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French Community Advisory Board TRT-5(*) Press Release

Roche sells poisoned Viracept® and does not answer questions

Roche must reply to all questions Roche must be held accountable

Since the 6th of June 2007, we have known that Viracept®, a protease inhibitor used in combination therapy for HIV patients and manufactured by Roche in Europe and in some other regions of the world (1), has been contaminated at high levels (2) by a known genotoxic product : ethyl mesylate (EMS).

While no data are available for humans, EMS is considered carcinogenic and teratogenic (i.e. it can induce cancer and cause birth defects). Marketing authorisation has been suspended by the EMEA (3), and Viracept® has been recalled, while it was recommended that all patients taking Viracept® be switched to another antiretroviral drug.

The follow-up of all patients exposed to Viracept® in 2007, and all pregnant women and all children who have ever been exposed to it, including *in utero*, - recommended by the EMEA and approved by the European commission - requires the registration of all these patients.

Although initially only batches from 2007 were thought to be contaminated, it very quickly became clear that some batches dating back to 1998 had already been contaminated too, though at lower levels (4). That is to say for a ten-year period, a very harmful substance has gone unnoticed and been taken daily by some people thinking they were using safe drugs.

TRT-5, following regulatory authorities, EMEA and AFSSaPS (5), has asked Roche many questions on several occasions regarding very important issues such as safety, monitoring and release of the authorized drug, the replacement of contaminated Viracept®, and the organisation of the follow-up of exposed patients.

Quick communications and a clear agenda for action were expected from Roche which has compromised the health of HIV-positive people for years, yet so far, we and public agencies have received only vague and unsatisfactory answers, if any at all.

TRT 5

TRT-5 [GROUPE INTERASSOCIATIF TRAITEMENT & RECHERCHE THERAPEUTIQUE]
TOUR ESSOR, 14_RUE SCANDICCI_93508 PANTIN CEDEX FRANCE www.trt-5.org

COORDINATION DU TRT-5 :
DOMINIQUE BLANC T. 01 41 83 46 11_ F. 01 41 83 46 19_ E-MAIL : blanc@trt-5.org & CORINNE TAERON T. 01 44 93 29 21_ E-MAIL : taeron@trt-5.org

ACTIONS TRAITEMENTS_ T. 01 43 67 66 00 : EUGENE RAYESS, FRANK RODENBOURG
ACT UP_ T. 01 49 29 44 75 : †NATHALIE DAGRON, FRANCOIS BERDOUGO, HUGUES FISCHER, FABIEN GIRAUDEAU, GUY MOLINIER, FABRICE PILORGE, MARYVONNE MOLINA
AIDES_ T. 01 41 83 46 46 : FRANCK BARBIER, EMMANUEL COOK, BRUNO SPIRE, AURELIE VERNY
ARCAT_ T. 01 44 93 29 29 : †MICHELE AILLOT, CORINNE TAERON, MARIANNE L'HENAFF, MIGUEL DE MELO
DESSINE MOI UN MOUTON_ T. 01 40 28 01 01 : GEORGES POINT
NOVA DONA_ T. 01 43 95 81 75 : CHRISTIAN HUCHET
SIDA INFO SERVICE_ T. 01 44 93 16 44 : MAREK KORZEC, ANNIE LE PALEC, JEAN-MICHEL VIMOND
SOL EN SI_ T. 01 48 31 13 50 : CAROLINE GASIGLIA

These are the requests we are making to Roche :

- Replace contaminated Viracept® with either safe batches produced by other companies such as Pfizer or Cipla, or provide a substitute antiretroviral drug for free to all patients, particularly those in developing countries where antiretrovirals are scarce, expensive and not readily available (and in other countries when necessary)
- Constitute registers of patients having taken Viracept®, and organise their follow up as needed
- Establish a timely plan to repair the harm done to patients and compensate them for the damage done
- Conduct for-far-lacking tests on animals to better anticipate the risk to humans
- Understand what is wrong with its production process and monitor clinical batches in order to establish safe and transparent procedures for the future. The mandatory inclusion of a finished-product chemical spectrum to be included in the batch-release process.

So far, no action has been taken by Roche to compensate the health-care system of many countries which have had to face Roche's carelessness, bad will and slowness.

Roche must reply to all questions...

Roche MUST be held accountable !

- **Roche must now implement any programme for supplying people with adequate antiretroviral drugs.**
- **Roche must now create a register of Viracept®-exposed patients to make appropriate follow-up possible.**
- **Roche must provide a compensation plan for patients and health-care systems !**

(*) TRT-5 is a coalition of 8 French NGOs – AIDES, Act Up-Paris, Actions Traitements, Arcat, Dessine Moi Un Mouton, Nova Dona, Sol En Si, Sida Info Service - lobbying for access to the best standards of care and on HIV/AIDS clinical research.

<http://www.trt-5.org>

For more details :

***Please find the joined letter from TRT-5 to Roche CEO, Franz Humer
And / or contact Corinne Taéron, TRT-5 member : 00 11 33 6 86 37 80 78***

(1) USA, Canada, Japan, Korea, Puerto Rico are not affected by the recall. In these regions, Viracept® is manufactured by Pfizer or Japan Tobacco.

(2) Contamination of some of the 2007 batches has been measured at 2,000 ppm, while toxicologists recommend less than 1 ppm for safety reasons.

(3) EMEA : European Medicines Agency.

(4) Some batches prior to 2007 show contamination levels ranging from 50 to 100 ppm.

(5) AFSSaPS : Agence Française de Sécurité Sanitaire des Produits de Santé (French Medicinal Products Agency).