

***Guide for sending information on the intend of marketing***



Version 3,0



MINISTERIO  
DE SANIDAD, CONSUMO  
Y BIENESTAR SOCIAL

 agencia española de  
medicamentos y  
productos sanitarios

 Sede  
Electrónica

Only those people holding key numbers for the **RAEVET II** application may access the application. Those users who did not hold a user key beforehand must apply for one to the Spanish Agency of Medicines and Medical Devices (AEMPS) in accordance with the procedure established in the virtual office.

<https://sinaem.agemed.es/WebComercializacion/login.aspx?opc=veterinaria>

The application is accessed from the screen shown in the figure. Both the 8 digits and the letter of the user's should be keyed into the user field for those having DNI (National Identity Document).



The screenshot shows the login interface for the RAEVET II application. At the top, there is a header with the Spanish Government logo (GOBIERNO DE ESPAÑA) and the Ministry of Health, Consumption and Social Welfare (MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL). The main title is "COMERCIALIZACION DE MEDICAMENTOS" with "RAEVET" and "Medicamentos de Uso Veterinario" below it. The logo of the Spanish Agency of Medicines and Medical Devices (AEMPS) is also present. Below the header, there is a note: "\*Manual (se recomienda leer el manual antes de usar la aplicación)". The login form is titled "Iniciar sesión" and contains two input fields: "Usuario:" and "Contraseña:". Below the fields is a button labeled "Inicio de sesión". At the bottom of the page, there are two bullet points: "• Únicamente podrán tener acceso a la aplicación aquellas personas que posean claves para la aplicación." and "• Para gestionar el acceso a esta aplicación acceda desde el siguiente enlace: [Gestión de usuarios](#)".

The application offers four different options to submit information to the AEMPS

- 1) Actualizar la información sobre formatos actualmente en el mercado
- 2) Intención anual de comercialización de medicamentos
- 3) Puesta en el mercado del primer lote
- 4) Imágenes del medicamento

The option 1 have to be updated every time the marketing situation changes. This situation (marketing, suspension or withdrawn) have to be identical to such declared in the annual declaration of intend of marketing (option 2)\*.

In order to use this application disable the block on pop-ups in your browser.

**\*WARNING!!!!!!**

The option 1 feeds the database CIMAVET. The applicant must update the option 1 after doing the intend of marketing: or from January 1st of the year for which is declared or, in any case, every format/presentations updating during the year.

Application for submitting information on commercialization of  
Veterinary Medicinal Products

**OPTION 1: UPDATING INFORMATION ON FORMATS CURRENTLY IN  
THE MARKET.**

## Marketing Authorization Holder (MAH) information

On the next screen the user may choose the MAH for which he/she is going to send information. The name of the MAH appears on a drop-down menu. If the user has permission with regard to more than one MAH, he/she may choose which one he/she is going to work with.

**ACTUALIZACION DE INFORMACION SOBRE FORMATOS ACTUALMENTE EN EL MERCADO**

	DETALLE LABORATORIO	LABORATORIO	
Dirección	<input type="text" value="Mataro, 28"/>	<input type="text" value="RECKITT BENCKISER HEALTHCARE S.A."/>	<input type="button" value="Buscar"/>
Código Postal	<input type="text" value="08403"/>	<input type="text" value="SSL INTERNACIONAL PLC"/>	
Localidad	<input type="text" value="Granollers (Barcelona)"/>	<input type="text" value="RECKITT BENCKISER DEUTSCHLAND GMBH"/>	
País	<input type="text" value="España"/>	<input type="text" value="BÚSQUEDA POR MEDICAMENTO"/>	
<input checked="" type="checkbox"/> <b>INFORMACION REVISADA. MARQUE ESTA CASILLA PARA REALIZAR LA INTENCIÓN ANUAL DE COMERCIALIZACIÓN !!</b>			

Once a MAH has been selected, click on “Buscar” (search).



## Option I: Updating information on formats currently in the market

**Marketed Formats:** Every MAH will see only its own veterinary medicinal products (VMPs) but not those for which it is merely the local representative when another company is the MAH.

Nº REGISTRO	COD. NACIONAL	SITUACIÓN	MEDICAMENTO	F. AUTORIZACIÓN	COMERCIALIZADO	NO COMERCIALIZADO
1869 ESP	571338	AUTORIZADO	CARPRODYL 20 MG COMPRIMIDOS PARA PERROS CAJA CON 20 COMPRIMIDOS ( 2 BLISTER)	14/04/2008	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1869 ESP	571339	AUTORIZADO	CARPRODYL 20 MG COMPRIMIDOS PARA PERROS CAJA CON 100 COMPRIMIDOS (10 BLISTER)	14/04/2008	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1869 ESP	571340	AUTORIZADO	CARPRODYL 20 MG COMPRIMIDOS PARA PERROS CAJA CON 200 COMPRIMIDOS (20 BLISTER)	14/04/2008	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1869 ESP	571341	AUTORIZADO	CARPRODYL 20 MG COMPRIMIDOS PARA PERROS CAJA CON 500 COMPRIMIDOS (50 BLISTER)	14/04/2008	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1870 ESP	572058	SUSPENSION POR NO DECLARAR INTENCION	CARPRODYL 50 MG COMPRIMIDOS PARA PERROS CAJA CON 20 COMPRIMIDOS (4 BLISTER)	14/04/2008	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1870 ESP	572059	SUSPENSION POR NO DECLARAR INTENCION	CARPRODYL 50 MG COMPRIMIDOS PARA PERROS CAJA CON 100 COMPRIMIDOS (20 BLISTER)	14/04/2008	<input checked="" type="checkbox"/>	<input type="checkbox"/>
1870 ESP	572060	SUSPENSION POR NO DECLARAR INTENCION	CARPRODYL 50 MG COMPRIMIDOS PARA PERROS CAJA CON 200 COMPRIMIDOS (40 BLISTER)	14/04/2008	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Marcar todos Marcar todos  
Desmarcar todos Desmarcar todos

1 2

Enviar AEM

- In order to show whether a format **is currently being commercialised** or **not**, please tick the corresponding box on the right side of the form (“Comercializado” “No comercializado”).
- Display all authorized formats by using the page numbers at the end of the form.
- Once you have ticked all the formats marketed, please press “Enviar a AEMPS” (Send to AEMPS). **If you do it wrong, please correct it and resubmit.**

Application for submitting information on commercialization of  
Veterinary Medicinal Products

**OPTION 2 : ANNUAL DECLARATION OF INTEND OF MARKETING OF  
VMPS.**

**Option 2: Annual declaration of intend of marketing ofVMPs**

Select the year in which you intend to market.

**REALIZAR INTENCION DE COMERCIALIZACIÓN:**  
Seleccione año de intención

201X Realizar Intención

There is also possibility to check last intentions.

**CONSULTA DE INTENCIONES DE COMERCIALIZACIÓN:**  
Seleccione el año en el que realizó la comunicación

Consultar

In order to be able to make the annual declaration of intend of marketing of VMPs, it is necessary to have previously updated the information on formats currently on the market **(option 1)**.



**Option 2: Annual declaration of intend of marketing ofVMPs**

## Marketing Authorization Holder (MAH) information

On the next screen the user may choose the MAH for which he/she is going to send information. The name of the MAH appears on a drop-down menu. If the user has permission with regard to more than one MAH, he/she may choose which one he/she is going to work with.

**INTENCION ANUAL DE COMERCIALIZACION**

	DETALLE LABORATORIO	LABORATORIO
Dirección	<input type="text" value="RUA DA QUINTA DO PINHEIRO, 5"/>	<input type="text" value="BAYER PORTUGAL S.A."/> <input type="button" value="▼"/> <input type="button" value="Buscar"/>
Código Postal	<input type="text" value="2794-03"/>	
Localidad	<input type="text" value="CARNAXIDE"/>	BÚSQUEDA POR MEDICAMENTO
País	<input type="text" value="Portugal"/>	<input type="text"/>

Once a MAH has been selected, click on “Buscar” (search).

**Option 2: Annual declaration of intend of marketing of VMPs**

Those medicines and formats which the MAH owns will appear

Nº REGISTRO	COD. NACIONAL	FORMATO	SITUACIÓN	F. AUTORIZACIÓN	CANTIDADES COMERCIALIZADAS 2017	(*)	(**)	DETALLE TASAS
2633 ESP	580158	TSEFALEN 500 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTON CON 12 COMPRIMIDOS (1 BLISTER)	AUTORIZADO	17/09/2012	0	<input type="checkbox"/>	<input type="checkbox"/>	
	580159	TSEFALEN 500 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTON CON 108 COMPRIMIDOS (9 BLISTER)	AUTORIZADO	17/09/2012	2837	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	581777	TSEFALEN 500 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTON CON 36 COMPRIMIDOS (3 BLISTER)	AUTORIZADO	17/09/2012	0	<input type="checkbox"/>	<input type="checkbox"/>	
2634 ESP	580160	TSEFALEN 1000 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTÓN CON 8 COMPRIMIDOS (1 BLISTER)	AUTORIZADO	17/09/2012	0	<input type="checkbox"/>	<input type="checkbox"/>	
	580161	TSEFALEN 1000 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTÓN CON 104 COMPRIMIDOS (13 BLISTER)	AUTORIZADO	17/09/2012	2112	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	581778	TSEFALEN 1000 MG COMPRIMIDOS RECUBIERTOS CON PELICULA PARA PERROS, CAJA DE CARTÓN CON 32 COMPRIMIDOS (4 BLISTER)	AUTORIZADO	17/09/2012	0	<input type="checkbox"/>	<input type="checkbox"/>	

- In order to state your intend of marketing of a format, please tick the box (\*)
- In order to apply for the withdrawal of the marketing authorization of the VMP for which you are making the declaration, please choose the (\*\*) box. . If you don't have intend to put in the market the VMP during the next year do not tick any option.
- You can save the information as many times as you want by pressing "Guardar" (**Save**) and accessing the application again later and modifying or ticking new boxes. **Warning!** Once **you have pressed "Enviar AEM" (Send to AEMPS)** you will no longer be able to change the information. Please contact [edossier@aemps.es](mailto:edossier@aemps.es) to correct it.

**Option 2: Annual declaration of intend of marketing ofVMPs**

An electronic slip will then appear including the amount you must pay depending on the VMPs notified. You should PRINT this.

COMERCIALIZACION DE MEDICAMENTOS

agencia española de medicamentos y productos sanitarios

<< Volver

DETALLE DEL ENVIO - PAGO DE TASAS

Cerrar sesión

Cumplimente los datos relativos al pago de tasas.

Nº Justificante:  Fecha Pago:

Guardar

Eliminar Selección

Actualizar de fichero del envío

Adjuntar

Agregar pago complementario:

Seleccione la vía de pago de tasas que ha seguido:

Pago Envío-Telemático

Pago Presencial - Transferencia Bancaria

IDº Envío: 10915

ADJUNTE EL FICHERO JUSTIFICANTE de pago de tasas sellado por su banco.

\* El fichero debe tener un tamaño (Máx. 10MB, .pdf ó .doc).

Examinar...

Adjuntar

Actualice la información del pago de tasas asociado a este envío pasado 24h para que se concilie correctamente con su banco.

\* Para realizar el pago telemático de tasas y/o descargar el 317 es necesario seguir el siguiente enlace:

Ir a Tasas

The information on the chosen mode of payment of charges must be filled in. The application allows this information to be completed at any time. In the case of payments made on the spot or from abroad (international transfer) the bank transfer slip must be attached. In the case of teleprocessed payments, the links should be followed.

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**OPTION 3 : PLACING THE FIRST BATCH ON THE MARKET**

**Option 3 : Placing the first batch on the market**

On the next screen the user may choose the MAH for which he/she is going to send information. The name of the MAH appears on a drop-down menu. If the user has permission with regard to more than one MAH, he/she may choose which one he/she is going to work with.

**COMUNICACION PUESTA EN MERCADO 1º LOTE**

<b>DETALLE LABORATORIO</b>	<b>LABORATORIO</b>
<input type="text" value="2, 3 &amp; 4 Airton Close, Tallaght"/>	<input style="background-color: #0070C0; color: white; border: 1px solid #0070C0;" type="text" value="BIMEDA ANIMAL HEALTH LIMITED"/>
<input type="text"/>	
<input type="text" value="Dublin 24"/>	<b>BÚSQUEDA POR MEDICAMENTO</b>
<input type="text" value="Irlanda"/>	<input type="text"/>

Once a MAH has been selected, please click on “Buscar” (**Search**).




## Option 3 : Placing the first batch on the market

All VMPs authorized after entry into force of the Royal Decree 1246/2008, of July 18th, will be shown.

Nº REGISTRO	MEDICAMENTO	SITUACIÓN	F. SITUACIÓN REG.	F. COMERCIALIZACIÓN
80501	10 MG/0,4ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80502	12,5 MG/0,31 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80503	15 MG/0,38 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80504	17,5 MG/0,44 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80505	2,5 MG/0,33 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80506	20 MG/0,5 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>
80507	22,5 MG/0,56 ML SOLUCION INYECTABLE EN JERINGA PRECARGADA	AUTORIZADO	22/12/2015	<a href="#">Seleccionar</a>

1 2

Fecha de liberación del 1º lote:  

Complete the release date for the first batch and click on “Grabar fecha” (record date). Once a date has been recorded click on “Seleccionar” (select) again to modify it. You can apply to AEMPS for the dates to be updated but the change will not be made automatically. The application will be validated beforehand.

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**OPTION 4 : PICTURES OF THE VMPs**

## Marketing Authorization Holder (MAH) information

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The screenshot shows a web form titled "IMAGENES DEL MEDICAMENTO". At the top left is a link "<< Volver" and at the top right is "Cerrar sesión". The form is divided into two main sections: "DETALLE LABORATORIO" and "LABORATORIO".

DETALLE LABORATORIO		LABORATORIO
Dirección	<input type="text" value="10 Great North Way, York Business Park, Nether Poppleton"/>	<input type="text" value="ANIMALCARE LTD."/> <input type="button" value="Buscar"/>
Código Postal	<input type="text" value="YO26 6RB"/>	
Localidad	<input type="text" value="York"/>	BÚSQUEDA POR MEDICAMENTO
País	<input type="text" value="Reino Unido"/>	<input type="text"/>

Once a MAH has been selected, click on “Buscar” (Search)

**Option 4: Pictures of the VMP**

Only the VMPs of the MAH appears on a drop-down menu. The VMP whose image will be charged must be chosen from the option “Seleccionar” :

Nº REGISTRO	MEDICAMENTO	SITUACIÓN	F. SITUACIÓN REG.	IMAGEN I	IMAGEN II	VB. AEMPS
1866 ESP	BENZAECARE SABOR 20 mg COMPRIMIDOS PARA PERROS	AUTORIZADO	02/04/2008			Seleccionar
1865 ESP	BENZAECARE SABOR 5 mg COMPRIMIDOS PARA PERROS Y GATOS	AUTORIZADO	02/04/2008			Seleccionar
1892 ESP	BUPREARE 0,3 mg/ml SOLUCION INYECTABLE PARA PERROS Y GATOS	SUSPENSION POR NO DECLARAR INTENCION	30/01/2018			Seleccionar
2431 ESP	BUPREARE MULTIDOSIS 0,3 mg/ml SOLUCION INYECTABLE PARA PERROS Y GATOS	AUTORIZADO	23/04/2012			Seleccionar
3519 ESP	CEPHACARE SABOR 1000 mg COMPRIMIDOS PARA PERROS	SUSPENSION POR FALTA DE MAQUETAS	22/01/2019			Seleccionar
1995 ESP	CEPHACARE SABOR 250 mg COMPRIMIDOS PARA PERROS	AUTORIZADO	04/03/2009			Seleccionar
1994 ESP	CEPHACARE SABOR 50 mg COMPRIMIDOS PARA GATOS Y PERROS	AUTORIZADO	04/03/2009			Seleccionar



**IMAGEN I:** esta columna indica si la imagen del Material de Acondicionamiento esta cargada en el sistema.  
**IMAGEN II:** esta columna indica si la imagen de la Forma Farmaceutica esta cargada en el sistema.  
**VB AEMPS:** esta columna indica si el medicamento ha sido verificado por la AEMPS.

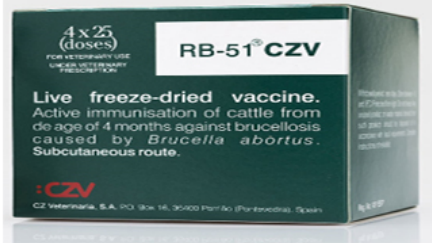
**RESOLUCIONES ADMITIDAS:** 320x180, 640x360, 1024x576 en jpg, png, tiff o gif.

**Option 4 : Pictures of the VMPs**

**ADJUNTE IMAGENES DEL MEDICAMENTO**

**.: Material Acondicionamiento**

Examinar... Actualizar




Live freeze-dried vaccine.  
Active immunisation of cattle from  
de age of 4 months against brucellosis  
caused by *Brucella abortus*.  
Subcutaneous route.

Fecha subida: 23/01/2019 Nombre del fichero: HH\_MAS\_001\_001.jpg

**.: Forma Farmaceutica**

Examinar... Actualizar



Fecha subida: 23/01/2019 Nombre del fichero: HH\_MAS\_001\_001.jpg

Salir

The charge of the image will be completed if you first press on “Examinar” for selecting the image, and then press on “Actualizar”.

Admitted resolutions:

**320x180**

**640x360**

**1024x576**

Admitted formats:

**.jpg**

**.png**

**.tiff**

**.gif**




**Option 4 : Pictures of the VMPs**

Once loaded it will be marked with a green "check", as appropriate, the following:

**Image I** - this column indicates whether the image of the box/label is loaded in the system.

**Image II** - this column indicates whether the image of the Pharmaceutical Form is loaded in the system.



Nº REGISTRO	MEDICAMENTO	SITUACIÓN	F. SITUACIÓN REG.	IMAGEN I	IMAGEN II	VB. AEMPS
1866 ESP	BENAZECARE SABOR 20 mg COMPRIMIDOS PARA PERROS	AUTORIZADO	02/04/2008	✓	✓	Seleccionar

**VB AEMPS:** It appears when AEMPS has verified the images.



Nº REGISTRO	MEDICAMENTO	SITUACIÓN	F. SITUACIÓN REG.	IMAGEN I	IMAGEN II	VB. AEMPS
1866 ESP	BENAZECARE SABOR 20 mg COMPRIMIDOS PARA PERROS	AUTORIZADO	02/04/2008	✓	✓	✓

Once the images have been verified by the AEMPS, they will be visible on the CIMAVET portal.