SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES

PROCEDURE FOR BATCH RELEASE OF VACCINES 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 vaccines onto the market.

In this section, the instructions for the procedure to market vaccines, 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 vaccines for human use

Instruction 1st

Batches of vaccines 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 other immunological medicines such as toxins, serums and allergens. Individualized vaccines are also excluded. 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

This request 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 oficial control authority batch release certificate for immunological products (Anexo IIA).
- Marketing information form, model for manufactures (Anexo IV).
- Summary of the production and control protocols for the batch to be released, in accordance with the administrative procedure for Official Control Authority Batch Release and the specific product guidelines.
- An image of the packaging material (photo or production mock-up) of the finished product for the batch in question.

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..

Procedure

This section provides an explanation of the instructions for the market release procedure of vaccines.

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..

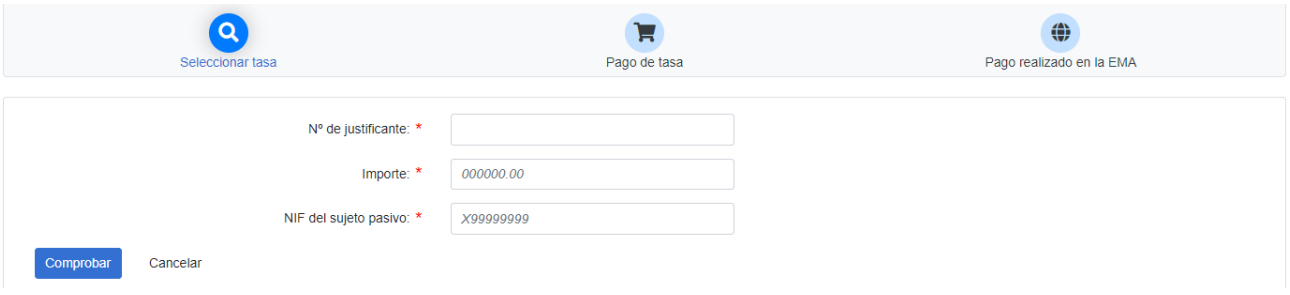

Figure 3. Payment of previous fees.

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.

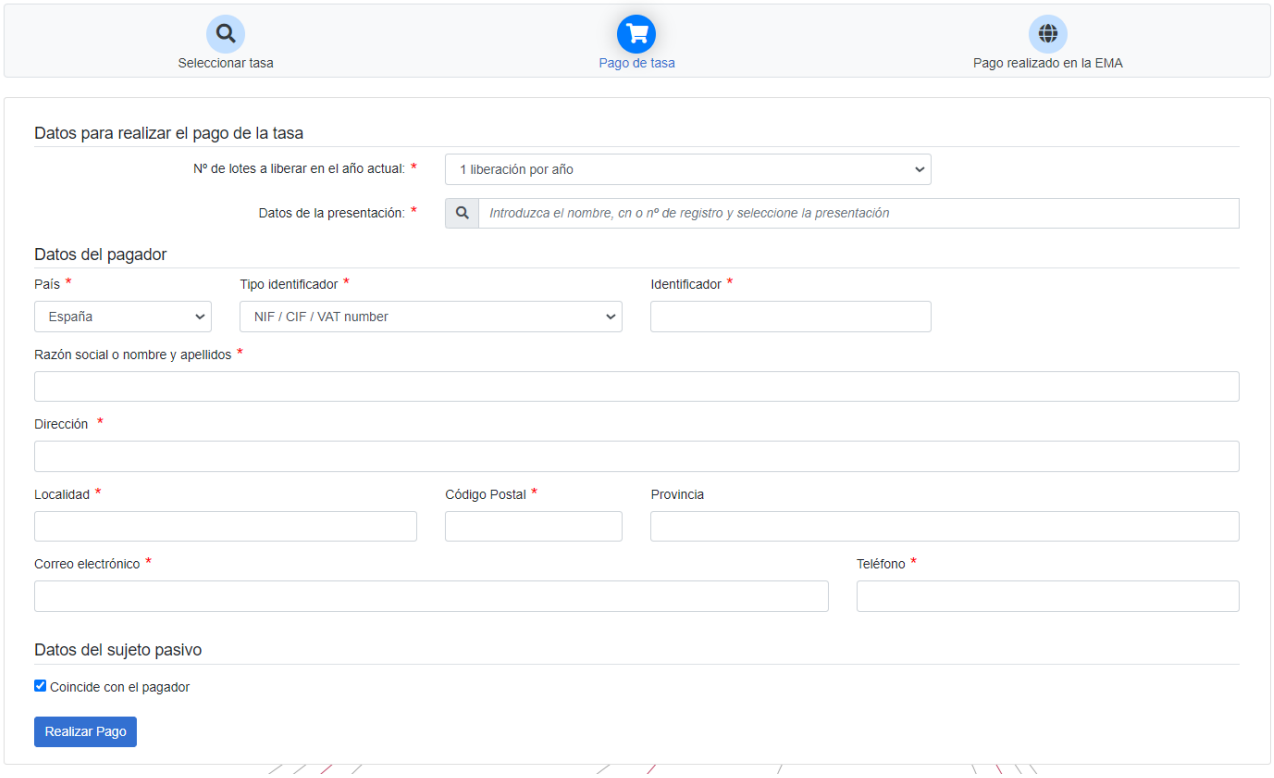

Figure 4. New fee payment.

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 vaccines

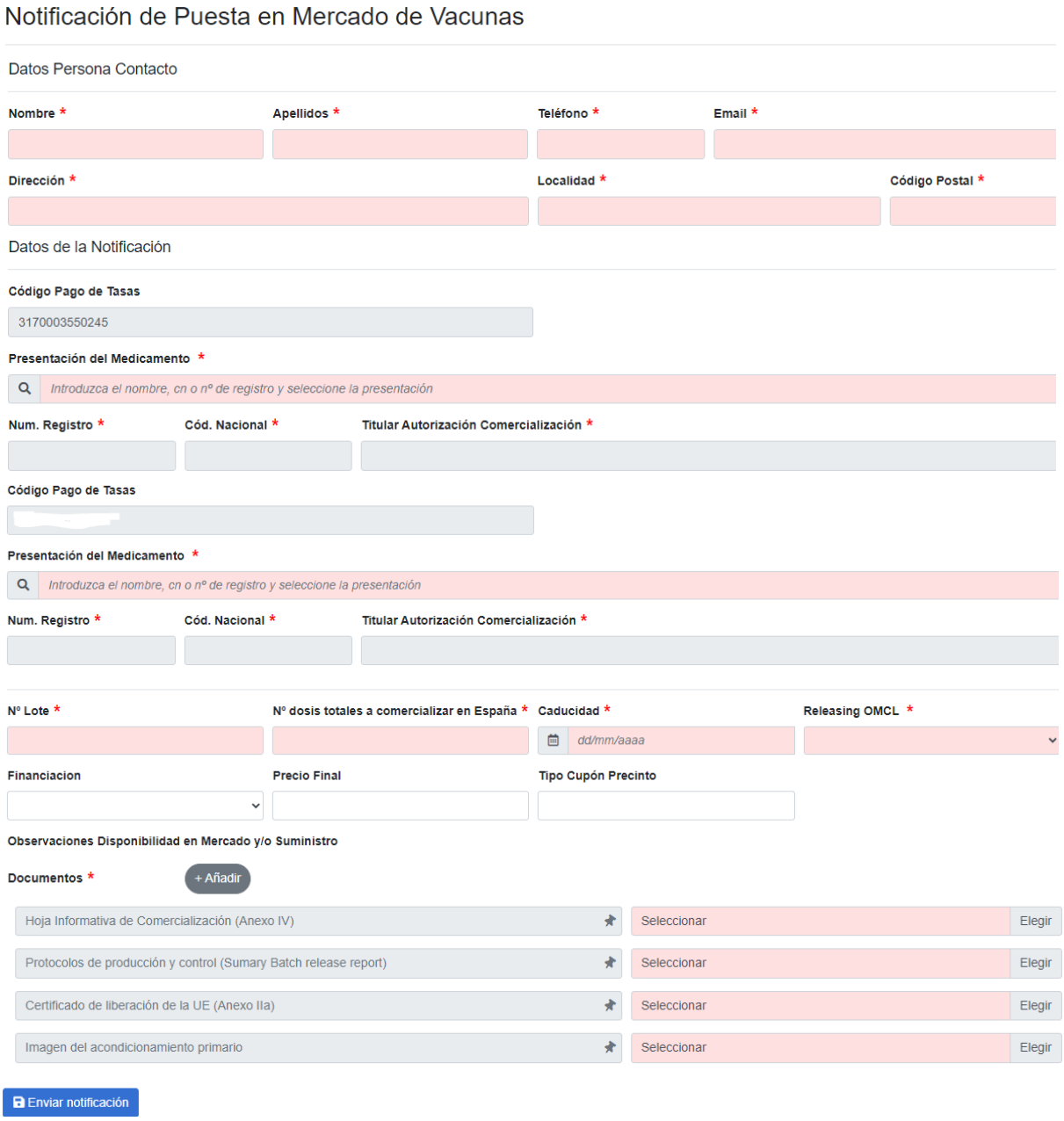

Figure 6. Batch release form for vaccines.

Mandatory fields are marked with a red asterisk.

- "Datos de persona de contacto" (Contact person information):
  The applicant company must fill in the notification 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.

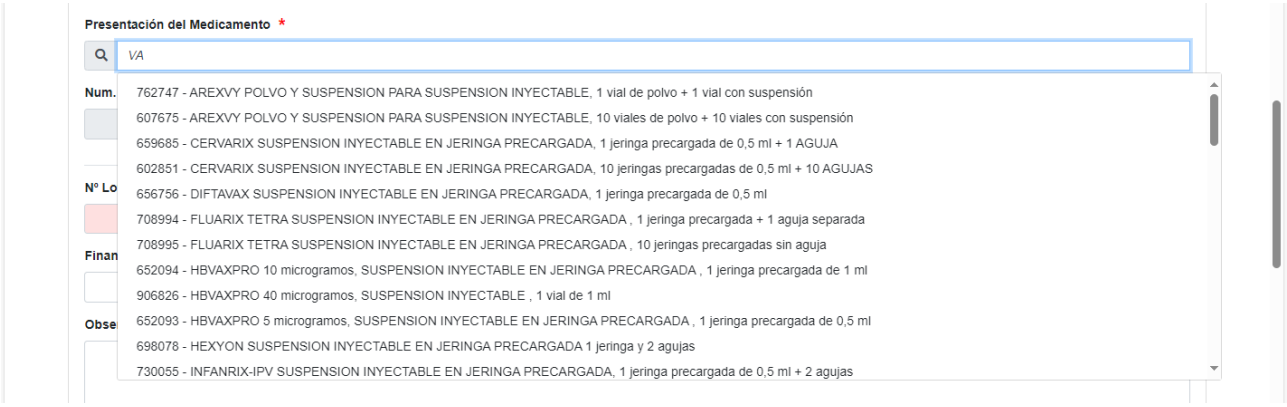

Figure 7. Medicines search form.

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.

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

- Batch number.
- Total number of doses to be marketed in Spain.
- Releasing OMCL.
- Expiry date.

All necessary documents must be attached.

As stated in Instruction 5, 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.

In the case of the seasonal flu vaccines, the waiting period of 5 days shall be reduced to 2 days.

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)	
Protocolos de producción y control (Sumary Batch release report)	
Certificado de liberación de la UE (Anexo IIa)	
Imagen/Maqueta del acondicionamiento del medicamento	

Como consecuencia de ello y hasta que se subsane el defecto correspondiente, a través de Aclaraciones a la solicitud, no se podrá poner en el mercado el producto, y una vez subsanado el mismo, tras el envío de la documentación solicitada, se deberá esperar el tiempo establecido (5 días naturales) siempre que no haya nueva información de defectos a subsanar

Figure 8. 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 business 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 vacunas”. A form will appear where you will need to enter the notification reference number for which the clarifications are being submitted.

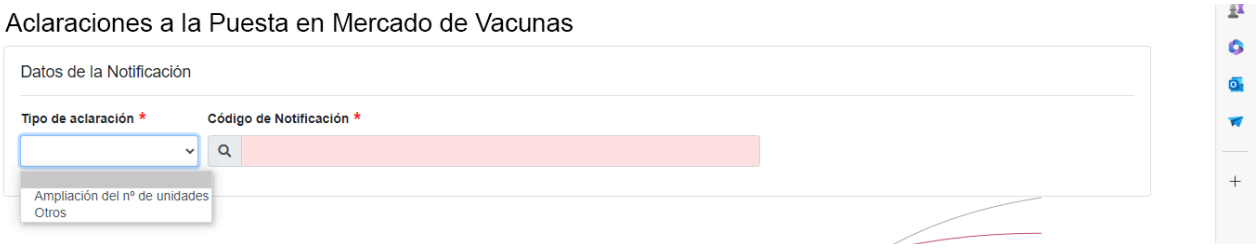

Figure 9. Access to submit clarifications.

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 nº 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.

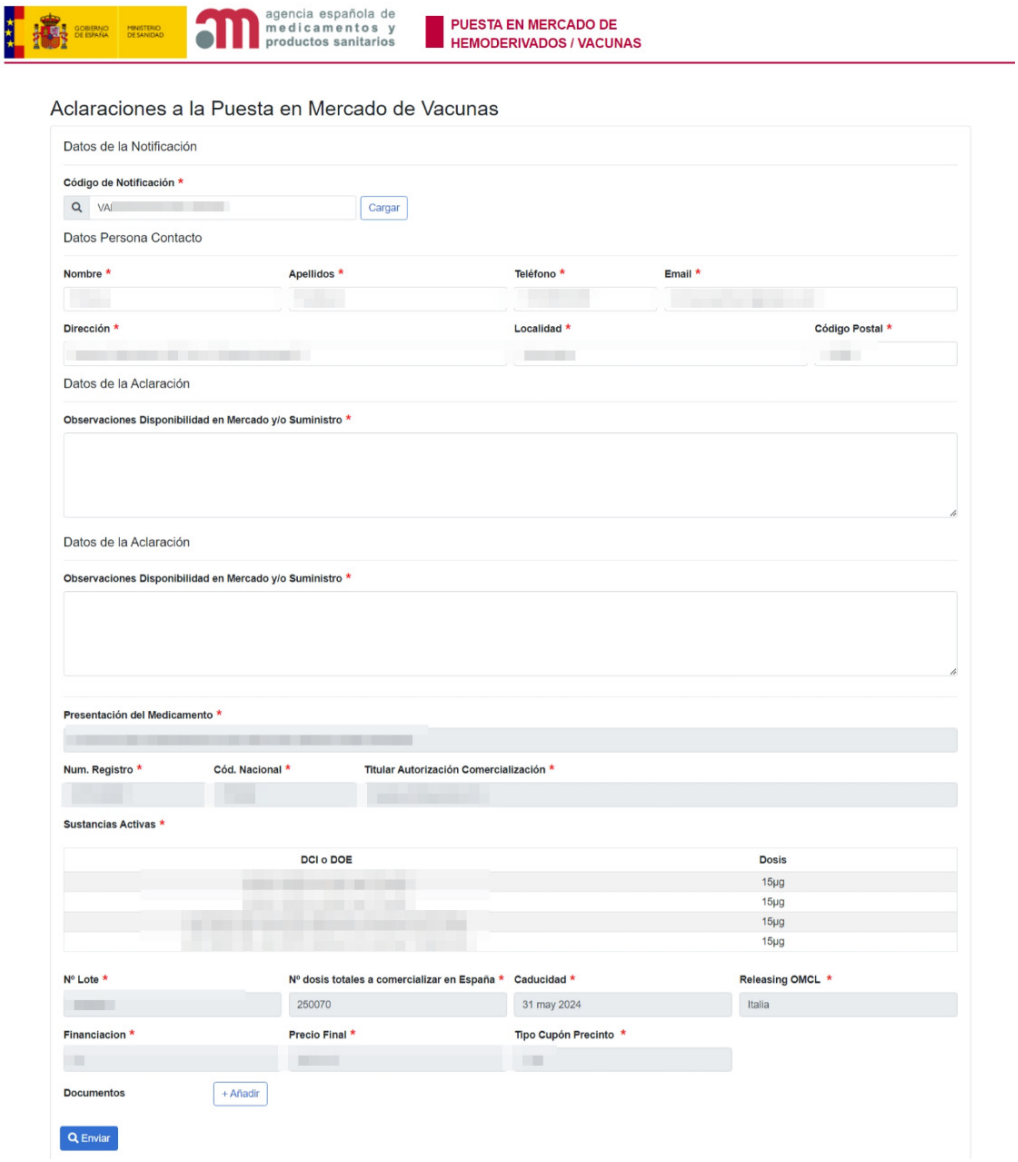

Ilustración 10. Clarifications form for vaccines market release.

From this point onward, the procedure is the same: after a period of 5 business days (2 in the case of seasonal flu vaccines) 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

Ilustración 11. Authorization form for the request of Batch Release without the 5-day wait.

Procedure for parallel distribution applications

The procedure begins when the parallel distributor (pharmaceutical company independent of the marketing-authorization holder) sends a “Solicitud de Puesta en mercado de Hemoderivados/Vacunas” (Request of market relese of blood products/vaccines) via email to the Division of Biological Products, Advanced Therapies, and Biotechnology (DPB), specifying the batch number of the vaccine to be imported and the source OMCL (the OMCL from which the parallel distribution will be taken place). The DPB will contact the vaccines contact person at that OMCL to request a copy of the European Batch Release Certificate (CEUR) for that batch. Once the DPB receives the CEUR, the parallel distributor will be informed of which OMCL issued the CEUR and an application should be submitted using the request form. In the application, the option “Pago realizado en la EMA” (Payment made at EMA) must be selected, so that using the EMA fee payment receipt, it is posible to submit the request without the payment of a Spanish fee.

The following documents must be submitted during the procedure:

- Marketing Information Form, adapted for this purpose (Figure 12).
- An image/mock-up of the packaging material of the finished product for the batch in question. The name and address of the parallel distributor must be visible, indicating that it has been subject to parallel distribution.
- Proof of EMA fee payment and EMA authorization (when it is a medicine authorized by the centralised procedure). The fee payment document is valid for one year from the date of payment.

These documents must be uploaded to the application in the most appropriate manner according to the instructions on each tab. Additionally, the distributing company may be required to provide, along with the request:

- Proof of authorization from AEMPS to perform activities as a parallel distributor.
- Proof of authorization from the marketing authorization holder (authorization from the Inspection and Control Department at AEMPS).

The remainder of the procedure follows the same steps as other notifications, with five days of positive silence and the option for clarifications when applicable.

Marketing Information Form

Notificación de intención de comercializar un lote de un medicamento inmunológico o derivados de sangre o plasma humano, que posee autorización de comercialización, en España, procedente de

Dirigido a	

Nombre Comercial	
Nº lote que aparece en el cartonaje	
Otros nº de lote asociados a este lote	
Nº de envases que se van a comercializar	
Nº Autorización de comercialización	
Nombre y Dirección del Titular de Autorización de comercialización	
Compañía responsable de la Comercialización Paralela	
Fecha de inicio del periodo de validez	
Fecha de Caducidad en el Estado miembro donde va a ser comercializado	
OMCL que emite el Certificados de Liberación de lote	
Fecha prevista de comercialización :	
Nombre y firma de la persona responsible de esta Distribución Paralela:	
Fecha	

Ilustración 12. Marketing information form adapted to parallel distribution.

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USER MANUAL

SELLO EXCELENCIA
300-399
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