

**Mirella Parachini, M.D., the President of Fiapac about
RU 486 in Italy: a bad game played without spectators:
But where are the women? Dezember-8-2009**

The developments of the introduction in Italy of the RU 486 pill – the abortion pill – as an alternative technique to surgical abortion, is the nth representation of this country's incapacity on two points: first, to take itself seriously. Secondly, to adjust itself to the evolution of medical science in matters of individual self-determination, and in this case of a particularly “incapable” patient: a woman who wants to interrupt a pregnancy!

Let's be clear: it does not mean that abortion is prohibited in Italy. What our politicians are so agitated about is that it should only take place according to the method they have established, in absolute indifference to the indications provided by international and Italian technical bodies which are expected to intervene.

Then here is the caricatural fact, the farce: the technicians are undoubtedly consulted and heard, but then no account is taken of what they recommended. And this is what happened with the inquiry conducted by the Senate Hygiene and Health Commission about the RU 486 pill, which was concluded yesterday.

But let's sum up:

In 2007, nearly twenty years after the introduction of the RU 486 pill in France, and successively in almost all European countries and in many countries of the world, the producer submits a request to commercialize the medicine in our country, with a “banal” procedure of mutual recognition as provided by European regulations.

The European directive Nr 2001/83 on the commercializing of medical products requires that a medicine has been approved by a member State, the other European countries may only regulate its use within their own national laws and set its price (“mutual recognition”). In the specific case of an abortion medicine, the methods of its use must be prescribed by the national law which regulates the legal abortion.

After two years to achieve the required actions, last July 30 the Italian Medicine Agency (AIFA) gives finally mandate to the General Director Prof. Guido Rasi to publish the authorization for the commercialization of the Mifegyne medicine (Mifepristone). In its announcement, AIFA declares that it has reached that decision “on the base of both the efficiency of the medicine and the observation of the objective of protecting the woman”.

But on September 2, in Frascati, the President of the PdL senators (Berlusconi's party), Maurizio Gasparri, declares: “The inquiry conducted by the weekly ‘Tempi’ (a non-scientific magazine) confirms the need of a parliamentary informative inquiry. Even those who support the law Nr 194 (the law in force about voluntary abortion in Italy) more than we do should be concerned to abide by that law also concerning the RU 486” (Adnkronos Press Agency). Thus, with the unanimous consent of all Senate parliamentary groups, the Hygiene and Health Commission starts the inquiry about the RU 486 pill with the specific mandate clearly expressed in the title, to evaluate not only that the procedures are consistent with the law Nr.194, but once more the epidemiologic data, “also with reference to the international studies on the risks-advantages relation”. But was that not already done by the AIFA? And before them, by the experts and technicians of the 21 European countries of the European Medicine Agency (EMA)?

And guess who are, among others, the technicians consulted by the Senate inquiry commission? The President and the Director of AIFA! And what says the Director of AIFA to the senators? “As to AIFA's qualifications, Professor Rasi has underlined that the Agency has a very precise and rather limited perimeter of action which consists in defining the procedure of dispensation and the limits of the administration of the medicines on the basis of criteria which take into account only the benefits and the risks”. Justly, so as to say: the methods of utilization are not our business. All right! The ball is at the centre. The Commission seizes the opportunity and says: “Therefore, the technical body alone cannot control the guiding consistency, but this has to be done in the first place by the competent authority, referring particularly to the Government”, and it therefore suggests “to adjourn that procedure and to ask and obtain the opinion of the Minister competent in

this matter, in order, if deemed necessary, to take up again the procedure from the beginning “. The ball is thus in the hands of Minister Sacconi who, in commenting the decision of the Commission, says: “the decision already taken according to that procedure by AIFA, is null since the opinion of the Government is needed before AIFA’s decision is expressed”.

You see? It took years before being told that “the parliamentary investigation has been very useful; it has perfectly clarified both the outlines of competency and the critical points at the level of security” (Roccella, the former feminist presently undersecretary of Department of Health).

And this adjourns the whole issue, like it or not for Italian women, the only ones in the world with a law recognizing that it is possible for them to interrupt a pregnancy, but only by a surgical method. Waiting for an approval which will include that the whole abortive procedure, in its various stages, shall be performed within a system of ordinary hospitalization, against all not only scientific but also practical evidence already tested in our own country, where the drug has been used on the basis of the formula of direct import, in application of the so-called Di Bella law Nr 94 of 1998, which allows, for individual patients, the use of medicines not yet registered in Italy.

But that is not the whole story.

Pay attention to the last paragraph of the Commission’s report: “Concerning the doubts about the deceases occurred after taking RU486 pills or associated prostaglandins, and in view of the difficulties to provide secure data, a request of arbitration is desired in order to reopen the key discussion on the risks/benefits relation and to start a new inquiry and decision by EMEA”.

Is the ball now in EMEA’s court? It’s quite so, no joke.

Mirella Parachini, M.D.
President of Fiapac
San Filippo Neri Hospital Roma
Department of Obstetrics and Gynaecology
private practice:
Via Cola di Rienzo, 190
00192 Roma (Italy)
mparachini@gmail.com