



Faus & Moliner Abogados

Impact of EU Legislative and regulatory requirements on the National Markets of Non-Prescription Medicines

How to ensure efficient authorisation and variation procedures for non-prescription medicines

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THE NEED FOR A BETTER REGULATION

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SOME NEW IDEAS

FINAL REMARKS

13554

MINISTERIO DE SANIDAD Y CONSUMO

agencia española de medicamentos y productos sanitarios

SUBDIRECCIÓN GENERAL DE MEDICAMENTOS DE USO HUMANO

División de Evaluación Clínica y Farmacología

24 de julio de 2008

Condiciones para autorizar medicamentos No sujetos a prescripción médica y/o Publicitarios

REGUNTAS SOBRE EL DECRETO 1345/2007

... clearer ...

... while guaranteeing the safety ...

... health protection.

Back to basics ...



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The self-care and self-medication sector:

- An innovative industrial sector.
- An asset to society through promotion of self-care and empowerment of patients.
- A 100% Net Asset for National Health Systems.

The rules

- General principles of administrative law.
- A tool, among others, to ensure:
 - Protection of public health.
 - EU market integration.
 - Other economic policy objectives.



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General principles of administrative law:

- Compliance, specially as regards delays.
- Ensure full application of EU rules.

Policy:

- Consider changes in administrative practice.
- Be open to changes in the law.
- Prepare for new systems.



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Written laws:

- Delays must be observed.

- Applicant to be informed on calendar within 10 days from receipt of application.

- If workload requires, additional resources may be put in place.

- In exceptional cases, an extra term not to exceed the length of the original one may be approved and notified to the interested parties.

In practice:

- Delays are not met.

- Acknowledge of receipt and calendar is sent when validation is confirmed.

- Unaware about additional resources having been put in place.

- Never seen this happen.



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Written laws (RD 1345/2007 and Agemed Instructions):

In practice:

- | | |
|---|--|
| <ul style="list-style-type: none">• Type IA, 30 days for validation. | <ul style="list-style-type: none">• Validation 2-3 months is frequent. |
| <ul style="list-style-type: none">• Type IB, 15 days to validate and 30 to resolve. | <ul style="list-style-type: none">• Average nearer to 6 months. |
| <ul style="list-style-type: none">• Type II, 15 days to validate and 90 to resolve. | <ul style="list-style-type: none">• Average nearer to 12 months. |
| <ul style="list-style-type: none">• MA applications, 10 days to validate and 210 days to resolve. | <ul style="list-style-type: none">• Whole process takes well over a year in average. |



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Some ideas (Policy):

- Recognize that a problem exists (i.e. collapse for SmpC approvals on renewals).
- Willingness to solve it: high quality procedures are a competitive tool.
- Anticipate changes where possible: Do and Tell for Type IA variations of national applications.



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Advertising of non-prescription medicines:

- Acknowledge ECJ ruling in Gintec case: harmonization of advertising rules is complete.
- Directive 2001/83/EC sets forth the right to advertise non-prescription medicinal products.
- Approval process does not and cannot require separate assessment of eligibility for advertising.
- Advertising of a non-prescription medicinal product can only be banned if message does not comply with rules.



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Some ideas (Policy):

- Isolate the matter from other issues.
- Reconsider position before being forced by a Court case.
- Free resources and allocate them to other tasks: i.e. to reduce delays.



OPEN TO CONSIDER NEW IDEAS

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Prior approval system for advertising may be revisited:

- Changes in prior approval system are possible:
 - shorten period for positive silence, currently 60 days,
 - convert process into a do and tell system.
- Other players shall be vigilant.
- Self-regulatory bodies may help.
- Administrative resources may be better used.



FINAL REMARKS AND CONCLUSIONS

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- Better regulation does not mean deregulation.
- Nothing is 100% new, see other EU Member States.
- Some of these changes shall happen, we better be prepared.
- Courts could force some changes. It is always better to lead the change process.
- Win-win is always good: suggested changes report benefits for MOH.



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End of presentation

Thank you for your attention