

**COURT OF APPEAL
RENNES**

**TRIBUNAL DE GRANDE INSTANCE
[Civil/criminal court of first instance]
LORIENT**

CHAMBERS OF
M. CONTAMINE
Examining magistrate

Prosecution ref.: 01 006 260
Examination ref.: 201/00032

DISCHARGE ORDER

We, Alexis CONTAMINE, Examining Magistrate at the *Tribunal de Grande Instance* of LORIENT, sitting in chambers:

Concerning the investigations into:

X for importing veterinary drugs without a licence – dealing in dangerous substances liable to cause confusion with a drug or healthcare product.

Civil parties:

SYNDICAT INDUSTRIE MEDICAMENT VETERINAIRE ET REACTIF
[No official Eng. equivalent – Veterinary and reactive drug industry association?]
electing address for service at the offices of Me PIERRE
having as counsel Me Nathalie TISSEYRE-BONNET at Me Lucie PIERRE

CONSEIL SUPERIEUR DE L'ORDRE DES VETERINAIRES
[FRENCH VETERINARIANS HIGHER COUNCIL]
of 34, rue Breguet, 75011 PARIS
having as counsel Me Jean DECHAZLEPRETRE AND Me Jean-Michel YVON

SYNDICAT NATIONAL VETERINAIRES EXERCISE LIBERAL
of 10, place Leon Blum, 75011 PARIS
having as counsel Me Jean DECHEZLEPRETRE and Me Jean-Michel YVON

CONSEIL REGIONAL ORDRE VETERINAIRES DE BRETAGNE
[regional council, veterinary association of Brittany]
of 23, rue Lesage, 35000 RENNES
having as counsel Me Jean DECHEZLEPRETRE and Me Jean-Michel YVON

UNION FEDERALE DES CONSOMMATEURS – QUE CHOISIR
[French consumers' association]
of 11, rue Guenot, 75011 PARIS
having as counsel Me Simone BRUNET and Me Lucie Pierre
Having regard to Articles 177, 183 and 184 of the Criminal Procedural Code,

Having regard to our order of notification to proceed of November 26th 2002

Having regard to the applications by the Prosecutor of the Republic of February 18th, 2003

On June 10th 2001, the inspectors of the National veterinary and health investigation brigade informed the public prosecutor's office of LORIENT that Spanish drugs were being imported and used illegally, mainly by bird (turkey) and cattle farms in the TGI ORIENT area.

The products made in Spain came from the ALBAITARITZA company at IRURTZUN, in the Spanish Basque country. They were brought into Brittany by a transport company, TFE.

On the Prosecutor's instructions, the inspectors obtained a list of customers whom the ALBAITARITZA company had supplied since the start of 2001. It emerged that at least 105 growers, spread over the departments of Morbihan, Finisterre, the Cotes d'Armor and to a lesser extent in the Landes, Lot and Pyrenees Atlantiques had used the Spanish veterinary products. It was estimated around eight tons had been supplied, disguised as food products.

On July 6th 2001, following information given by the carrier, TFE, the investigating brigade of PONTIVY, assisted by the inspectors of the BNEVS, raided MESLAN (56), at a location where 80 kg of drugs had been delivered, labelled as 'food products'.

The products intended for use on cattle were seized.

The directors of GAEC were questioned. They admitted that they had obtained products from the Spanish company at prices which were much lower than those which applied in FRANCE. They also said that the ALBAITARITZA company had an agent, Jean Yves PAUL, who lived at BERRIEN (20).

On July 10th 2001, investigations were opened against X for importing veterinary drugs without a licence, and giving them to animals intended for human consumption or improperly keeping substances or compositions which were unlicensed under the regulations on veterinary drugs and substances intended for animal consumption, and marketing substances or preparations packaged or labelled in such a way as to render them liable to be confused with food.

The veterinary and reagent industry association (S.I.M.V.) and the regional council of veterinary surgeons of Brittany, the national association of independent veterinary surgeons and the Higher council of veterinary surgeons have joined themselves as civil parties to the proceedings, and were ultimately joined by the UFC "Que Choisir?"

The SIMV stated that, in terms of veterinary drugs, the rule was that an import licence was required, wherever drugs came from, that licence being issued by the AFSSA.

Moreover, all veterinary drugs had to undergo licence trials (product licence).

It supplies a list of drugs marketed by the ALBAITARITZA company for which no product licence exists in France.

AUDACE (the association of European agrochemical users and distributors) appeared before the examining magistrate of its own accord, its chairman, Daniel ROQUES, having been interviewed by the police.

He explained that the major brands used exclusive distribution networks to deliver their products: having implemented the formalities required, they controlled prices and intended to

maintain them. Parallel importers, on the other hand, are operators who use the principle of free circulation of products under Article 28 of the EC Treaty, acquiring stock from wholesalers or retailers in the country of origin at prices lower than the exclusive brand networks. He believed only parallel imports provided any challenge to the distribution monopoly held by the major companies and were therefore of restoring the principle of competition on price.

He added that the Court of Justice of the European Communities (ECJ) had a long history of condemning unjustified obstacles to parallel imports, and cited the *DASSONVILLE* judgment in particular.

Daniel ROQUES did not deny that the drugs could not be put into circulation except under the supervision of the public authorities or product licences as provided for by Directive 93/40/EEC and ratified in national law by Law 94-114 of February 10th, 1994 (Arts. L 5141-5 and 5141-7 of the Code of Public Health).

On the other hand, he argued that the procedure which France had implemented was highly time-consuming and expensive, and that three scenarios had to be distinguished:

- Either a drug did not have a product licence in the Community and had therefore to undergo a product licence procedure, involving tests and scientific analysis;
- Or a drug had a product licence in the Member State into which it was imported and therefore had to enjoy a limited product licence in the country of importation; the only thing then to be verified was whether the product satisfied the health conditions of the country of importation;
- Or the product imported had a product licence in its country of origin, but was also similar to a reference product which itself had a product licence in the country of importation.

In this third hypothesis, the provisions of the Directive on issuing a product licence do not apply, as this would run contrary to the principle of the free movement of goods.

He argued that the CJEC (*case C-100/96* of March 11th, 1999) was aware of the need to verify that both products came from the same source, and that, without being identical on all counts, had to be made to the same formula and using the same active ingredient, and with the same effects. It was also up to the importing Member State to verify this point.

Now, France does not have any legislation on this third hypothesis and has also recognised that it falls short of Community law.

Lastly, Daniel ROQUES produced a number of judgments given by the national courts in support of his arguments, including the *Cour de Cassation*.

Acting under letters rogatory, the farmers who had bought the veterinary drugs from the ALBAITARITZA company were interviewed. From a large number of interviews, it was evident that the bird farmers were aware that this company existed from professional meetings or by word of mouth. Orders were issued by telephone, then confirmed by fax and delivered by carrier within 15 days (TFE in many cases), together with an order. A veterinary surgeon from the Spanish company also visited the operations regularly, which was not necessarily the case with French vets.

The bird farmers interviewed also stressed the financial benefits of dealing with the ALBAITARITZA company, the drugs being three to five times less expensive than in France for the same effect. It also emerged that the bird farmers completed the health forms and stated precisely what products they were using.

The veterinary drugs marketed by the ALBAITARITZA company and found by the police at the operations were seized.

Inaki REVILLA, chairman and CEO of the ALBAITARITZA company, and Francisco Javier ERNETA, veterinary surgeon, were interviewed as witnesses, with the examining magistrate present.

When asked about the waybill of hauliers TFA showing 'food products', Inaki REVILLA said that this might have been added by the carrier itself and he had no interest in mis-stating any details for VAT returns in any case.

He also supplied lists of products exported to France. He said that all the drugs had product licences in Spain and were equivalent to products in FRANCE which had product licences in France. For each drug, M. REVILLA gave the name of the company making the equivalent product in France. Some products were made and then bought in FRANCE and then resold in FRANCE by ALBAITARITZA.

All drugs shipped to FRANCE were accompanied by orders in three languages (French, Basque and Spanish). These instructions stated the waiting times for each veterinary product, that is, once given to animals, how long the meat, milk or eggs from those animals were prohibited to avoid drug molecules getting into food for human consumption.

As to the differences in prices between FRANCE and SPAIN, Francisco Javier ERNETA explained that the distribution systems in the two countries were very different: veterinary surgeons had a monopoly over distributing such drugs in FRANCE, but not in SPAIN.

On importing veterinary drugs without a licence and giving such drugs to animals intended for human consumption

Article 28 of the EC Treaty states that *quantitative import restrictions and any measures of equivalent effect are prohibited as between Member States.*

The DASSONVILLE judgment (July 11th, 1974, 9/74 Rec. 1974 p. 837) defined the concept 'measure of equivalent effect' as any commercial rules and regulations of Member States *"liable to undermine intra-Community trade, whether directly or indirectly, currently or potentially. The wording used by the Court since 1974 reflects the intention to combat the various attempts on the part of States to compromise the aim of the free circulation of goods in favour of their nationals."* (Gavalda – Parleani, [Community commercial law], ed. Litec). This case law was upheld in particular by two judgments concerning the pharmaceutical industry and parallel imports (ECJ *Centraform v. Sterling Drug* and *Centraform v. Winthrop* Oct 31, 1964; Rec. p.1174), and has always been upheld by the Court. [not original case wording – translator]

ECJ judgment *C 100/96* of March 11th, 1999 on phytopharmaceutical products also lays down some principles which can also be applied readily to veterinary products *mutatis mutandis*. The Court found that *"the provisions of Directive 65/65 on issuing product licences cannot apply to a pharmaceutical speciality which already holds a product licence in a Member State and the import of which into another Member State constitutes parallel imports in respect of a pharmaceutical speciality already holding a product licence in that second Member State. In this case indeed, the pharmaceutical speciality imported cannot be considered as being marketed in the importing Member State for the first time."* [Again, not original case wording – translator]

The Court also found that it was up to the competent authorities of the Member State to verify that, without being identical on all counts, both pharmaceutical specialities were made to the same formula, used the same active ingredient and had the same therapeutic effect.

From the documents supplied by the ALBAITARITZA company, it appears that the veterinary drugs it imports into FRANCE were covered by product licences in Spain, and that all products have their French equivalents which were themselves under a product licence. These products must therefore be allowed to circulate freely in the European Economic Area under Article 28 of the EC Treaty (cf. PARIS Court of appeal, March 8th, 2001, *BOURDON case*).

The fact that France does not have legislation ratifying its obligations under Community law in terms of licences for veterinary drugs amounts to a shortcoming which means that no charges can be brought against the ALBAITARITZA company or the growers who purchased its products.

Following ECJ judgment C 100/96 on phytopharmacological products, a decree by the Ministry of Agriculture and Fisheries of April 4th, 2001, established a simplified procedure for marketing such products originating in the European Economic Area, but this is not currently the case with veterinary drugs.

On marketing substances or preparations presented or labelled in such a way as to cause confusion with a food

The waybills seized stating 'food products' are on the letterhead of the company TFE. It should also be noted that the word 'fresh' is also used in some cases. Certain documents accompanying the waybills also include specific instructions to the haulier, i.e. that the products must be kept at a temperature of between 2° and 4° at all times in transit.

When questioned on this point by the ALBAITARITZA company, the TFE operations manager for "Landes-Pyrenees" explained that the words 'food products' on the waybills were included automatically as standard on all TFE's national waybills.

TFE's manager in SPAIN added that these words only appeared on forms for French agencies, and not the international waybills (CMR) issued in SPAIN.

It also appears that, if the carrier is not TFE, the waybill drawn up in Spain specifically states 'veterinary products'.

From all these facts, it cannot be concluded that there is any intent to defraud on the part of anyone, and that there cannot therefore be any grounds for bringing criminal charges.

Whereas in these circumstances there are insufficient grounds for charging anyone with committing the offences above,

FOR THESE REASONS

We declare that there are no grounds to proceed here, and order the file to be lodged with the clerk of the court to be re-opened if there are any further charges.

Given at LORIENT, March 14th, 2003

The Examining Magistrate

Copies of this order have
been sent by registered mail
** To the civil parties and their counsel
** To the witnesses called and their counsel
March 14th, 2003

The Clerk