Our Ref: 05/2012

CONSULTATION DOCUMENT ON PROPOSED AMENDMENTS TO SUBSIDIARY LEGISLAITON 458.16 (LEGAL NOTICE 279 OF 2007 AS AMENDED – PHARMACY LICENCE REGUALTIONS, 2007) AND TO SUBSIDIARY LEGSIALTION 458. 49 (LEGAL NOTICE 292 OF 2006 – PRESCRIPTION AND DISPENSING REQUIRMENTS RULES, 2006).

Objectives and Scope

The European Commission has embarked on the Better Regulation Staregy in 2006, by aiming for a better regulatory environment for business - one that is simpler, understandable, effective and enforceable. In order to reach this, the Commission jointly with Member States target to reduce the administrative burden for companies of existing regulation by 25% by 2012. Malta's target is to reduce administrative burdens resulting from information obligations on businesses which are exclusively a consequence of rules formulated at National level by 15% by 2012.

The Better Regulation Unit (BRU) within OPM is mandated to act as the single central authority on Better Regulation. In this regard, the Medicines Authority and the Licensing Authority have been working closely with the BRU to ensure that Better Regulation principles and procedures are applied consistently in the area of Pharmaceuticals. A report by pwc, commissioned by BRU, has recently been presented to the Authority and includes measurements of administrative costs arising from National legislation and proposals for simplification.

The requirement for documentation of dispensed medicines in registers by pharmacists was identified as a potential area where adminstartive burden could be reduced.

The current requirement for pharmacists is to keep records of prescriptions dispensed in their daily register. The reasons or scope for this requirement are the following:

1) To have a full back traceability of products to patient level for patient safety issues and public health issues,
2) To be able to reconcile products and their quantities dispensed over a period of time for specific categories of drugs, example antibiotics, for a number of scopes such as for enforcement purposes, pharmaco-epidemiological purposes and other health safety aspects;
3) To protect the dispensing pharmacist in case of allegations made against him/her by patients/ consumers.

To this effect it is being proposed to amend the current legislation to reduce the administrative burden as much as possible on the operator more specifically on the dispensing pharmacists whilst keeping all the above mentioned scopes and reasons in effect.

Therefore it is being proposed that the requirement for the registering in the daily register of all dispensed Prescription Only Medicines is removed and replaced with the requirement of:

1) Keeping the dispensed prescriptions for a specific period of time after which they can be disposed of. Six months was established as a good enough timeframe for the above scope and reasons to be achieved without burdening the operator unnecessarily, keeping in mind that most dispensed medicines would be consumed within a six month time window from purchase;
2) Continueing to register in the daily register only those medicines which are dispensed against repeat prescriptions and the partially dispensed prescriptions (since in both these cases the prescriptions will have to be handed over to the patients).

The above shall not apply for Drugs of Dependence and Abuse (DDAs) in which case pharmacists should continue with the current practice of registering all their purchases and sales.

Based on data provided by stakeholders, it has been calculated, by pwc, that the proposed simplification will save €2.2million to operators.

Main Changes

Therefore in congruence with the above the following main changes are being proposed:

1. For subsidiary legislation 458.16 (Legal Notice 279 of 2007 as amended- Pharmacy Licence Regulations, 2007).
   (i) Amend regulation 12, keeping the duty of the managing pharmacist to keep seperate written or electronic records for the sale of repeat prescriptions or for partially dispensed prescriptions, whilst removing altogether the requirement to keep such written or electronic records for all the other type of prescriptions, excluding those for narcotics and psychotropic drugs i.e. the green prescriptions. Instead of the written or electronic records the phramcist can keep the prescription itself as a means of record for a period of at least six months.

2. For subsidiary legislation 458.49 (Legal Notice 292 of 2006 – Prescription and Dispensing requirements Rules, 2006).
   (i) Regulation 3 is amended so as to allow the possibility of using electronic signatures on electronically generated prescriptions;
   (ii) Regulation 5 is amended so that this regulation is now applicable only to the partially dispensed prescriptions or to repeat prescriptions, given that the other prescriptions will be retained by the pharmacist;
   (iii) Regulation 6 is amended so that the written or electronic records in registers do not apply for those prescriptions which are retained by the pharmacist.

Comments

Your comments on the proposed Legal Notices are invited.

Comments are to reach the Medicines Authority in writing or via email consultations.medicinesauthority@gov.mt by the **15th June 2012.**

Should any further information be required kindly contact the Medicines Authority using the following contact details:

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L.N. of 2012

MEDICINES ACT
(CAP. 458)

Pharmacy Licence (Amendment) Regulations, 2012

IN exercise of the powers conferred by article 66 of the Medicines Act, the Minister of Health, the Elderly and Community Care, after consultation with the Licensing Authority, has made the following regulations:-

Title and Scope

1. The title of these regulations is the Pharmacy Licence (Amendment) Regulations, 2012 and they shall be read and construed as one with the Pharmacy Licence Regulations, 2007 hereinafter referred to as "the principal regulations".

Amends regulation 12 of the principal regulations.

2. Regulation 12 of the principal regulations shall be replaced by the following:

(1) It shall be the duty of the managing pharmacist to keep separate written or electronic records into which shall be entered:

(a) the sale of every medicinal product dispensed against a repeat prescription;

(b) the sale of every medicinal product dispensed against a partially dispensed prescription.

(2) All other medicinal products dispensed against prescriptions and not mentioned in paragraph 1 above, shall not need to be registered and the prescription against which they were dispensed should be retained by the managing pharmacist for a period of 6 months from date of dispensing, after which the said prescriptions can be disposed of. The dispensing pharmacist must record on the prescription the date upon which the prescription was dispensed, his/her signature and pharmacy council registration number. This provision shall not apply for narcotic drugs and psychotropic substances whose purchase and sale shall continue to be registered in line with the requirements of the Dangerous Drugs Ordinance and its subsidiary legislation.

L.N. of 2012

MEDICINES ACT
(CAP. 458)

Prescription and Dispensing Requirements (Amendment) Rules, 2012

IN exercise of the powers conferred by article 66 of the Medicines Act, the Minister of Health, the Elderly and Community Care, after consultation with the Licensing Authority, has made the following regulations:-

Title and Scope

1. The title of these regulations is the Prescription and Dispensing Requirements (Amendment) Rules, 2012 and they shall be read and construed as one with the Prescription and Dispensing Requirements Rules, 2006 hereinafter referred to as "the principal regulations".

Amends regulation 3 of the principal regulations.

2. Paragraph (d) of regulation 3 of the principal regulations shall be replaced by the following:

(d) in the case of electronically generated prescriptions, bear the details in paragraphs (a), (b) and (c) and must be officially signed by the prescriber, which may include electronic signatures.

Amends regulation 5 of the principal regulations.

3. Regulation 5 of the principal regulations shall be replaced by the following:

(1) For repeat prescription and partially dispensed prescriptions, which are given back to the patient, the dispensing pharmacist shall write clearly and legibly thereon in ink or any other indelible manner the word "dispensed", date of dispensing, the quantity supplied, the Pharmacy Council registration number, signature and endorse the prescription with the pharmacy stamp.

Amends regulation 6(1) of the principal regulations.

4. Regulation 6(1) of the principal regulations shall be amended as follows:

(1) The words "a repeat prescription or partially dispensed "shall be introduced before the word " prescription" in first sentence of regulation 6(1) so that it would read: 'A pharmacist dispensing a repeat prescription or partially dispensed prescription shall enter into any record kept under the Medicines Act the following particulars:'