SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES

PROCEDURE FOR BATCH RELEASE OF BLOOD PRODUCTS ONTO THE SPANISH MARKET

USER MANUAL | VERSION 3.0

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

INDEX

Introduction

Subject

The purpose of this document is to provide a user manual for the electronic procedure for Batch Release of Blood Products onto the market.

In this section, the instructions for the procedure to market blood-derived products, as well as the applicable fees, are detailed:

1.14	Reconocimiento de certificado de liberación de lote y autorización de puesta en el mercado nacional de lote de vacunas o hemoderivados.	84,76 €
1.15	Reconocimiento de certificado de liberación de lote y autorización de puesta en el mercado nacional de lote de vacunas o hemoderivados (entre 6 y 10 liberaciones año).	423,78 €
1.16	Reconocimiento de certificado de liberación de lote y autorización de puesta en el mercado nacional de lote de vacunas o hemoderivados (entre 11 y 40 liberaciones año).	1.271,35 €
1.17	Reconocimiento de certificado de liberación de lote y autorización de puesta en el mercado nacional de lote de vacunas o hemoderivados (entre 41 y 160 liberaciones año).	2.966,47 €
1.18	Reconocimiento de certificado de liberación de lote y autorización de puesta en el mercado nacional de lote de vacunas o hemoderivados (> 160 liberaciones año).	4.237,82 €

The payment, except for case 1.14, is made once a year, choosing the most appropriate option based on the number of annual requests. Requests can be submitted once the corresponding fee has been paid.

For any inquiries related to this procedure, please contact the AEMPS Fees and Refunds Department at the phone number +34 918225534 or via email at tasasydevoluciones@aemps.es.

Instructions for completing the form for market release of blood products for human use

Instruction 1st

Batches of blood-derived products for human use shall not be placed on the market without authorization, according to the following procedure.

Instruction 2nd

This provision does not apply to plasma- derived products used as an excipient or reagent in the production of other medicines or health products. Neither does apply to foreign medicines or products undergoing clinical trials.

Instruction 3rd

Before proceeding with the market placement of the medicine in question, a market batch release request shall be sent to the Division of Biological Products, Advanced Therapies, and Biotechnology (DPB) of the Spanish Agency of Medicines and Medical Devices (AEMPS).

For this purpose, the electronic platform developed by the AEMPS for submitting requests is available and operational. It can be accessed through the Agency's website: https://www.aemps.gob.es.

The address to be connected to is the following: https://hemoyvacunas.aemps.es.

Instruction 4th

The application shall be accompanied by the following documentation:

Annexes from the document "EC Administrative Procedure for Official Control Authority Batch Release". OMCL, Batch Release - Human Biologicals:

- EU official control authority batch release certificate for medicinal products derived from human blood or plasma (Annex IIB).
- EU official control authority batch release certificate of approval for plasma pool (Annex IID).
- Marketing information form, model for manufacturers (Annex IV).
- Declaration of compliance with Note 1/98 of the General Directorate of Pharmacy (Circular 1/98 de la Dirección General de Farmacia), or, alternatively, a document stating the country of origin of the plasma.

Instruction 5th

After a period of 5 working days from sending the last valid documentation without a negative pronouncement, and taking into account the special need for these products, the lot is deemed approved for marketing. The electronic system allows the laboratory making the request to have proof that the request has been made, and the AEMPS to be aware that the communication has been sent.

In the event that there is a computer system crash the applicant will proceed through email (hemoderivados@aemps.es), or an alternative procedure.

Instruction 6th

In the case that the batch of the blood-derived product in question does not have a European Union Batch Release Certificate, before proceeding with the market placement of the medicine, a market batch release request must be sent to the DPB, including a declaration that the batch has not been sent to another Official Medicines Control Laboratory (OMCL) for release. Additionally, it will be accompanied by the following documentation:

- Marketing information form, model for manufacturers (Annex IV).
- The following samples will be sent:
  - 4 containers of 1.5 ml each of the plasma pool which the medicine is derived, to be sent in accordance with the corresponding procedures, or alternatively, an OMCL Certificate for the release of the plasma pool corresponding to the medicine in question.

If within the period of 60 days after shipping there is no communication notifying of the existence of problems in the documentation or samples sent, the release of the lots onto the market can proceed.

Procedure

This section provides an explanation of the instructions for the market release procedure of blood-derived products.

Access to the application

To access the application, open a browser and go to https://hemoyvacunas.aemps.es, where the initial screen will display access to the notification forms for market release and clarifications, for both vaccines and blood-derived medicines.

Figure 1. Initial screen.

Notificación de puesta en mercado de hemoderivados: Access to submit a new application.

Aclaraciones a la puesta en mercado de hemoderivados: Access to add any additional information to an already submitted application, or to add more batches to those indicated in a previously submitted request. The reference application number must be provided to link additional information. Modifications to the number of requested batches are also allowed.

Imprimir justificante: Access to the supporting document in PDF format with the notification data, as well as any associated clarifications already submitted. The reference number associated with the notification is required.

When submitting a new application, the form displaying the different options for adding the fee payment will appear. This is required for the notification procedure.

Figure 2. Access method to the notification form .

If it is the first time accessing the application from the PC/browser, no previously used fees will appear. However, if a notification was previously submitted or a payment process has been completed, the previously used receipt numbers will appear, as they are stored locally in the browser.

For previously used fees, it is possible to:

- Delete a fee if you do not want it to appear again in this form.
- Update the information (receipt status and/or number of notifications submitted).

The information displayed about previously used fee receipts is:

- Receipt number. If the status is valid, it is possible to use it by clicking on it.
- Date the payment was made or receipt status.
- Taxpayer ID (NIF) of the liable party.
- If the status is valid, the submitted notifications will be shown; otherwise, the amount and maximum number of permitted releases will be displayed

If a fee has been paid but it does not appear in the form, please use the “Añadir tasa ya pagada” (Add already paid fee) option, for which you will need to enter the receipt number, the exact amount and the taxpayer ID (NIF) of the liable party.

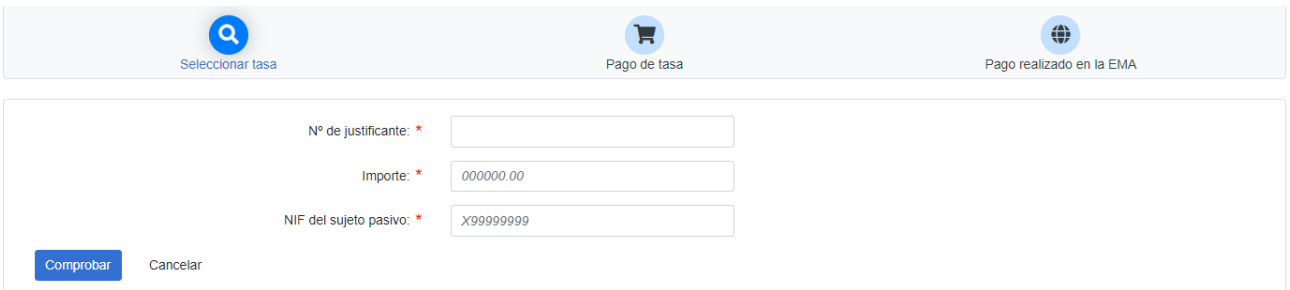

Figure 3. Payment of previous fees.

If you need to make the payment, you must use the “Pago de tasa” (Fee payment) option and complete the following form with the payment details.

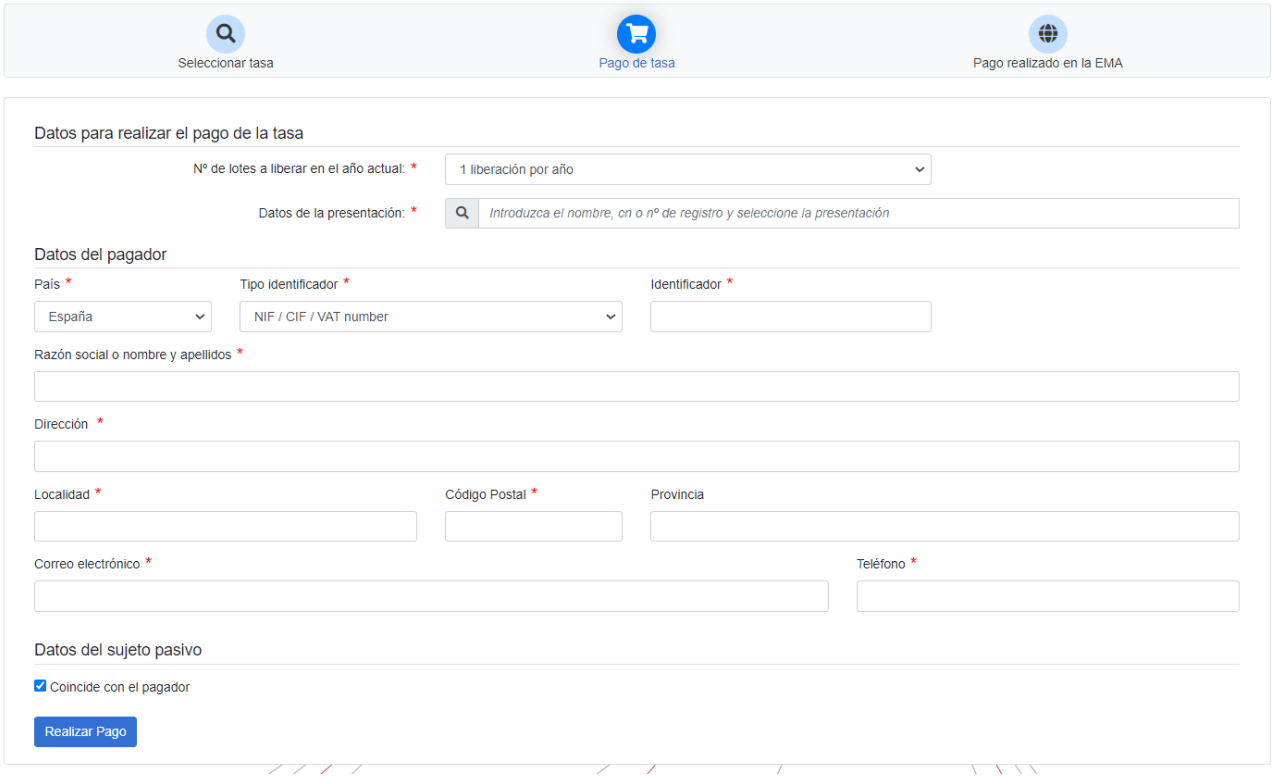

Figure 4. New fee payment.

Once the necessary form data is completed, click the “Realizar pago” (Make payment) option. This will transfer you to the Fee Payment application, where you must complete the payment process using one of the available options.

If the payment is made online using the payment gateway, you will be returned to the form with the “Código Pago de Tasas” (Fee payment code) field already completed, allowing you to proceed directly with the notification.

If you choose the option to pay by bank transfer during the payment process, you will be returned to the fee selection form, and a new receipt will appear with the status “Pendiente de pago” (Pending payment).

Figure 5. Fee payment by bank transfer.

You will not be able to use this payment receipt until the bank confirms that the transfer has been successfully completed. This usually takes 1 business day after the transfer has been initiated.

Batch release form for blood-derived products

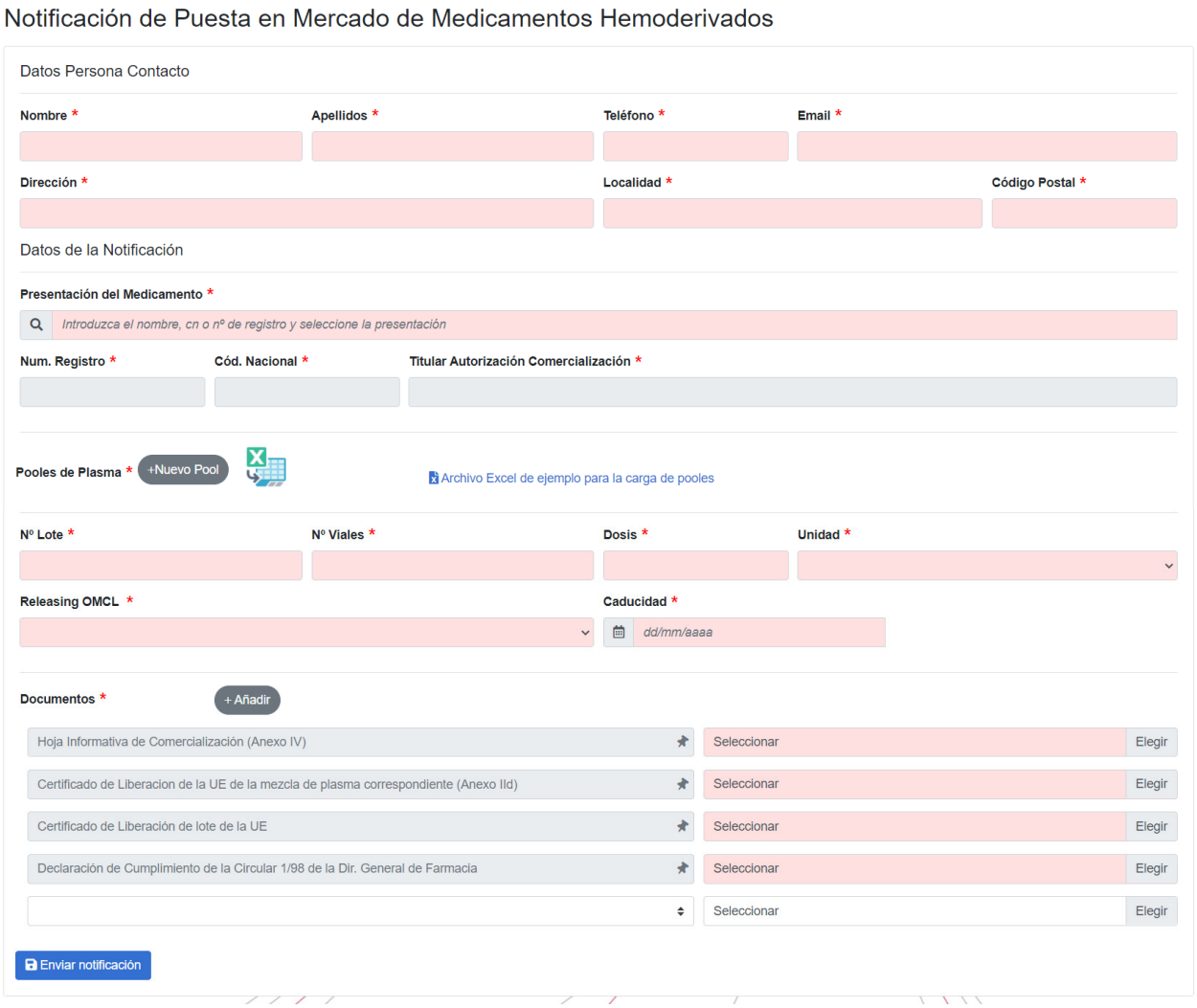

Figure 6. Batch release form for blood-derived products.

Mandatory fields are marked with a red asterisk.

- "Datos de persona de contacto" (Contact person information):
  The applicant company must fill in the contact details of the contact person responsible for the market placement request for blood-derived products. This information, once a notification is completed, is automatically saved in the browser's local storage, so in future visits to the form, the most recently data from that PC and browser will be available.

- "Datos de la notificación" (Notification details):
  - "Medicamento" (Medicine): Enter the name of the medicine, the registration number or the national code. If any of this information is found, a list of presentations matching the entered data will be displayed, and the corresponding row should be selected.

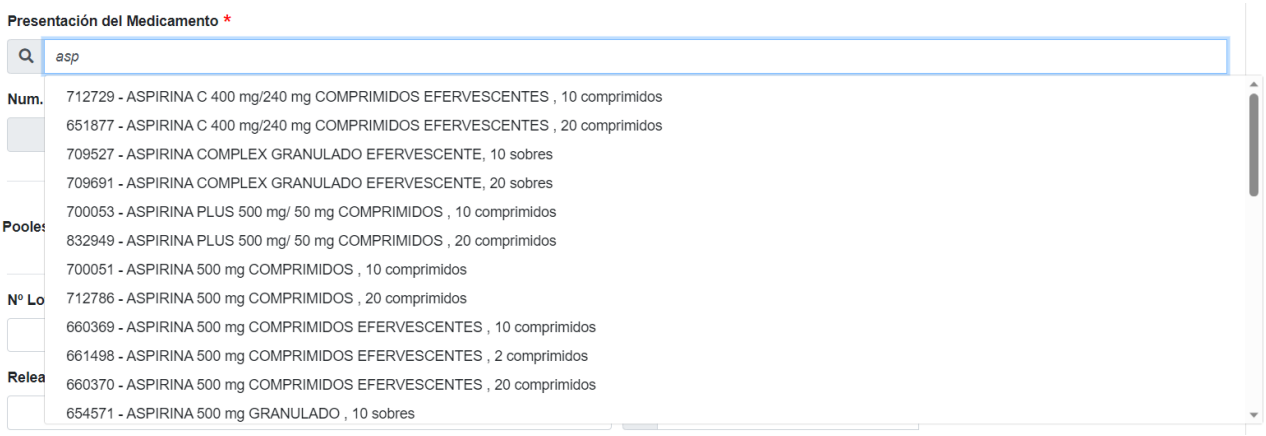

Figure 7a. Medicines search form

When a medicine is selected from the list, the remaining medicine data (registration number, national code, holder, and active substances) will be automatically filled in.

Figure 7b. Medicines search form.

To enter information related to plasma pools, it is possible to do so manually or by using an Excel file containing the encoded information.

Figure 8. Information related to plasma pools.

Other fields related to the product must also be filled in:

- Batch number
- Number of vials.
- Doses.
- Units.
- Expiry date.
- Releasing OMCL.

All necessary documents must be uploaded.

As stated in Instruction 5th, after a period of 5 working days from the submission of the latest valid documentation without any negative response, and considering the special need for these products, the batch will be deemed approved for commercialization..

In the event of issues with the documentation, whether due to errors or incompleteness, the applicant company will receive an email with a “solicitud de aclaraciones” (request for clarifications) document, which will outline the reasons for the request and/or the documents that need to be corrected. The document is automatically generated from the application, and the company receives an automatic email with the following form, indicating the information that needs to be corrected.

COMUNICACIÓN DE DOCUMENTACIÓN INCOMPLETA O ERRONEA

La solicitud indicada en la tabla siguiente debe subsanar el error indicado en la misma.

Nº REFERENCIA DE LA SOLICITUD:	
FECHA ENTRADA:	
NOMBRE DEL MEDICAMENTO:	
LOTE:	
PRINCIPIOS ACTIVOS:	
TITULAR:	
DOCUMENTACIÓN A COMPLETAR o SUBSANAR ERROR	
Hoja Informativa de Comercialización (Anexo IV)	
Certificado de Liberacion de la UE de la mezcla de plasma correspondiente (Anexo IId)	
Certificado de Liberación de lote de la UE	
Declaración de Cumplimiento de la Circular 1/98 de la Dir. General de Farmacia	
Documento acreditativo del pago de la tasa establecida	

Figure 9. Request for clarifications form.

As a result, and until the corresponding issue is corrected through the clarifications process, the product shall not be placed on the market. Once the issue is corrected and the requested documentation is submitted, the established time (5 working days) must be waited, as long as there is no new information regarding issues to be corrected.

Clarifications form

To submit requested information in clarifications or to request an increase in the previously requested number of batches, access the initial page and select “Aclaraciones a la puesta en mercado de hemoderivados”. A form will appear where you will need to enter the notification reference number for which the clarifications are being submitted.

Figure 10. Access to submit clarifications.

After entering the reference number, the associated data will load, and it will be possible to add clarifications and additional documents.

- If it is documentation to be corrected due to an error in the initial request, select “Otros” (Other) option, and the document will appear in the tab that opens.
- If an increase in the number of previously requested batches is required, select the “Ampliación n° de unidades” option. A new Marketing Information Form (annex IV) is required, specifying the additional number of batches that are to be placed on the market as an expansion of the batch.
- In the case that the number of units is less than previously requested, please enter the number of units to be subtracted from the initial request using the negative symbol (-), attaching a new Marketing Information Form (annex IV) with the correct number of units.

From this point onward, the procedure is the same: after a period of 5 business days from the submission of the latest valid documentation without any negative response, and considering the special need for these products, the batch will be deemed approved for commercialization.

Authorization without the 5-day waiting period

Taking into account the potential situations of special need for these products, there is the possibility, upon request by the company providing the reasons, to request the waiver of the 5-day waiting period. This situation must be communicated by attaching a document justifying the need and notifying it via email to the Batch Release mailbox hemoderivados@aemps.es. After reviewing the request, if it is correct and deemed appropriate, the Division of Biological Products, Advanced Therapies, and Biotechnology (DPB) will send the company (positive response) a mail containing the document authorizing the market placement of the batch of the medicine in question, without needing to wait the 5 days established in the procedure.

SOLICITUD DE PUESTA EN MERCADO SIN ESPERAR 5 DÍAS

Examinada la documentación aportada según *SOLICITUD* ***Nº*** _____ les notificamos que, ante las razones de urgencia expuestas por su compañía, y teniendo en cuenta la conformidad de la documentación aportada en la solicitud, se les autoriza a poner en mercado:

NOMBRE DEL MEDICAMENTO:
LOTE:
PRINCIPIO ACTIVO:
SOLICITUD Nº REF / FECHA ENTRADA:
TITULAR:
UNIDADES:
FECHA:

Puesta en Mercado de Hemoderivados y Vacunas

Agencia Española de Medicamentos y Productos Sanitarios
División de Productos Biológicos, Terapias Avanzadas y Biotecnología
Parque Empresarial Las Mercedes,Edif. 8, c/Campezo, 1
28022 Madrid
Tlf.00 34 91 822 58 18
Fax 00 34 91 822 58 92
e-mail: hemoderivados@aemps.es

Figure 11. Authorization form for the request of batch release without the 5-day wait.

PROCEDURE FOR BATCH RELEASE OF BLOOD PRODUCTS ONTO THE SPANISH MARKET

USER MANUAL

SELLO EXCELENCIA
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