ACR can suggest a scheme whereby the POYC unit, together with participating pharmacies, compiles a database listing brands of medicines accepted/not tolerated by patients. The quantities can then be extrapolated and sent to the CPSU and appropriate quantities of various brands ordered, followed by appropriate distribution to pharmacies.
- The system of reimbursements proposed in point 6 may prove to be another solution, allowing the patient to buy the preferred brand of medicine.