

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA

- Universidad Carlos III Madrid
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- Autor: Alberto Gómez Lafón
  - Consejero Técnico de la División de Sistemas Informáticos - AEMPS
  - E-Mail: agomez@agedmed.es

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **ANTECEDENTES**

- Proyecto de Vademecum Mediterráneo
  - Participantes:
    - Italia, España, Francia, Portugal y Grecia
  - Periodo: 1986/7
- Proyecto Ecphin
  - Participantes: Los 15 EE.MM. de la Unión Europea
  - Periodo: 1989 - 1992

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **ANTECEDENTES IDA**

- **IDA (Interchange Data Administration)**
  - Financiación a cargo de la Comisión Europea
  - Desarrollo de Proyectos hasta su fase piloto
  - Creación de la red EUDRANET
  - Evolución TESTA
    - RDSI (ISDN)
    - Frame Relay
  - Alternativas:
    - VPN

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **PRECEDENTES EMEA**

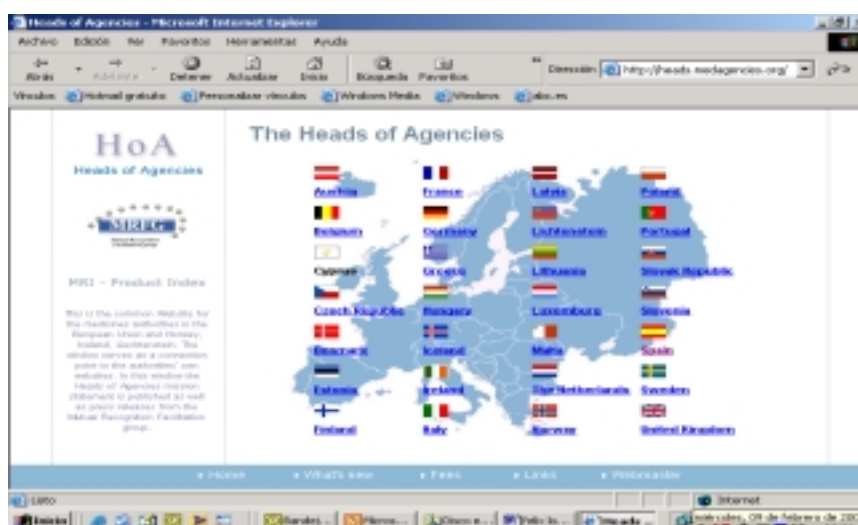


## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **PRECEDENTES EMEA**

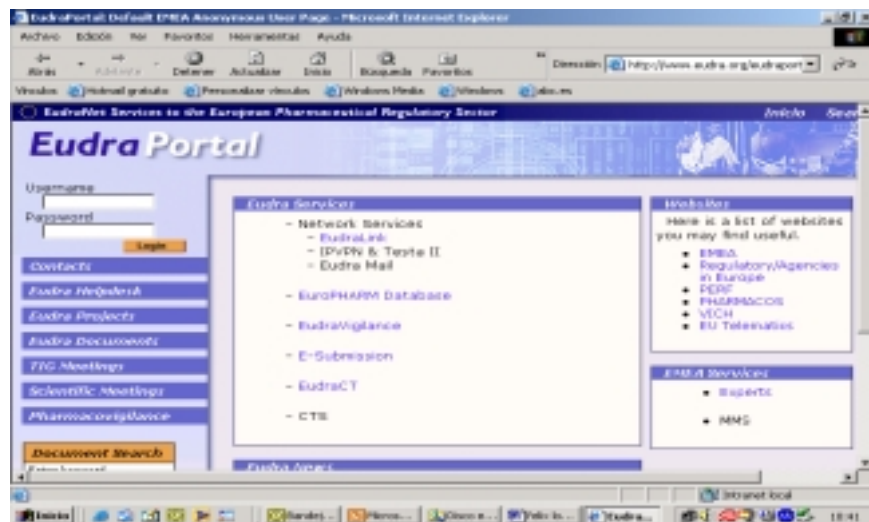
### • Agencia Europea de Medicamentos EMEA

- Año: 1993
- Base Organizativa:
  - CPMP
  - CVMP
  - COMP
  - Asesores externos
- Política en I.T.
  - Grupos de Trabajo TIG
  - TSC (Steering Committee)
  - TMC (Management Committee)

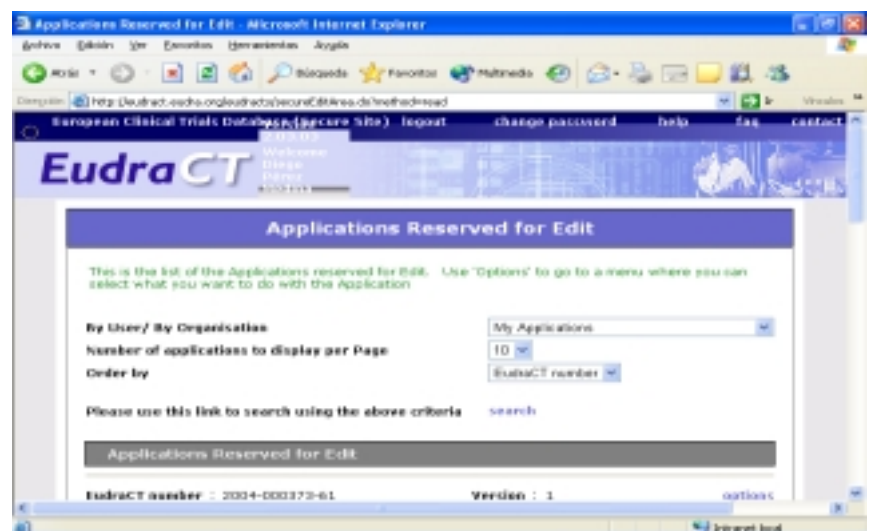
## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **S. ACTUAL WEB HEADS**



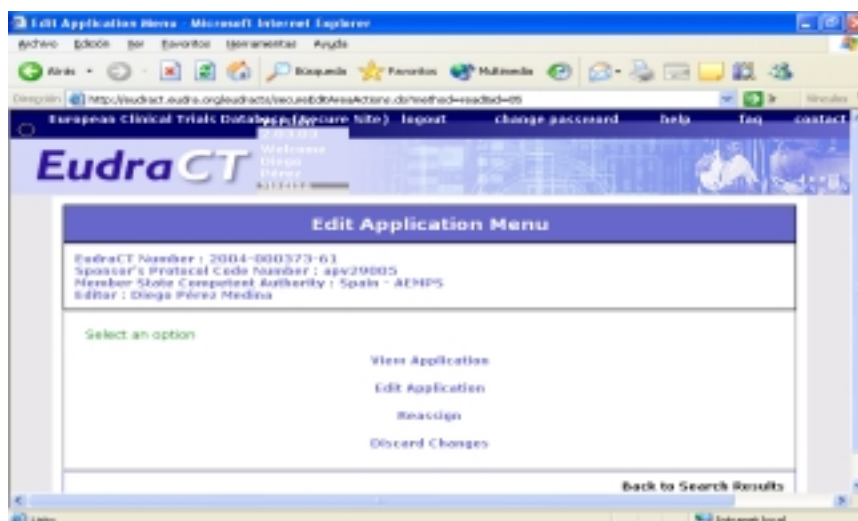
## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA S. ACTUAL EUDRA PORTAL



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA EUDRACT



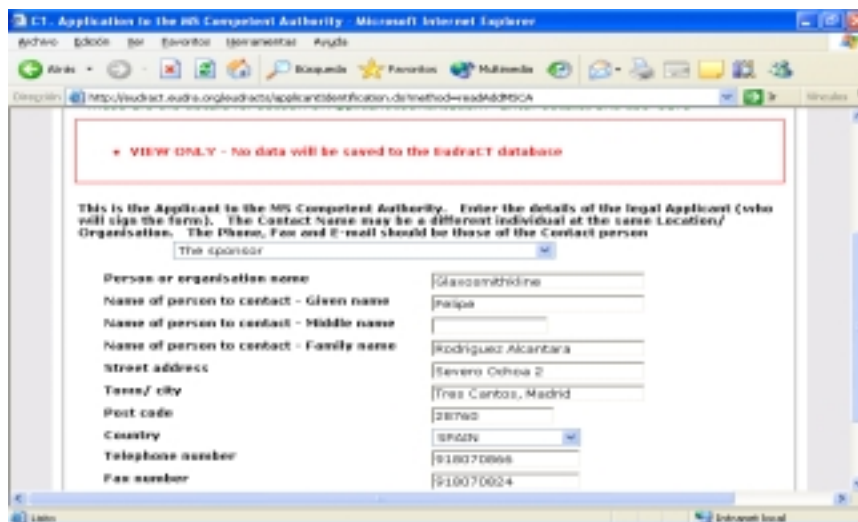
## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **EUDRACT 2**



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **EUDRACT 3**



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **EUDRACT 4**



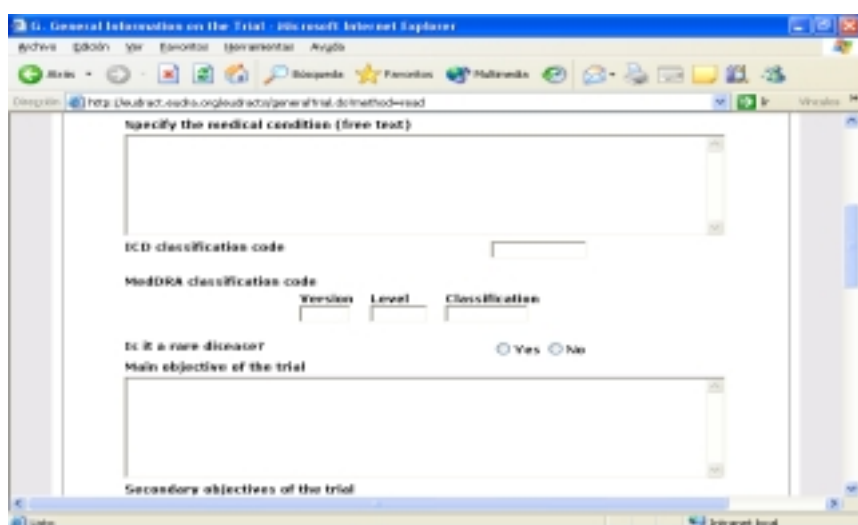
\* VIEW ONLY - No data will be saved to the eudract database

This is the Application to the MS Competent Authority. Enter the details of the legal Applicant (who will sign the form). The Contact Name may be a different individual at the same Location/ Organisation. The Phone, Fax and E-mail should be those of the Contact person

The sponsor

|   |                     |
|---|---------------------|
| Person or organisation name             | Glasnostidine       |
| Name of person to contact - Given name  | Paispa              |
| Name of person to contact - Middle name |                     |
| Name of person to contact - Family name | Rodriguez Alcantara |
| Street address                          | Severo Ochoa 2      |
| Town/ city                              | Tres Cantos, Madrid |
| Post code                               | 28760               |
| Country                                 | SPAIN               |
| Telephone number                        | 918070866           |
| Fax number                              | 910070024           |

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **EUDRACT 5**



Specify the medical condition (free text)

ICD classification code

MedDRA classification code

| Version | Level | Classification |
|---------|-------|----------------|
|         |       |                |

Is it a rare disease? ☐ Yes ☒ No

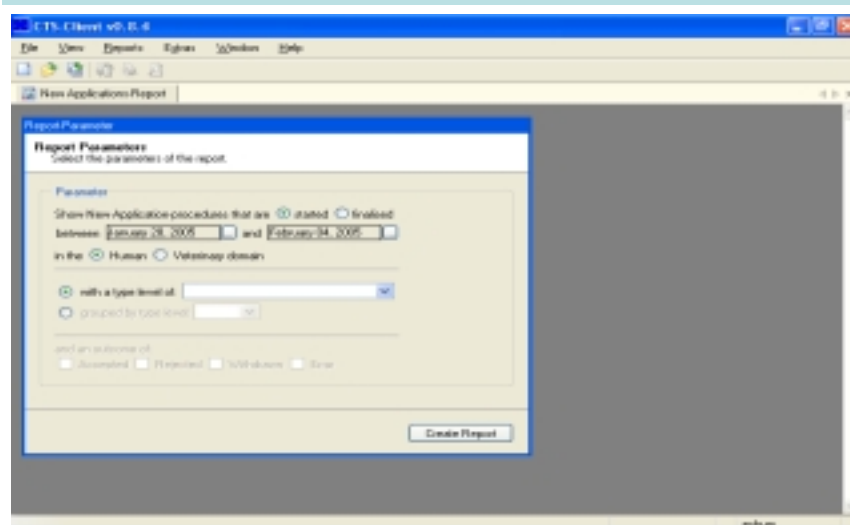
Main objective of the trial

Secondary objectives of the trial

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **P. CENTRALIZADO**

- Ejecución y Responsabilidad exclusiva de la EMEA.
- Obligatorio para:
  - Productos Biológicos
  - Medicamentos para: Cancer, Diabetes, Sida, Neurodegenerativas y M. Huérfanos
  - En los próximos cuatro años ampliación a: Autoinmunes y Viricas

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **CTS**



ICTs Client v0.8.4

File View Reports Extras Window Help

New Application Report CZ/14/0164/0001

| Number          | Bulkname  | T. | M.A. Holder     | Productname            | Status     | Date       |
|-----------------|-----------|----|-----------------|------------------------|------------|------------|
| CZ/14/0164/0017 | CZ/14/104 |    | Zierens, a.s.   | RESPON 1               | In process | 02/02/2005 |
| CZ/14/0164/0020 | CZ/14/104 |    | Zierens, a.s.   | RESPON 3               | In process | 02/02/2005 |
| CZ/14/0164/0021 | CZ/14/104 |    | Zierens, a.s.   | RESPON 4               | In process | 02/02/2005 |
| CZ/14/0164/0046 | CZ/14/104 |    | Zierens, a.s.   | RESPON 4               | In process | 02/02/2005 |
| DE/14/005/0001  |           |    | Seaworth G.     | Belant                 | In process | 01/02/2005 |
| DE/14/013/0001  |           |    | STADA Pharma    | Metformin STADA 1...   | In process | 02/02/2005 |
| DE/14/014/0001  |           |    | Akut Phoenix    | Metformin AL 1000 mg   | In process | 02/02/2005 |
| DE/14/0267/0001 |           |    | Altanova Ags.   | Nitroglyc "Altanova"   | In process | 28/01/2005 |
| DE/14/0267/0002 |           |    | Altanova Ags.   | Nitroglyc "Altanova"   | In process | 28/01/2005 |
| FR/14/040/0001  | FR/14/381 |    | Encepharma      | Metastopiriv Enceph... | In process | 02/02/2005 |
| FR/14/040/0002  | FR/14/381 |    | Encepharma      | Metastopiriv Enceph... | In process | 02/02/2005 |
| FR/14/040/0003  | FR/14/381 |    | Encepharma      | Metastopiriv Enceph... | In process | 02/02/2005 |
| FR/14/0260/0001 |           |    | Mullerchost     | FDGScan                | In process | 28/01/2005 |
| FR/14/0230/0001 |           |    | Huamex UK       | Explet                 | In process | 28/01/2005 |
| NL/14/056/0001  | NL/14/566 |    | GlaxoSmithK...  | Paracetol 10 mg tablet | In process | 02/02/2005 |
| NL/14/0567/0004 | NL/14/566 |    | GlaxoSmithK...  | Paracetol 654 10...    | In process | 02/02/2005 |
| NL/14/0568/0001 | NL/14/566 |    | GlaxoSmithK...  | Paracetol 654 10...    | In process | 02/02/2005 |
| NL/14/0569/0001 | NL/14/566 |    | GlaxoSmithK...  | Paracetol 654 10...    | In process | 02/02/2005 |
| NL/14/0112/0001 | /         |    | Gatoris ca.     | Gatoris                | In process | 23/01/2005 |
| NL/14/0112/0002 | /         |    | Gatoris ca.     | Gatoris                | In process | 23/01/2005 |
| NL/14/0112/0003 | /         |    | Gatoris ca.     | Gatoris                | In process | 23/01/2005 |
| NL/14/0112/0001 | /         |    | Gatoris ca.     | Gatoris                | In process | 23/01/2005 |
| NL/14/0112/0002 | /         |    | Gatoris ca.     | Gatoris                | In process | 23/01/2005 |
| SE/14/0486/0001 | SE/14/406 |    | Movacit 5 mg... | Docan                  | Submitted  | 02/02/2005 |
| SE/14/0487/0001 | SE/14/406 |    | Movacit 5 mg... | Docan                  | In process | 02/02/2005 |

Parameters Report

1 of 20 Procedures selected

The screenshot displays the ICTS Client v0.8.4 application window. The main menu includes File, View, Reports, Extras, Window, and Help. The title bar reads "ICTS Client v0.8.4". The main window contains a "New Application Report" form for "CZ44/0164/002". The form is divided into several sections: "Type Level" (set to "Czech Republic"), "MR Holder" (Cernik, a.s., U Katskavy 130, Dole Mladobuz, 102 37 Praha 10), "Product Name" (RUSPEN 2), "Pharmaceutical Form" (77, Film-coated tablet), "RMS Contact" (Name: Miroslav Hlavac, Phone: 420272185717, FAX: 420267260104, Site: CZH), "DMEs" (a grid of checkboxes for various codes), "ATC Codes" (Code: R05A03B, Description: Pseudoephedrine), and "Pre-Procedure" (Czech Republic, Product Name in Czech Republic: RUSPEN 2, Natural Reference/License Number in Czech Republic: 56/095/02-C, RMS). The "Pre-Procedure" section also includes a table with columns "MS", "A", "W", "B", and "V", and rows "H0", "LV", and "PL".



ICTS Client v0.8.4

File View Reports Cases Window Help

New Application Report CZ/VA/01/04/0003

Pharmaceutical Form

77 Film-coated tablet

☒ ATC Codes  
☐ Act. Substances

Code: N02BA08 Description: Fipirostone

Pre-Procedure Mutual Recognition Arbitration **General Situation**

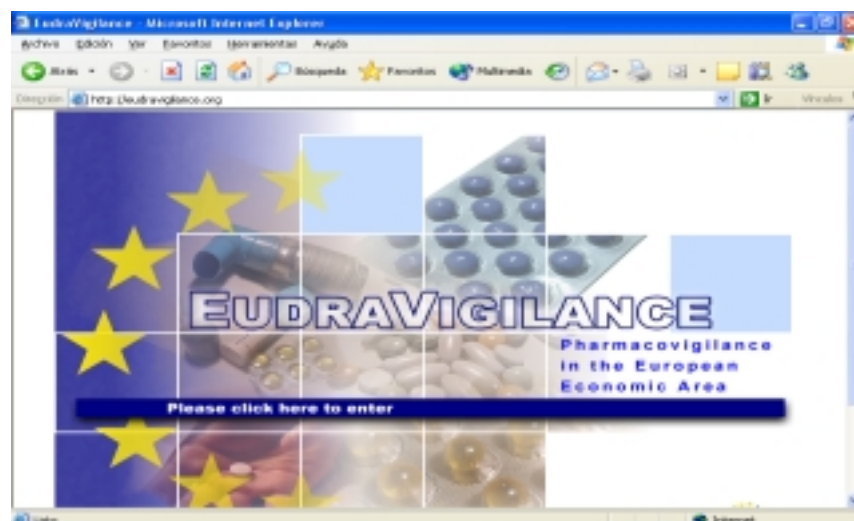
| Event              | Date  | Due Date   | Done       | CZ         | PL         | LV         | HU         |
|--------------------|-------|------------|------------|------------|------------|------------|------------|
| Created            |       |            |            | 14/01/2005 |            |            |            |
| Validation         |       |            |            |            | 25/01/2005 | 25/01/2005 | 25/01/2005 |
| Start              |       | 02/02/2005 | 02/02/2005 |            |            |            |            |
| Pre Day 50 Cont... | 50    | 24/02/2005 |            |            |            |            |            |
| Pre Day 90 Cont... | 05/03 | 25/04/2005 |            |            |            |            |            |

MS, A, W, B, V

CZ ☐  
 HU ☐  
 LV ☐  
 PL ☐

The screenshot displays the RAEFAR website within a Microsoft Internet Explorer browser. The address bar shows the URL <http://www.agencia-efar.es>. The page layout includes a top navigation bar with links like 'Inicio', 'Bases de datos', 'Noticias', 'Servicios', 'Contacto', and 'Ayuda'. The main header features the logo of the 'Ministerio de Sanidad y Consumo' and the 'RAEFAR' logo, which is a green square with a white cross. The central content area is dominated by a large graphic with the text 'Medicamentos de uso humano' in a yellow arc and 'RAEFAR' in a green box. The left sidebar contains a list of links categorized under 'Registros N.E.', 'Vendiciones', 'Concesiones', 'Caudales de muestra', and 'Concesiones Absolutas'. The bottom of the browser window shows the Windows taskbar with various application icons and the system clock.

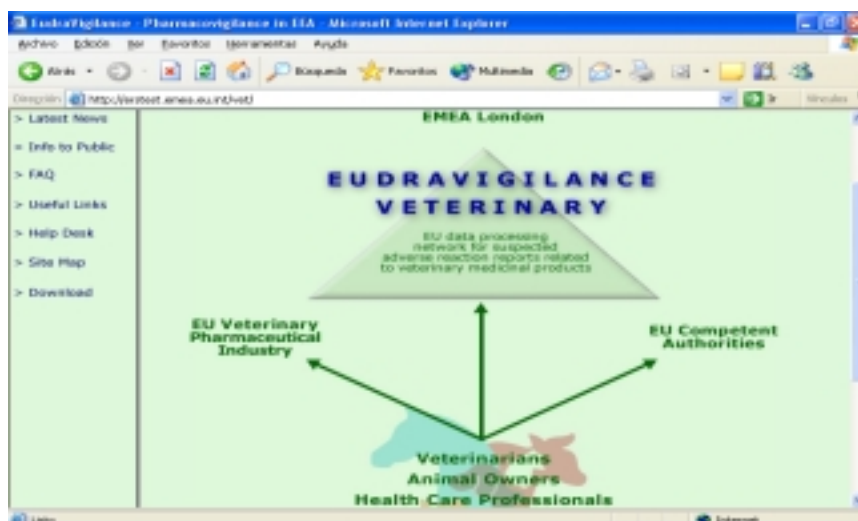
## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA EUDRAVIGILANCE



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA EUDRAVIGILANCE 2



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA EUDRAVIGILANCE VET



## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA EUDRAVIGILANCE VET 2

The screenshot shows the "EudraVigilance Veterinary Restricted Area" interface. It includes a sidebar with "EV Services" (EWEEB, EEP Post), "EV Registered Partners" (Manage your profile, Organisations List), and "User Support" (Help Desk). The main content area is titled "Pharmaceutical Companies" and "Regulators". Below the "Regulators" heading, there is a table listing various regulatory authorities across different countries.

| Organisation Name                                | Organisation ID | Country |
|--|-----------------|---------|
| Agence nationale de médicament vétérinaire       | FRANVNDAS       | FR      |
| AGENCIA ESPAÑOLA DE MEDICAMENTOS                 | ESPAVNDAS       | ES      |
| BESGSEV  | BESGSEV         | BE      |
| Bundesamt für Veterinärwesen                     | DEVNDAS         | DE      |
| Bureau d'inspection des médicaments vétérinaires | DEVNDAS         | DE      |
| Danish Medicines Agency Task                     | DEVNDAS         | DE      |
| Directorio Geral de Veterinária                  | PTDEVNDAS       | PT      |
| Institute for Veterinary Medicinal Products      | DEVNDAS         | DE      |
| Irish Medicines Board                            | IRVNDAS         | IE      |
| Legemiddelverket                                 | NOVNDAS         | NO      |
| Medical Products Agency Sweden                   | SEVNDAS         | SE      |

Address: http://veterinarian.vet.vt.edu/veterinaryproduction/v2.1.1/

Display Settings

Send ADRs Send Ackns WEB Trader ADRs Send Products Products ViewDRA Human ViewDRA

Reset App Reset Session Clear Validate Send XML RTP Duplicate Renewal R R

Message

Safety Reports

- Safety report
  - Animal treated
    - Breed (x)
    - Animal data
      - Animal advice
        - Animal cause
        - Animal treat
        - Animal mode
        - Animal label
      - Case summary
      - Duplicate report
      - Literature reference
      - Clinical trial (x)
      - Linked report (x)
      - Primary source
      - Other people (x)

Message Receiver

| Description                  | Name/Value |
|------------------------------|------------|
| Report identification Number |            |
| Type of report               |            |
| Information Type             |            |
| Case registration type       |            |
| Worldwide case number        |            |
| Original receive date        |            |
| Must recent info date        |            |
| Primary source country       |            |
| Occur country                |            |
| Notification report          |            |
| Notification reason          |            |
| Suspect duplicate            |            |

Animal treated Species

Animal data

Add Rechallenge information

Case summary

Duplicate report (x)

Literature reference (x)

[illegible]

SISTEMAS DE INFORMACION FARMACEUTICOS EN  
LA UNION EUROPEA **EUROPHARMA D.B.**

- Precedentes: Ecphin
- Creación de TIG liderado por Portugal
- Contenido:
  - Datos Administrativos
  - Datos Farmacoterapeuticos básicos
- Operatividad: A lo largo de 2005

SISTEMAS DE INFORMACION FARMACEUTICOS EN  
LA UNION EUROPEA **S. Telemáticos Horizontales**

- Autenticación
- Establecimiento de un Modelo de Datos
- Inclusión de Plantas Medicinales
- Gestión de Diccionarios
- Cumplimiento y adaptación de aspectos legales
- Potenciación de Eudranet

The screenshot shows the FEDRA web application interface. At the top, there is a header with the Ministry of Health and Consumer Affairs logo and the text 'Ministerio de Sanidad y Consumo'. Below this, the 'Agencia Española de Medicamentos y Productos Sanitarios' logo is visible. The main content area features a map of Spain with various regions highlighted in different colors, indicating the distribution of adverse reactions. The interface includes a sidebar with navigation links, a top navigation bar, and a footer with the FEDRA logo and version information.

## SISTEMAS DE INFORMACION FARMACEUTICOS EN LA UNION EUROPEA **ESPAÑA - VIGIA-VET**

