

Risky Business: Big changes, coming soon, to a pharmaco near you!

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Nostrapharmus predicts big changes in the way R&D projects are selected, big changes in the role of the regulator. Very soon, a general adoption of Risk Management (RM) in regulation and in development investment will increase both flexibility and safety. **And** it will greatly enhance the industry's capacity to develop drugs for future need.

What's driving change?

The present, paper-heavy system of regulation doesn't stop Serious Adverse Events (SAEs). And when things go wrong, tick the right boxes and your pharmaco's probably off the hook – legally, at least. But the public wants heads to roll. Who's next in line? No wonder the regulators are looking for a new approach!

The tick-box system doesn't increase safety; so much as encourage risk-averse investment. Nor does it deliver better or faster drug development – which ought to be a required output. It's a one-size-fits-all, punitive approach that says *I can't tell you what to decide, but get it wrong and I'll zap you*. That's a régime that saps initiative and makes its victims sneaky, too, as any psychologist will tell you! Hence all those play-it-safe 'me-toos', added-values and market segmenting. Yet the opportunities are there. Cancer attracts investment aplenty: the pay-back is clear and as short as it gets. But that leaves a universe of unmet needs that aren't addressed because the one-size-fits-all régime makes them too risky to be prudent business. For most of them, you wouldn't reach payback before the patent ran out. Business decisions are contingent. Must we wait for the pandemic? No wonder pharmacos are desperate to find a way forward.

Shareholders are likely to agree. They don't want to see their shares crashing when somebody dies *and* the perpetrators get off. No wonder investors are finding pharma less attractive than they used to.

As a patient, I want remedies that are effective, free of side effects, cheap, and simple to use. In that order. The more serious my illness, the more important effectiveness becomes. My decision on treatment is contingent. So if business and therapy decisions are contingent, why not regulatory decisions, too? No wonder I'm looking for a bit more initiative and imagination from pharmacos and regulators alike.

The stakeholders seem to have a shared interest in a more flexible, contingent and sophisticated regulatory process.

Risk Management is the answer

The new, outcome-focused approach, where you're accountable for your SAEs whether technically compliant or not, is welcome in principle, but it needs to be backed by a systematic methodology. That methodology is, without question, RM and its accompanying IT, the smart route to fewer AEs, safe drugs, and well-aimed investment. But it's easy to do it superficially, endangering public safety. So regulators fear pharmacos will use it as a short cut to compliance. What it requires as a

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regulation tool is involvement and understanding from professional-level regulators rather than admin-level bureaucrats. We should be comfortable with that. Other industries, where public safety is key, have demonstrated pro-active regulation and found it more help than hindrance.

It demands transparency, notably in how we reach our decisions. But that transparency permits more flexibility when we're working on an unmet need than if we're on a 'me-too'. It's time, too, to face the fact that different categories of development project demand different regulatory criteria, and that different categories of company (according to AE track record, and co-operative transparency, for instance) require different levels of supervision.

Quids pro quo!

As regulators concede more flexibility, they'll seek to influence R&D portfolios by providing incentives for those needed but currently non-viable projects. Today, a bad compliance report damages both trust and value. But a good one excites no interest. More useful if it could cite specifics – for example 'an exemplary use of risk-management techniques, focussing care where it is most needed', 'an investment in patient safety 20% above the industry average'. Good PR, and investors would scent better returns for lower levels of risk. Why not double patent length when people are crying out for a remedy that's not currently viable? Offer regulatory approval very early as soon as the most likely treatment is identified, before major trials? Sound risky? *That's* already happened!

Nostrapharmus says "A risk-based approach to compliance is on its way. The burden will be enduring. But it will be well worth it: the benefits are there for the taking. Ten years on, a risk-based approach, varying the régime with the situation, will be the norm from companies and regulators alike. As they promote RM in pharmacos, regulators will rapidly adopt what they advocate. They'll concentrate their attention where it will have the biggest pay-off in public safety and health – or lose all credibility. So the regulator's new role, more important and much more useful than before, influencing the approach to the future rather than identifying the unadmitted errors of the past, will protect us from the risks of today's medicines AND from the risk of not having the right medicines in the future. Regulatory incentives will give pharmacos the incentive to invest in future need, reducing the very real risk of ignoring important, unmet needs that, as things stand, offer no commercial pay-off. Public Good and Private Profit: it's win-win at last!"



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