



These Guidelines
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Guidelines on the Simplification of On-line Forms

These are Guidelines intended to help applicants when using the new simplified on-line Application Forms

In line with the simplification and reduction of bureaucracy policies the Veterinary Medicines Section within the National Veterinary Laboratory (NVL) of the AHWD has studied the various ways in which the current on-line Forms could be simplified.

A reduction in existing bureaucratic procedures is set through the better use of ICT and through the elimination of repeated requests for information.

This is intended to be a positive change through elimination of unnecessary burdens to the business sector while still keeping the proper and expected regulatory control.

This process is continuous and eventually further improvements are planned in the on-line Forms.

Feedback from you is appreciated as you have the first hand experience when filling in the Forms and submitting them to the VMS for evaluation.

It is as important that you transmit the information to the companies that you are affiliated with. These will now have a greater role to play.

Guidelines for each type of Form are being provided

These guidelines compliments the instructions given during the seminar of the 31-07-2019 for all users of on-line Applications Forms.

All Application form can be accessed from the Veterinary Medicines 's Section Website

<https://agrifish.gov.mt/en/nvl/Pages/missionStatement.aspx>

Application Forms to Open and Operate Veterinary Pharmacies, Veterinary Wholesale Dealers and Medicated Feed Mills

To open a Veterinary Pharmacy and a Medicated Feed Mill

If the details of the applicant are the same as those inserted in Page 1 then only the field entitled 'Telephone' needs to be filled in the Details of the Veterinary Pharmacy Owner, or in the case of a Medicated Feed Mill, in the Details of the Medicated feed mill owner.

Abbreviations:

AHWD: Animal Health and Welfare Department

MAH: Marketing Authorisation Holder

RH: Registration Holder

LD: Local Distributor

EU/EEA: European Union/ European Economic Area

VMS: Veterinary Medicines Section

AA: Authorisation Holder

MRP/DCP: Mutual Recognition Procedure/Decentralised Procedure

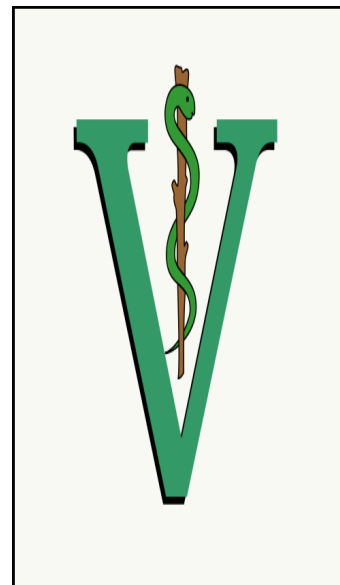
S.L: Subsidiary Legislation

To open a Veterinary Wholesale Dealing Activity

There is a difference between '*Details of the owner of the wholesale Dealing activity*' and the '*Name of the wholesale dealing activity and details of the operational site*'.

The former is the person who is registering for the wholesale dealing activity. These details could be the same ones as those indicated in Page 1. If that is the case fill only the field entitled 'Telephone'

The latter refers to the place from where the wholesale dealer will be physically operating, e.g. the stores and means of transport. This is the 'Operational Site'.



Moreover, the wholesale dealer may have an additional site where he is registering his activity but where no physical movement of medicine takes place. This is the 'Legal Site'. You need to fill in the details of this site only if they are different from those of the 'Operational Site'

Applications for Authorisation and Registration Routes

Centralised Procedure

If in section 'Details of MAH' it is the first time the MAH is submitting an application and the details are the same as in Page I, fill in only the field entitled 'Telephone'. If the MAH is an MAH of an existing product in Malta, you need only to insert the number that has been given to that particular MAH by the VMS

If the 'Person / Company authorised for communication on behalf of the MAH are the same as those in the field which is above this field there is no need to re-enter the details again.

In 'Intended local distributor' put only the number given to you by the VMS.

There is no need any more to submit a 'letter of access'

Registration according to Reg 7 of S.L 437.47

If in the section 'Details of RH' it is the first time the RH is submitting an application and the details are the same as in Page I, fill in only the field entitled 'Telephone'. If the RH is a RH of an existing product in Malta, you need only to insert the number that has been given to that particular RH by the VMS.

If the MAH in the country of source is not the same as the RH and it is the first time that particular MAH is featured in the application form you need to fill in all the fields. If the MAH is not the same as the RH but that MAH has already featured in a past application you need only to insert the number that has been given to that particular MAH by the VMS.

If the details of the 'Person / Company authorised for communication on behalf of the MAH are the same as those in the field above this field there is no need to re-enter the details again.

In 'Intended local distributor' field insert only the number given to the LD by the VMS. The number has been individually communicated to each LD and will be available on the website.

The 2 fields related with 'Product Details' have now been merged into a single field

**THE FEEDBACK
FROM THE USERS
OF THE SYSTEM IS
ESSENTIAL TO
CONTINUALLY
FIND OPPORTUNITIES
FOR IMPROVEMENT
AND ACT ON
THEM**

MRP/DCP Final Stage

and

Authorisation according to Reg 4(2) of S.L 437.47

If in 'Details of MAH, or AA in the case of Regulation 4(2) Authorisation, ' it is the first time the RH or AH is submitting an application and the details are the same as in Page I, fill in only the field entitled 'Telephone'. If the MAH or AH is a MAH or AH of an existing product in Malta, you need only to insert the number that has been given to that particular MAH or AH by the VMS.

If the details of the 'Person / Company authorised for communication on behalf of the MAH, or AH in the case of Regulation 4(2) Authorisation, are the same as those in the field above this field there is no need to re-enter the details again.

In 'Intended local distributor' field insert only the number given to the LD by the VMS The number has been individually communicated to each LD and will be available on the website.

There is no need to submit a 'letter of access'

In the case of MRP/DCP it is not anymore a requirement to submit mock-ups bearing the Maltese MA number. These can be provided after the licence has been issued.

Applications for Licensing Schemes

Research Purpose Licence



If it is the first time you are submitting an application and the details are the same as in Page 1 fill in only the field entitled 'Telephone'. If you are already a 'Project Manager of a product fill in only the box entitled

'Project Manager Number' with the number that has been given to you by the VMS.

In the field 'Details of Person/company supplying the medicine', if the same details have already been supplied in a past application insert only the number of the 'Person/Company supplying the medicine'. This number has been communicated to you by the VMS and is unique for each supplier



Cascade Licence

In 'Details of Veterinarian' if you have submitted an application in the past and the details have not changed fill in only the field entitled 'Warrant number'. If you have not submitted a request in the past and the details are the same as in page 1 fill in only the fields entitled 'warrant number' and 'Telephone'

Requests for Veterinary Prescription

In 'Details of Veterinarian' if you have submitted an application in the past and the details have not changed fill in only the field entitled 'Warrant number'. If you have not submitted a request in the past and the details are the same as in page 1 fill in only the fields entitled 'warrant number' and 'Telephone'

Please note that now the maximum number of prescription booklets you can order at any one time is 3.



The 'Details of location' has been merged with 'Details of Veterinarian'. The booklets will be posted at the address indicated in this field.



Comments to the VMS

It will be assumed that whoever accesses and send the on-line form is the person who would like to leave a comment.

The 'Description of comment' should be as much in detail a possible. Depending on the nature of the comment, contact details of other persons may have to be given.

Reports of Adverse Drug Reactions and Product Defects

It will be assumed that whoever accesses and send the on-line form is the person who would like to make the report

In the field 'Details of person having the adverse drug reaction', if the details are the same as in Page 1 fill in only the fields with an asterisk which are not requested in page 1, e.g. known disease, occupation and age. These fields have been marked with an asterix.

**REPORT ANY
SUSPECTED
ADVERSE DRUG
REACTION AND
PRODUCT
DEFECTS.....
YOUR REPORTING
MATTERS!**

**'The time-frame
for the processing
of all Application
Forms is 45 days'**

**'The above time-
frame does not
include any clock-
stops'**

**'In the case of
Comments,
Reports for Adverse
Drug Reactions
and Product
Defects Action
may be taken
immediately
according to the
severity of the
case'**

Post-Authorisation Procedures Applications

Withdrawal of Veterinary Medicinal Products

Please note how all fields under 'Product to be withdrawn' have been removed. Only the 'Desired date of withdrawn' and Marketing Authorisation/Licence/Authorisation/Registration number have been left from the previous form.



Please also note how a statement was added on the form to indicate that the 'Desired date of withdrawal' cannot be before the submission of the application form.

Notification of Changes in National Registrations and National Authorisations

Please note how all fields under 'Product Details' have been removed. Only the 'Marketing Authorisation/Licence/Authorisation/Registration number' have been left from the previous form.

It is important that the VMS is notified of all changes relating to the product Information (Package Leaflet, labelling and Summary of Product Characteristics) This includes also the details of the MAH, AH, RH and LD.

Please remember that when making the request for the annual extension a list of the notifications that had occurred in the previous year has to be submitted.

'It is essential that the VMS always has the information up-to-date. This is important not only for the system to run efficiently and smoothly but also in cases where issues with the products arise, both at local and EU/ international level'

Important Points to Keep in Mind



Once Application Forms are submitted they are automatically sent to a generic e-mail. From there they are scheduled to a Product Co-ordinator who will start evaluating them.

In case you have a query about the Form related with Adverse Drug Reactions and Product Defect you can send it to alertmedicine@gov.mt in. In the case you have a query regarding all other Forms you can send it to veterinarymedicine@gov.mt. The scheduler at the VPRD will tackle your query if it is of an administrative nature. If it is of a technical nature the scheduler refer you to the relevant Product Co-ordinator.

Once you have made contact with the Product Co-ordinator please continue corresponding with him/her on his/her e-mail and do not use the generic e-mail anymore.

The efficiency of the evaluation by the Product Co-ordinator depends also on the quality of the submission. Therefore, avoid giving missing information or documents. This will avoid delays and clock-stops.

Please always make your payments according to the latest instructions on the website. If there is any change in the Fee structure you will be contacted immediately. Moreover, the website will be updated accordingly.