Ivermectin: the dark side of decisions

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Article L1451-1-1 of the Law n°2011-2012 of December 29, 2011 - art. 1 was drafted following the contaminated blood and Mediator scandals, in order to put an end to conflicts of interest and abuses in the decisions of the Medicines Agency. Decisions concerning medicinal products must be totally transparent, and to this end the text provides that ***the debates***, first and foremost those concerning the acceptance and refusal of marketing authorisations, RTU and ATU[i], **must be recorded and kept, with *"the details and explanations of the votes, including minority opinions".***

To better understand the ANSM's medically incomprehensible decision to refuse the RTU for ivermectin, we wanted to know what the debates had been, who had defended what, on what basis, and we asked for the recording of the deliberations that led to this refusal, in accordance with the law. ANSM's response:

"In this respect, Articles L. 300-2 and L. 311-1 of the Code of relations between the public and the administration provide that the documents requested have the character of an administrative document, communicable to any third party who requests it.

However, in this case, ***no such documents exist****. "*

The law has not been respected, the deliberations must remain "secret defence"! The ANSM had to justify this situation, so it explained itself, moving a little further onto the opaque side of transparency.

"Indeed, the relevance of developing the above-mentioned RTU was the subject of ***a purely internal evaluation****, carried out by the competent departments of the agency. In this respect, it may be recalled that although Article R. 5322-14 of the Public Health Code allows the Director General of the Agency* ***to set up consultative expert bodies, the setting up and subsequent referral to these bodies is not, however, an obligation and remains purely discretionary. .... Finally, the provisions of the Public Health Code specific to the preparation of the RTU do not provide for the mandatory consultation of such bodies either.*** *"*

There was no consultative body? No consultation of experts? We don't know who decided, how and without consultation. We don't even know if doctors participated!

Although the ANSM was created to remedy the lack of transparency, **everything has to be remade**.

We learn that to grant or refuse a RTU, there is no need for experts, no need for consultation, no need for advisory bodies, no need for debate, it can be done at the discretion of the director and unknown people, who are not accountable to anyone! I think it would be interesting to ask for the same documents for other molecules like Remdesivir or Bambalaba! We might be surprised about the way our above-the-law authorities operate.

And without laughing, the Agency adds as a pretext "*the exceptional situation we are experiencing, which required the Agency to carry out the evaluation in question within a constrained timeframe, while preserving the interest of public health."* Three months to evaluate a 30-year-old drug that already has a marketing authorisation, i.e. to read a few studies, versus 15 days to evaluate unknown drugs without a marketing authorisation? Who are we kidding?

How can the President, the Minister and the elected representatives accept such behaviour, when in the past they have done everything possible to

prevent it from happening again? What is the point of the laws that were made to guarantee the transparency of these administrative decisions?

It seems that ivermectin is entitled to special treatment, not only in France. The behaviour is the same everywhere: unable to counter medical evidence (the presumption of efficacy), the ANSM, the WHO, the EMA, the NIH openly cheat, without scruples, with the blessing of so-called democratic governments.

Remember the WHO. It commissioned a report by Andrew Hill, which concluded: *"This meta-analysis of 18 RCTs involving 2282 patients showed a 75% improvement in survival, faster clinical recovery time and evidence of a dose-dependent effect on viral clearance in patients receiving ivermectin compared with control treatment."* WHO decision: "Move along, nothing to see here!"

Remember the EMA. It ruled against ivermectin, then admitted the same conditions as the ANSM: there was no vote, since it was not seized of any application for use, and that *"updates to existing sections that do not affect the noted recommendations are approved by the Panel co-chairs without a Panel vote."* !

Now the NIH. Following the EMA's response above to a British group requesting an explanation, Americans wanted to know how the NIH made its decision on ivermectin on 14 January, by making a FOIA request like us. When the NIH did not respond, a complaint was filed in federal court. After many exchanges and challenges from the NIH, it seems that there was no vote, which the NIH contests, without providing any proof from what I understand in this article.

If the real reasons are not to be communicated to the public, the "official" explanations of these organisations are essentially based on 3 things, as if there was a consultation. 1) Doubts about molecular concentrations in the in vitro study, when the problem has long since moved from Petri dishes to humans; 2) They cite studies that are too small, so out of 6 studies the ANSM cites 3 studies with 67 treated patients, ignoring the 54 studies with more than

17,600 patients, and 3) they reject the un-reviewed or unpublished studies, as if they were unable to read them themselves.

As for these many unpublished studies, why aren't they published? This is another element of what some would call an anti-ivermectin conspiracy: the major journals refuse to publish. When authors do manage to publish, it is in secondary or unrelated journals. Thus the study on the first Ehpad in France (Hauts de Seine) will be published after a year, in a dermatology journal, not an infectious diseases or general journal, just like the Bernigaud study in the Ehpad of Seine et Marne. This systematic rejection has reached such a point that the editors of Frontiers in Pharmacology have just decided to resign in the face of these publication refusals.

Social networks are not to be outdone and are participating in this desire to hide the truth about ivermectin. See this impressive regulation of YouTube on this subject. It goes beyond censorship! It is *"forbidden to contradict information from local health authorities or the WHO"*, *"it is forbidden to recommend the use of ivermectin, to say that it is an effective treatment"*.

Why are there such blockages, why are people trying to hide the truth about Ivermectin by all means, legal and illegal? The latest EU press release of 6 May may provide the beginnings of an explanation: *"Complementing the EU's successful vaccine strategy, the European Commission is now proposing a strategy for COVID-19 treatments to encourage the development and availability of much-needed treatments to combat this disease. The strategy includes clear actions and targets, including the authorisation of three new treatments to address COVID-19 by October 2021 and possibly two more by the end of the year. "*

It has taken 16 months since the beginning of the epidemic for the Commission to decide to look at treatments other than vaccines? It will release funds for research, development, clinical trials and orders. But for ivermectin, macrolides, HCQ or other generic products? Certainly not!

Why now and not before? Did the EU wait for the big companies to make announcements about the upcoming release of new molecules, as we have

just seen in the last few weeks, before taking an interest in treatment? Coincidence? Are all these medical authorities more concerned about the health of the pharmaceutical industry than the health of the population? One wonders. Are there conflicts of interest in the decisions taken and to be taken? You won't find out, as they "forgot" to record the shadow proceedings.

i An **ATU (temporary authorisation for use)** is the French version of **compassionate use** and is granted by the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM) in France subject to the following conditions:
– Specials are to be used for treating, preventing or diagnosing serious or rare diseases
– **No other appropriate treatment is available**
– There is sufficient scientific evidence to show their efficacy and safety
In practice, there are two kinds of ATU: **cohort ATUs and named patient ATUs**.

In France, the ANSM grants an **RTU (temporary recommendation for use)** to cover **off-label prescriptions that do not comply with the marketing approval** obtained, as long as:
– There is a **therapeutic need**
– The **risk/benefit ratio is considered as favourable**, in particlular **in reference to published scientific data concerning efficacy and tolerance**
The aim is to ensure that **medicinal products are used safely** through **patient follow-up organised by the laboratories concerned**.