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European Commission
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ON THE PROPOSED AMENDMENTS TO BE MADE TO COUNCIL DIRECTIVE 91/414/EEC OF 15 JULY 1991 CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS (PPP) ON THE MARKET

2005

AUDACE regrets that it is unable to respond to the draft amendments to Directive 91/414/EEC submitted by DG SANCO and the associated impact assessment by May 20th for lack of time.

Our intervention today will therefore be limited to summarising the main elements which we believe typify the extremely hostile climate in which the generic industry independent of the major producers is suffering, and the undoubted effects on products available to users in terms of quantity, quality and risk management (see AUDACE's contribution towards a Thematic Strategy on the Sustainable Use of Pesticides. [.pdf - 509 KB]) and ultimately at price level.

We will be happy to provide the Commission with any further contribution it may consider necessary to clarify our proposals below, and to explain our responses on the amendments as a whole, let alone the impact assessment (IA) in more detail.

1 THE COMMUNITY MARKET

The definition of the Community market as used in the impact assessment does not seem realistic, and might give the impression that the market is less concentrated and more competitive than it actually is.

The market is highly concentrated, with six companies accounting for 95% of the market, European companies holding 60%, with Member State Germany having a predominant role.

The other companies involved, such as those listed in the 55 generic companies on page 12 of the impact assessment do not appear relevant in terms of the Community market for PPPs.

Since the Directive was implemented in 1993, this has created a cost and uncertainty environment that is incompatible with developing and marketing generic PPPs independently of the major manufacturers.

Including the active substances as listed in Annexe 1 to the Directive has resulted in generic products disappearing, through being taken over or being subjected to the marketing logic of the six predominant companies.

Likewise, some Indian and Chinese active substance producers have become custom manufacturers in line with the interests of the six major manufacturers. The latter bring them into competition with one another without them being able to access the Community market directly or sell to local generic companies holders of the marketing authorisation (MA) and formulation capacity.

Secondly, the idea that parallel imports respond to demands for multiplicity of supply and account for 15% (IA page 9) of intra-Community trade seems very far removed from the PPP market reality in the EU.

In fact, parallel imports barely account for 1% of the market at present.

It is true to say, on the other hand, that there is fraud in parallel imports, and that monitoring procedures and appropriate sanctions should be implemented as the Commission believes.

2 AREAS

As we see it, Community legislators could have done without this scenario, which merely involves harmonising active substances in the EU market by applying a complete and total harmonisation of marketing active substances and PPPs since 1991.

Considering that the need to partition the Community market into geographical areas for reasons of the climate, soils and agriculture, let alone as suggested by a Minister of Agriculture and competent national authorities for reasons of regional diet is undoubtedly not objective insofar as

1. No products have been formulated specifically to date for any given region, whether it be in the extreme North, South, East or West of the EU
2. Marketing licences are national, and there is just as much climatic difference between different regions within the same Member State
3. The safety margins used in evaluating the toxicity and eco-toxicity of each PPP are or are not relevant to different climatic extreme etc. in the territory of the same Member State, which can also change considerably from one year to the next even within the same region of that Member State
4. And, finally, most industrial PPP production units now specialise in substances and formulae at global level. Indeed, the major companies have focused their production on a given site for reasons of economies of scale.

   If approaches used at global scale vary as a function of the raw materials used (solvent types and other ingredients) depending on how these substances are available to industry and their prices, there are no objective variations arising out of essential demands such as protecting public health, the environment and their biological effects.

3 GENERICS

Arguments against a strong generic industry focus on three main questions aimed at technological innovation and the compatibility of such products with the risk reduction strategies associated with the use of PPPs.

We propose to look at these questions in the order in which they are normally asked of the competent national authorities.

Is opening up the market to cheaper generic products compatible with a strategy of reducing risks involved in using PPPs?

1- Commercial prices are about financial management, not risk management

Commercial prices are what are offered to the market, excluding taxes and/or government duties.

They are set entirely at the will of the industry and distribution carried out in accordance with the rules of competition, and independently of any idea of 'area' as the Commission suggests.

They are set in a competitive environment which the State can only control in rare, exceptional cases, generally relating to dumping or, to be more precise, breaches of competition or monopoly rules.

Unless it is a buyer itself, the State cannot favour or restrict a player's access to the market via regulatory procedures, in this case marketing authorisation, under which that player is liable to influence existing selling prices.

An administrative practice that would tend to consider that a high selling price would discourage a product's use would be the typical finding of the inadequacy, or even failure, of the risk assessment process and regulatory framework laying down the conditions in which products must be used.

2- Incompatibility in law of the State being against generics

Restricting access to markets for generics through marketing authorisations maintains the production and distribution monopoly conferred by patents, although there is a strict time limitation on their use under all international conventions (including ADPIC).

In law, generics are the ultimate result and direct consequence of patents.

If the State opts for the high prices a monopoly involves, this amounts to a kind of tax in favour of private interests.

Such transfers must be unconstitutional.

3- Arbitrariness

The impact of low prices on any increase in the number of PPPs used could be based on two assumptions:

- They make it possible to apply plant protection treatments to areas which could otherwise not be covered before for financial reasons, but meeting regulatory requirements.

- They increase dosages and uses through being abused.

The first assumption cannot stand, given the risk assessment process that must be undergone before the first MA is issued for a patented product for which use in the effective agricultural area (SAU- in French surface agricole utile) was not limited.

Making the second assumption amounts to arbitrariness against agricultural practices and, equally indisputable, questioning the effectiveness or efficacity of controls on the farm or conditional support (new CAP)

It would, again, be arbitrary to forget, quite simply, that reducing plant protection costs helps increase the income and productivity of farmers, whose responsibilities under GAP [Good

Agricultural Practices] trumpeted so highly and politically adds to their natural good financial management abilities.

Put in a nutshell, the idea that any increase in the PPPs used could be a direct result of opening the market up to cheaper generic products helps encourage passions for a thoughtless risk culture, to the detriment of their effective management, makes a mockery of current national and Community regulatory practice, is contrary to the principles of law and to a certain idea of a 'good sense of the countryside' [the French favoured idiom is ‘farmer’s common sense’] which the politicians are so fond of referring to today.

While that answers the first question, it also raises a second:

Is opening the market up to cheaper generic products beneficial to a strategy of reducing the risks involved in using PPPs?

4- Generics encourage innovation

Under a permanent monopoly, manufacturers have never seemed focused on innovation.

It is of course faced with the threats from generics and with the aim of blocking them that better formulae appear just before patents are due to run out.

Suddenly, the latter are more suited to meet essential requirements, and are also aimed at blocking access to the market for generics that are merely a copy of the formula of the old patented speciality.

The same applies to innovation in terms of active substances, which is rarely seen while a patent is still live.

Barring the market to generics amounts to undermining any technological progress liable to improve PPP compositions and/or formulae with a view to safeguarding public health and the environment.

This stagnation is all the more harmful, given that innovation can help eliminate harmful substances.

It should also be remembered that it is precisely on this point that criminal proceedings are currently under way in Belgium against one of the major producers which maintained its own state of the art for eighteen years until implementing it enabled it to exclude the generics competing with it from the market.

5- Without true generics, the market is more likely to lead to an increase in volumes used

Real generics are those which are made completely independently of the original patent holder.

And it is they alone that create the situation to which this statement relates.

Such generics are not advertised or promoted to encourage their (over)consumption.

They are generally found in distribution outlets that the major R&D companies scorn.

Their market share reflects their low profile.

The situation is quite different when generics are designed to perpetuate patents artificially through hindrance resulting both from difficulties to obtain marketing authorisation and from the capacity of the patent holders to discourage any involvement in what they consider to be 'their' markets.

The most notable example of this is glyphosate, the patent for which came into the public domain in 1991 and for which all marketing authorisations current in 2005 are based on the old patent holder's data file.

In 1991, the market was 15 million litres.

By 2004, it was 90 million.

Admittedly, its potential market is around 350 m litres, excluding GMOs. But let's not lose hope, the manufacturers will manage, just as they managed to quadruple it in fifteen years

through a price-cutting strategy to dissuade any other operator under the effects of the data protection under Directive 91/414/EC and anti-dumping procedures against glyphosate from China.

The disastrous publicity for the product did the rest.

6- Generics are necessary to 'niche' markets and minor uses

There can be no argument that including substances in Annexe 1 of Directive 91/414 deprived the market of specialities whose effects on health and the environment were considered acceptable while perpetuating others much more open to discussion.

But there is another, equally damaging effect such inclusions have: they mean discontinuing substances patent holders consider uninteresting in terms of profitability, which deprives some minor crops of any phytosanitary protection whatsoever.

For generics, profitability criteria are different.

This is why a strong generic industry is essential, and is consistent with a risk management strategy that includes preserving the diversity of plant products.

Precisely the same applies to minor uses, for which efforts to obtain extended marketing authorisation are not something the major companies are renowned for.

7- Generics up against resistance

The attraction of novelty, combined with the effects of advertising hype that accompany new speciality launches leads to their virtual hegemony and to resistance phenomena from the parasites they fight, increasingly hard, close and frequent.

By way of example, the arrival en masse of strobilurines has, in less than five years, shown how essential the old triazoles were.

Here, once again, the existence of a generic industry strong enough to keep old specialities on the market, which the major companies have abandoned in favour of new ones, arises out of a necessity, the agricultural relevance of which should be taken into account.

Now a subsidiary question:

Would opening up the market to cheaper generic products discourage alternative to the use of PPPs?

8- <u>No</u>

The future of alternatives to PPPs depends on what farmers do.

Their willingness to use them is based more on their sense of the common good than the price of products.

Nor does any alternative, and that includes organic farming, rule PPPs out entirely from its specifications.

They are also considered more expensive than using PPPs systematically.

So, given that any sustainable alternatives do not depend on the price of inputs they replace, cheaper generics help them keep their heads above water financially.

While these arguments in favour of generics may not be exhaustive, our conclusions will draw on a comparison with pharmaceutical products, even if this might be considered invalid, given that these product costs are refunded by national Social Security systems.
Are governments making a mistake in promoting so clearly market access for generic products, while at the same time pursuing their aim of reducing unnecessary consumption of pharmaceutical products significantly?

Could the reasoning behind the State paying for these products not also apply to the farmers who pay for PPPs?

Is appealing to doctors' and pharmacists' sense of civic responsibility more likely to succeed than appealing to that of those concerned with agricultural production?