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1. Introduction

The commencement of the Fourteenth Law amending the Medicinal Products Act of 29 August 2005 (Federal Law Gazette/BGBl I p. 2570) on 6 September 2005 extended the notification requirements for medicinal products to include placing on the market (called "notification of marketing" in the following [German: "Anmeldung"]) and cessation of placing on the market (called "notification of cessation of marketing" in the following [German: "Abmeldung"] by the holder of the marketing authorisation.

The electronic sunset clause (also called “SSC” in the following) procedure was developed with the aim of providing a simple and user-friendly procedure for keeping the notification procedure resource-sparing and thus cost-efficient which also dispenses with the "classical" written correspondence as far as possible. The individual procedures are described in more detail in the following chapters. Both the forms and further information can be found on the homepage of the Federal Institute for Drugs and Medical Devices (BfArM) under www.bfarm.de by clicking on "Sunset Clause"; the forms are provided in German and in English.

The corresponding BfArM pages can also be reached from the homepage of the Federal Office of Consumer Protection and Food Safety (BVL) under www.bvl.bund.de.

1.1 Legal Basis

Among other changes, sub-sections 1b and 1c were added to Section 29 AMG in the 14th Law Amending the German Medicinal Products Act.

Section 29 sub-section 1b AMG:

The marketing authorisation holder shall notify the competent higher federal authority immediately of the date on which the medicinal product is to be placed on the market, taking into consideration the different pharmaceutical forms and strengths authorised.

Section 29 sub-section 1c AMG:

The marketing authorisation holder shall notify the competent higher federal authority in compliance with sentence 2 in the event of temporary or permanent cessation of the marketing of the medicinal product. Notification shall be submitted at least two months before the suspension of marketing. This shall not apply in the event of circumstances over which the marketing authorisation holder has no control.

In connection with the implementation of Article 1 sub-section 6 of the Third Act to Amend Provisions under the Law Concerning Medicinal Products and Other Provisions, Section 29 AMG (among others) was extended to include sub-section 1g.

Section 29 sub-section 1g AMG:

The marketing authorisation holder of a medicinal product for use in humans shall notify the competent higher federal authority immediately of the reasons for the temporary or permanent cessation of the marketing of the medicinal product, the recall, renouncement of marketing authorisation or the decision not to submit an application for renewal of marketing authorisation.

Especially, he has to declare, whether the measure in accordance with sentence 1 is based on one of the reasons laid down in Section 25 sub-section 2 sentence 1 numbers 3, 4 or 5, Section 30 sub-section 2 sentence 1 number 1 or Section 69 sub-section 1 sentence 2 number 4 or number 5. The notification in accordance with sentence 1 must also be made if the measure is taken in a third
country and is based on one of the reasons stated in sentence 2. Furthermore, if a measure in accordance with sentence 1 or 3 is based on one of the reasons stated in sentence 2, the marketing authorisation holder also has to notify the European Medicines Agency.

In accordance with Section 31 sub-section 1 sentence 1 number 1 AMG, the marketing authorisation shall expire if an authorised medicinal product is not placed on the market within three years of the granting of the marketing authorisation, or if an authorised medicinal product that was placed on the market in accordance with the marketing authorisation is not placed on the market for three successive years.

1.2 Technical Basis
The competent authority is notified of marketing/cessation of marketing of a medicinal product by way of an online form. In order to be able to use this, the pharmaceutical manufacturer (this will generally also be the Marketing Authorisation Holder (MAH)) has to register once for the procedure. MAHs registered for the online procedure will be listed on the BfArM homepage at www.bfarm.de under "Sunset Clause". After having registered for this procedure, MAHs can log into the system with their corresponding pharmaceutical company numbers (PNR) and a password in order to notify the authority of marketing/cessation of marketing of medicinal products for which they have a marketing authorisation or registration.

The forms allow both single notifications, as well as collective notifications (only possible in cases where all information entered is identical). In the case of medicinal products for use in humans, the reasons for cessation of marketing are to be stated additionally in accordance with Section 29 sub-section 1g AMG. After the MAH has submitted the data, it is entered in the AMIS database and processed automatically.

The forms can be accessed on workdays between 8:00 am and 6:00 pm; the remaining time is reserved for internal data processing and updating of the databases.

In the summary of all notifications made, the MAH has the possibility of correcting or deleting transmitted notifications up to 4 weeks after they have been made.

The SSC status report shows the MAH the notification status and, if applicable, the remaining term of his valid marketing authorisations and registrations. The report "expiries due to SSC" shows the MAH all his medicinal products the marketing authorisation/registration of which has expired based on the SSC.

1.3 Default Settings in the AMIS Database
All medicinal products with a marketing authorisation/registration are preset in the AMIS database with the following defaults:

- medicinal products which were already licensed before the 14th Law Amending the German Medicinal Products Act came into force are preset with "are marketed by MAH". In these cases, the consecutive number 0001 in the SSC table in AMIS is preset with "Anmeldung: 05.09.2005" (cf. Chapter 3.3 Screenshot 16)
Medicinal products which were licensed after the 14th Law Amending the German Medicinal Products Act came into force are preset with "are not marketed by MAH". In these cases, the consecutive number 0001 in the SSC table in AMIS is preset with "Abmeldung: [date the notice of marketing authorisation was delivered]" (cf. Chapter 3.3 Screenshot 16)

Notifications can be submitted via the online portal for all licensed or registered medicinal products within the responsibility of BfArM or BVL regardless of whether their marketing authorisation/registration is suspended or not. It is not possible to submit notifications concerning centralised marketing authorisations or marketing authorisations within the responsibility of the Federal Agency for Sera and Vaccines (Paul-Ehrlich-Institut).

1.4 Costs/Feels
In accordance with the currently valid AMG Fee Regulation, the notifications pursuant to Section 29 subsections 1b and 1c AMG are subject to fees.

1.5 Languages
The forms are provided in German and English. The first page to appear upon accessing the online form is the service page (Screenshot 1). Here you can choose the language you prefer. By clicking the corresponding field in the upper right corner of the input screen you can switch back and forth between German and English at any time.

Screenshot 1: Service page
2. Registering for the Online Procedure

Before you can participate in the electronic notification procedure you will have to be registered for the procedure accordingly.

In order to initiate the registration process, please click on "Register". This will subsequently open the registration form which requires the following mandatory information:

- PNR (pharmaceutical company number)\(^1\)
- ENR (a valid processing number ("Eingangsnummer") within the MAH's portfolio)
- e-mail address (to which the activation code will be sent)
- surname, first name and office telephone number of the person submitting the notification (information is optional)
- information whether the person submitting the notification is the marketing authorisation holder or an authorised representative of the marketing authorisation holder\(^2\)
- password (to be entered twice)
- confirmation prompt

**IMPORTANT NOTE:** This online procedure is intended to reduce the administrative effort to a minimum, both for the MAHs as well as for the higher federal authorities BfArM and BVL. In order to prevent misuse during registration for the online procedure there are two instruments that ensure the safety of the process.

1. All registered MAHs are published in a list on the BfArM's homepage under "Sunset Clause" which is updated daily (direct link: [https://sunset-clause.dimdi.de/ssc/pub/pnrreport.html](https://sunset-clause.dimdi.de/ssc/pub/pnrreport.html)). This gives MAHs the possibility of checking themselves whether an online registration has been made with "their" PNR.

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\(^1\) The PNR can be obtained via AMIS Public Part at [www.dimdi.de](http://www.dimdi.de)

\(^2\) A power of attorney which is necessary for new registrations (original or certified copy) should be sent to the BfArM to the attention of 13.1.03N. A copy with a reference that the original power of attorney was already submitted to the BfArM/BVL is also acceptable.
2. All registrations for the online procedure are verified by the higher federal authorities BfArM and BVL with regard to plausibility and the marketing authorisation holder is contacted if necessary.

Should a registration for the online procedure have been made without the consent of the marketing authorisation holder despite these safety measures, the competent higher federal authority should be contacted (cf. Chapter 5) so that the administrator can reverse this registration and any notifications possibly received.

Screenshot 3: Registration form
After you have entered the data, click on "Register". If the system does not diagnose incorrect or incomplete data, the activation code is sent to the provided e-mail address. Should the data be incorrect or incomplete you will be requested to enter the information again.

**IMPORTANT NOTE:** Only one activation code per day can be requested.

Screenshot 4: Error reports in connection with registrations for the online procedure

The activation code will be sent to the provided e-mail address within a few minutes (Screenshot 5).

Screenshot 5: E-mail with activation code
The registration process is complete after the activation code has been entered in the corresponding display screen and the activation has been finalised (Screenshot 6). In order to do this, the activation code has to be copied into the clipboard and is then to be entered in the corresponding template. For this purpose you need to open the start screen (Screenshot 2) and click on "activate account". Enter the PNR and the activation code in the corresponding field and then click on "Activate" (Screenshot 6).

**IMPORTANT NOTE**: The complete registration (i.e. including the activation) has to be finalised within one workday between 8 am and 6 pm. At the end of the day, the activation code becomes invalid and the registration process has to be repeated at a later time.

If the registration has been successful you will receive a positive report (Screenshot 7).
After the account has been activated, the MAH will be included in the list of all MAHs registered for the procedure on the BfArM homepage the following workday (Screenshot 8). This list is supposed to serve as a control instrument for the MAHs so that they can check whether a registration was made for their PNR.

**IMPORTANT NOTE:** This list merely states that a registration has taken place and does **not** yield any information on whether notifications were made.

<table>
<thead>
<tr>
<th>PNR</th>
<th>pharmazeutischer Unternehmer</th>
<th>Datum der Registrierung</th>
</tr>
</thead>
<tbody>
<tr>
<td>1234567</td>
<td>Muster GmbH</td>
<td>27.10.2008</td>
</tr>
</tbody>
</table>

Screenshot 8: Report, registered MAHs

As an additional safety step, the registrations are verified with regard to plausibility by administrators of the BfArM/BVL and in cases of doubt the person indicated and/or the marketing authorisation holder are contacted.
3. Selection Menu/Login

A login with PNR and password is possible immediately after successful registration. In order to do so, you will have to open the start screen (Screenshot 2). Should a login not be possible, an error report will be generated (Screenshot 9).

![Screenshot 9: Error occurred during login](image)

After login, a selection menu with the selection options appears (Screenshot 10):

You can then access the page you want by clicking on the corresponding term.

![Screenshot 10: Selection menu](image)

As of Version 3.0 of the electronic application different user roles are no longer required for the individual authorities (BOB). If the products within your portfolio are both human and veterinary medicinal products, i.e. within the jurisdiction of either BfArM or BVL, you can now submit the notifications cross-institutionally in one session.
3.1 Notification on Placing on the Market of Medicinal Products (Section 29 sub-section 1b AMG)

The form for notifying marketing of a medicinal product (Screenshot 11) contains the following information:

- PNR and name of MAH (PNA)
- provided e-mail address

The date of the notification (current date) is entered automatically. The following information is to be given:

- ENR
- Date of placing on the market by the marketing authorisation holder

If the ENRs for the notifications are known, you can enter them directly in the corresponding fields. In the case of single notifications, the ENR is to be entered in the field following "ENR", and in the case of collective notifications, the ENRs are to be entered in the larger window below.

IMPORTANT NOTE: The ENRs entered for collective notifications are to be separated by commas.

If the ENRs are not known, a list of the possible ENRs can be activated via the "search" field (Screenshot 12). This list can be shortened by entering the first numbers of the ENR.

Example: You are only looking for ENRs starting with 215xxxx. Enter the numbers 215 in the ENR field and then start the search function. The search results will only list ENRs starting with 215. We strongly recommend using the search function when selecting ENRs in order to keep errors down to a minimum.

Screenshot 11: Form for notification of marketing of a medicinal product
For single notifications, the data are entered in the form by clicking directly on the ENR. The ENRs for collective notifications are selected by making a mark in the first column; further ENRs can be added by clicking on the double arrow. Subsequent clicking on "list of ENRs" makes the marked ENR appear in the form (Screenshot 11).

If several ENRs are selected in this manner they appear in the bottom field separated by commas. Clicking on “Send Data” in the notification form (Screenshot 11) starts the transmission of the data and completes the procedure. After the data have been transmitted successfully they are deleted from the form and further notifications can be made. If the data are recognised as being incorrect you will receive a corresponding error report (Screenshot 13).

Screenshot 13: Error report if entry is incorrect or incomplete
In the case of incorrect reports, the data are not deleted from the form which allows the user to make corrections. If you click on the error report you will be directed to the corresponding place in the form.

IMPORTANT NOTE: If the procedure is ended by clicking on "Selection Menu" (cf. e.g. Screenshot 11) all not yet transmitted data are lost.

Limitations regarding notifications of marketing:

- The valid time frame for a notification of marketing is today's date +/- 4 weeks. This means that the "Date of placing on the market" should not be more than at most 4 weeks after or 4 weeks prior to the time of notification.

Reasoning: In accordance with Section 29 sub-section 1b AMG, the MAH shall immediately notify the competent higher federal authority of the date on which the medicinal product is to be placed on the market. Thus, the specific date should be known at the time of the notification. Failure to make a notification in due time is an administrative offence in accordance with Section 97 sub-section 2 number 7a AMG.

In the case of a notification of marketing that is made more than 4 weeks in advance you are kindly requested to submit the notification at a later date. In the case of notifications of marketing with retroactive effect of more than 4 weeks you are requested to review the correctness of the marketing information and to confirm this by clicking on "OK". It is conceivable that this notification will be examined by the competent higher federal authority for the presence of an administrative offence.

Should a notification outside these time limits become necessary in order to reverse an already completed notification of cessation of marketing, this can be done in the list of notifications via the function "contrary notification" (cf. Chapter 3.5 Screenshot 19).

- The "date of placing on the market" must not be before that given in the notice of marketing authorisation.

- If the marketing authorisation has already expired in accordance with Section 31 sub-section 1 number 1 AMG at the time of "date of placing on the market", a notification is no longer possible.

- If the SSC status of the medicinal product is "marketed" ("angemeldet"), no new notification of marketing can be made.

- If the SSC status of a medicinal product is "not marketed" ("abgemeldet"), the "date of placing on the market" must be later than the effective date of the notification of cessation.

- If a (prospective) notification of cessation of marketing has already been announced for a medicinal product, no further prospective notification of marketing is possible.

- A notification of marketing is not possible if the marketing authorisation was suspended at the time of the given "date of placing on the market". In accordance with Section 30 sub-section 4 AMG, medicinal products shall not be placed on the market if the marketing authorisation has been suspended.
3.2 Notification on Cessation of Marketing of Medicinal Products (Section 29 sub-section 1c AMG)

The notification on cessation of marketing (Screenshot 14) is submitted via the second option in the selection menu (Screenshot 10) and is analogous to the procedure for notifications of marketing.

The following information is to be given:

- ENR
- Date of cessation of marketing by MAH
- Date of expiry of the last batch placed on the market by the MAH (called "shelf life" in the following)
- Reasons for the cessation of marketing of the medicinal product for human use in accordance with Section 29 sub-section 1g AMG

Screenshot 14: Form for notification of cessation of marketing of a medicinal product
The end of shelf life constitutes the starting date for calculating the 3-year period in accordance with Section 31 sub-section 1 number 1 AMG (sunset clause). If you do not indicate the date, the 3-year period will start counting as of the date of cessation of marketing.

In the case of medicinal products intended for use in humans, at least one reason for the notification of cessation of marketing must be selected. Furthermore, in such cases statement whether the reason(s) is/are due to measures in a third country is necessary. Please note that the checkbox "Other reasons" is automatically selected as soon as the free text field is filled in. This selection is reversed if the content of the field is deleted again. The free text field should contain at least 10 and at the most 1000 technically valid characters. As a rule, the following characters are not permissible for technical reasons: tabulators; '; "; >; <. If data is missing or recognised as incorrect you will receive a corresponding error report.

**IMPORTANT NOTE:** Collective notifications are also always based on identical reasons for cessation of marketing. Thus, if the reasons for this differ, separate notifications have to be made for the individual ENRs. For more information regarding collective notifications please refer to Chapter 3.1.

**Limitations regarding notifications of cessation of marketing:**

- The valid time frame for a notification of cessation of marketing is between 2 months and 1 year prior to cessation of marketing. The date of the end of shelf life of the last batch placed on the market must not be more than 10 years in advance.

Reasoning: In accordance with Section 29 sub-section 1c AMG, the MAH shall notify the competent higher federal authority in compliance with sentence 2 in the event of temporary or permanent cessation of the marketing of the medicinal product. Notification shall be submitted at least two months before the cessation. Failure to make a notification in due time is an administrative offence in accordance with Section 97 sub-section 2 number 7 AMG. The specific, actual date of cessation of marketing should be known at the time the notification is made.

In the case of a notification of cessation that is made more than 1 year in advance or with an end of shelf life that is more than 10 years in advance you are kindly requested to submit the notification of cessation at a later date. In case of notifications less than 2 months prior to cessation of marketing you are requested to review the correctness of the information on cessation and to confirm this by clicking on "OK". It is conceivable that this notification will be examined by the competent higher federal authority for the presence of an administrative offence.

Should a notification of cessation outside these time limits become necessary in order to reverse an already completed notification of cessation of marketing, this can be done in the list of notifications via the function "contrary notification" (cf. Chapter 3.5 Screenshot 19).

- The "Date of expiry of the batch last placed on the market" must not be before the "Date of cessation of marketing".
- If the SSC status of the medicinal product is "not marketed" ("abgemeldet"), no new notification of cessation can be made.
- If the SSC status of a medicinal product is "marketed" ("angemeldet"), the "Date of cessation of marketing" must be later than the effective date of the notification of marketing.
- If a (prospective) notification of marketing has already been announced for a medicinal product, no further prospective notification of cessation of marketing is possible.
3.3 The SSC Status Report

The new "SSC status report" can be activated via the selection menu (cf. Screenshot 10). Here you can find information on the SSC status and if applicable the remaining term of your currently effective portfolio of medicinal products (cf. Screenshot 15).

Please bear in mind that, for technical reasons, the notifications of that same day will not yet be considered in the status report.

The report is structured in ascending order of SSC end. You can also sort the table according to other criteria by clicking on the column headings. It is also possible to limit the report with the help of filters; e.g. the list can be narrowed down to those medicinal products the marketing authorisation of which will expire within a specified period of time in accordance with Section 31 sub-section 1 number 1 AMG (SSC). More information on these filter functions can be found in Chapter 3.6.

Screenshot 15: SSC status report
If you click on the "INFO" button in the penultimate column you will see the current sunset clause information from the AMIS database for the ENR concerned (cf. Screenshot 16). Due to technical reasons the information is only provided in German and the notifications made that same day will not be considered until the next day.

<table>
<thead>
<tr>
<th>Eingangsnummer</th>
<th>Arzneimittelname</th>
<th>Satzart</th>
<th>Bescheidet Zu.:</th>
<th>Zul.-Zulassung nach §21/25 AMG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ZUL</td>
<td>19.02.2008</td>
<td>25.02.2008</td>
<td></td>
</tr>
<tr>
<td></td>
<td>POS:VLG</td>
<td>19.02.2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P31(3)A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Verkehrsfähig:</td>
<td>J</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>erstmalig im Verkehr gebracht am:</td>
<td>15.08.2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antragsdatum der Erstanmeldung:</td>
<td>26.08.2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SSC-in Verkehr:</td>
<td>J</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SSC-Abmeldung:</td>
<td>01.12.2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SSC-Ende:</td>
<td>31.07.2015</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The notification with the serial number 0001 is set by default - cf. Chapter 1.3

Screenshot 16: SSC information from AMIS

Clicking on the button for the list of notifications in the last column filters the list according to the ENR in question and displays the valid notifications (cf. Chapter 3.5).

The report can be printed via "Print View" and is available for download via "Data Export" as a temporary CSV file.
3.4 Report: Expiries due to SSC

A further option of the selection menu (cf. Screenshot 10) is the new report "expiries due to SSC". This option displays all medicinal products with the currently effective PNR allocation, the marketing authorisation/registration of which has expired due to the SSC (cf. Screenshot 17). As with the "SSC status report" it is possible to access the SSC information from the AMIS database for the ENR concerned via the corresponding buttons or to switch to the list of notifications.

Please bear in mind that, for technical reasons, the expiries of that same day will not yet be considered in the report.

Screenshot 17: Report: Expiries due to SSC

As described in Chapter 3.3, the current sunset clause information from the AMIS database for the medicinal product concerned appears after clicking on the "INFO" button.

You can access the list of notifications by clicking on the corresponding button.

The report can be printed via "Print View" and is available for download via "Data Export" as a temporary CSV file.
3.5 Summary of All Notifications Submitted

The selection menu (Screenshot 10) shows a list of all the notifications made. This summary has been improved so that it now includes all notifications of all ENRs with a currently valid PNR allocation. Thus, notifications of previous applicants are also listed; notifications regarding ENRs that have already been sold are no longer shown.

If shown "in packets", groups of 20 ENRs are listed; the "complete list" displays all notifications. We recommend choosing the option "in packets" if very many notifications have been made since compilation of the "complete list" can take several minutes depending on the number of notifications. All ENRs can be searched for regardless of whether "in packets" or "complete list" was selected (cf. Chapter 3.6). The table can be sorted by clicking on the column headings (Screenshot 18).

The ENRs are listed separately regardless of whether submitted as individual notifications or groupings of similar notifications.

Screenshot 18: Summary: all notifications submitted
Among others, the list of notifications shows the status of the notification. Due to technical reasons the status of the notification is currently only displayed in German.

Possible status of a notification:

valid notifications ("gültig"):
- "korrigierbar" (amendable): complete and correct notifications <= 28 days
- "abgeschlossen" (completed): complete and correct notifications > 28 days

invalid notifications: ("ungültig")
- "historisch" (historical): after correction, amendable notifications are given the status "historisch", the amended notification is listed again
- "unwirksam" (cancelled): notifications with the status "korrigierbar" are changed to "unwirksam" after their deletion
- "fehlerhaft" (incorrect): incomplete or incorrect notifications

While in the status "korrigierbar" (amendable), the MAH can still change the following:

- date of notification of marketing/cessation of marketing
- shelf life

IMPORTANT NOTE: After 28 days, the status is automatically changed to "abgeschlossen" (completed). This 28 day period is not affected by any amendments.

In order to be able to change a notification you have to click on the respective notification number (cf. Screenshot 18). This opens the form where the a.m. amendments can be made. After having made these amendments it is absolutely necessary to transmit the data as the changes can only be implemented if this has been done.

If an amendable notification is changed incorrectly and this error is not resolved during the session, the original amendable notification remains valid. From now on, incorrect notifications are no longer transmitted to the sunset clause database. Therefore, the status "fehlerhaft" (incorrect) is no longer applicable for new notifications.

The MAH can delete notifications with the status "korrigierbar" (amendable) by clicking on the garbage can symbol. These notifications are switched to the status "unwirksam" (cancelled). Such "cancelled" notifications are not subject to fees.

You can no longer delete or correct notifications with the status "abgeschlossen" (completed). However, incorrect but already completed notifications can be reversed via the function "contrary notification" in the list of notifications. A contrary notification is generated by clicking the corresponding symbol (cf. Screenshot 18). This means that a notification of cessation of marketing is converted to a notification of marketing and vice versa. The form generated cannot be edited (cf. Screenshot 19).

Contrary notifications are immediately switched to the status "abgeschlossen" (completed) and are not subject to fees.
IMPORTANT NOTE: If a (correct) current notification has been made but you still wish to correct or amend the data of a previous already completed notification, please contact the administrator directly by e-mail (sunset-clause@bfarm.de).

If the list of notifications contains notifications that were not made by the current marketing authorisation holder, the PNR of the MAH who originally submitted the notification is listed in the column "Initial PNR".

If the notification was made by the current marketing authorisation holder, this field remains empty.
As described in Chapter 3.3, the current sunset clause information from the AMIS database for the medicinal product concerned appears after clicking on the "INFO" button.

You can access the SSC status report by clicking on the corresponding button (cf. Screenshot 18).

The overview can be printed via "Print View" and is available for download via "Data Export" as a temporary CSV file.
3.6 Filter Functions in "List of Notifications" and Reports

For a better overview it is possible to use filters to limit the information in the "Summary of all notifications" as well as in the reports. The available filters are described in the information field (Screenshot 20). Filters can be placed concurrently in several columns allowing a very individual query. Filters are activated by clicking on the arrow buttons beneath the column caption and selecting the appropriate filter.

Subsequently, the cells below the selected filters are filled in. This can either be done by entering a free text, by "dragging and dropping" a displayed content into the appropriate field, or by making a selection from the drop-down list.
Clicking on the field "update list" reduces the list of notifications to those notifications that meet the specifications of the filters selected (Screenshot 22).

By clicking on "Reset filters" and "Update List" you can access all notifications again.
Screenshot 23 gives an example of how you can limit your medicinal products within the competence of the BfArM to those scheduled to expire in 2015 based on the sunset clause.

Screenshot 23: SSC status report with filters

Screenshot 24 gives an example of how you can limit the notifications to those made by the previous applicant ("> 0") or by the current marketing authorisation holder ("< 0").

Screenshot 24: List of notifications with filters
4. Sunset Clause Customer Service

You can access the sunset clause customer service by clicking on "Private". Here you can review your personal information (Screenshot 26) and change it if necessary. If you have forgotten your password, you can request a so-called one-time password here (Screenshot 25); click on "forgot password" to do so. Then you will be asked the previously specified security question. If this is answered correctly, the one-time password with which you can log into the sunset clause customer service and specify a new password will be sent to the e-mail address provided in the user settings.

Screenshot 25: Sunset clause customer service

You can update your data by clicking on "Change Data" (cf. Screenshot 3). Please bear in mind that whenever saving changes it is always necessary to enter and confirm the correct password.

Screenshot 26: Example for personal data in the sunset clause customer service
5. Contact
Should you have questions or issues that are not covered by these Explanatory Notes please e-mail us at sunset-clause@bfarm.de. You are also invited to send suggestions or comments to this address. Please also consult the FAQs regarding the sunset clause notification procedure published on the BfArM homepage.

6. Summary of Changes

6.1 Major Changes in Version 1.1 of 20 November 2005:
- Updated screenshots
- Inclusion of service page (cf. Chapter 1.5)
- Update of the procedure for changing the password and inclusion of display of personal data (cf. Chapter 4)

6.2 Major Changes in Version 2.0 of 9 April 2006:
- Extension to include veterinary medicinal products (responsibility: BVL)
- Inclusion of the function "in packets" for making notifications
- Filter function in the summary of all notifications made
- Updated screenshots

6.3 Major Changes in Version 3.0 of 10 January 2012:
- Cross-authority submission of notifications is possible
- Changes in status versions
- Restriction of notification possibilities
- Improved list of notifications
- New reports: "SSC status report" + "Report: expiries due to SSC"
- Linking of report and list of notifications as well as link to SSC information in AMIS
- Printing functions and data export
- Updated screenshots

6.4 Major Changes in Version 4.0 of 28 October 2013:
- Extension of the form: "Notification of cessation of marketing of a medicinal product" based on Section 29 sub-section 1g AMG. This change only concerns medicinal products for use in humans.