

The Crofter: Sustainable Communications

Editorial

Greetings from the croft! In this special issue on medical journalism, we have two contributions that discuss topics that have enjoyed attention in the press: 1. the emerging environmental problem because of the growing drug market for pets, and 2. vaccine inequality. Louisa Marcombes provides

an overview of veterinary environmental risk assessments (ERAs) and upcoming changes when Directive 2001/82/EC will be repealed and replaced by Regulation (EU) 2019/06 in 2022. Jen Bell discusses how distributed manufacturing and other considerations can help make the vaccine industry more sustainable. I hope you enjoy

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reading about these two emerging areas where medical writers and communicators can have an impact.

Kimi

Paradigm shift, same old, or something in-between? What does the new EU veterinary medicines directive mean for the environmental risk assessment of veterinary medicinal products?

The emission of veterinary pharmaceuticals into the environment is an emerging problem,^{1,2} not least because of significant growth in the pet drug market.³ A 2014 report by CHEM Trust has identified the presence of pharmaceuticals in the environment as not only a threat to ecosystems but also to human health with the potential for contamination of drinking water and crops.² Behind the stories that have reached the mainstream media, such as mass death in India of vultures that have fed on carcasses of cattle that had been treated with the non-steroidal anti-inflammatory agent diclofenac,⁴ there is a mounting body of evidence of the damage caused by veterinary medicinal products (VMPs) in the environment.⁴ Despite this, extensive knowledge gaps remain about how and to what extent pharmaceutical emissions impact the environment.²

The environmental risk assessment (ERA), an “analysis of the potential risk that the use of a medicine poses to the environment”,⁵ has been, in one form or another, a legal requirement for the EMA’s marketing authorisation (MA) process for VMPs since the mid-1990s.¹ ERAs are the regulatory framework designed to mitigate the impact of VMPs on the environment. It has been proposed by Casa-Resino et al.⁶ that such legislation should satisfy three basic



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requirements: 1. that the environmental risk for every marketed VMP is known, 2. that the technical requirements to measure this risk do not result in excessive regulatory burden, and 3. that the conclusions of ERAs are consistent and reliable across all VMPs.

The legal basis of ERAs of VMPs authorised by the EMA are currently determined by Directive 2001/82/EC. On January 28, 2022, this directive will be repealed, and its replacement, Regulation (EU) 2019/06, comes into force. Here, the current format of veterinary

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ERAs is reviewed, followed by a preview of what changes can be expected with the new legislation. The regulatory change is then discussed in the context of the recent controversy surrounding the use of the antiparasitic treatment, fipronil, in pets and, finally, what this means for medical writers with interest in the environment and sustainability.

The environmental risk assessment (ERA) process

Under the current EU Directive, 2001/82/EC, the ERA framework is a two-phase procedure (Figure 1).¹ Phase I screens the candidate VMP for the risk of significant exposure of the environment to the active substance in the context of its intended licensed use. Guidelines by the Veterinary International Conference on Harmonisation (VICH), VICH GL 6,⁷ have facilitated a much-needed consistency in the standard of Phase I ERAs since its publication in 2000. VICH GL 6 is an algorithm composed of 19 polar questions. There are two possible outcomes: low risk or elevated risk. An outcome that indicates a low risk of

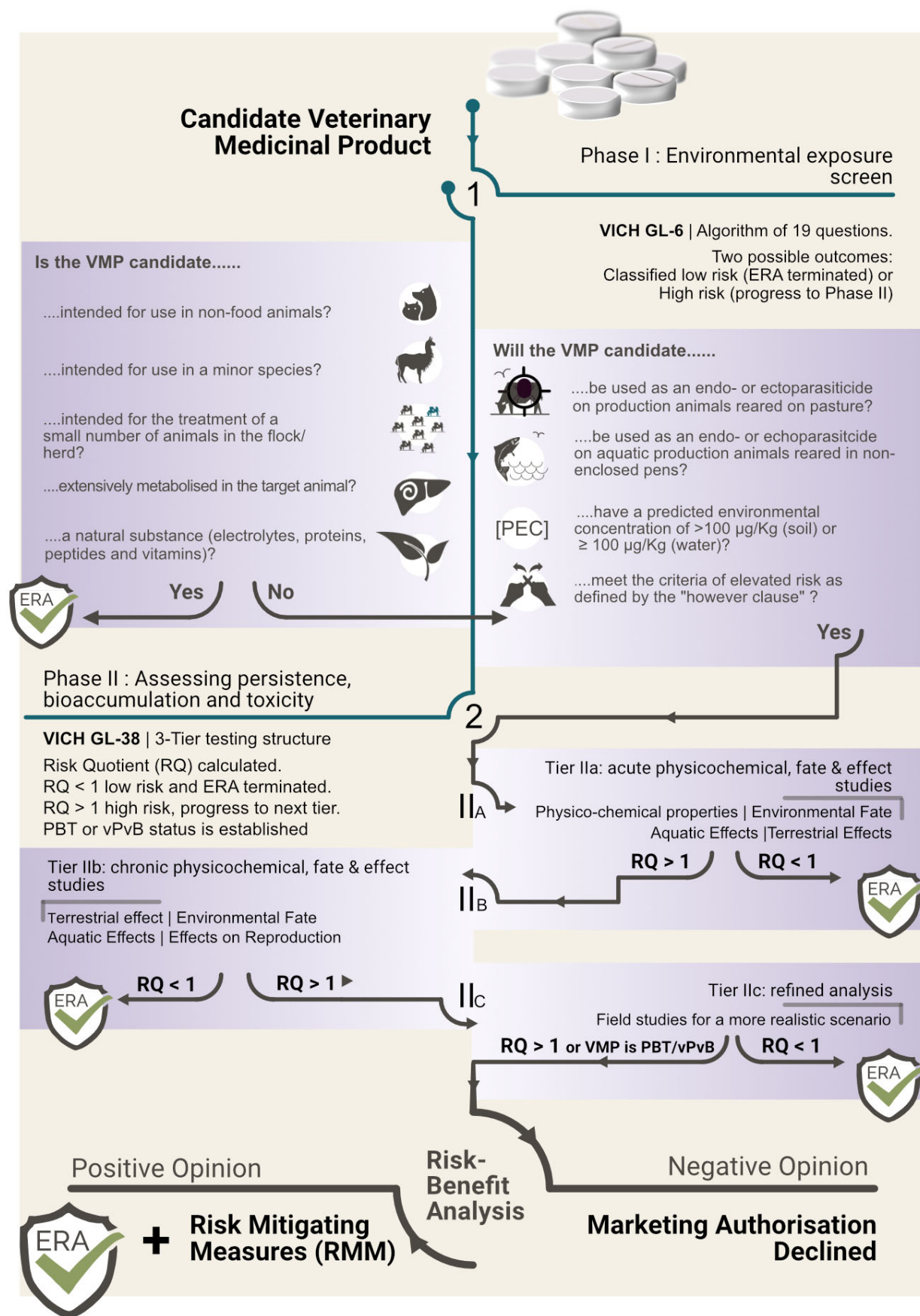


Figure 1. Schematic representation of the environmental risk assessment procedure (ERA) framework for the Authorisation of Veterinary Medicinal Products by the European Medicines Agency (based on Directive 2001/82/EC)

Abbreviations: ERA, environmental risk assessment; VMP, veterinary medicinal product; VICH GL, Veterinary International Conference on Harmonisation Guideline; RQ, risk quotient; PBT, persistent, bioaccumulative, toxic; vPvB, very persistent, very bioaccumulative; RMM, risk mitigating measures.



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environmental exposure is sufficient to terminate the ERA. This is systematically the case for VMPs where the target species is a non-food producing animal, a minor species, or intended for limited treatment of individuals in the flock or herd (Figure 1).

VMPs for which a high risk of environmental exposure is anticipated, including all endo- or ecto- parasiticide treatments intended for production animals at pasture or fish in open pens, results in progression to Phase II for higher-tier risk assessment. Likewise, for the same category of production animal target species, VMPs which exceed a set environmental threshold (predicted environmental concentration [PEC] of candidate VMPs in soil [$> 100 \mu\text{g/kg}$] or water [$> 1 \mu\text{g/L}$]) will proceed to phase II assessment (see Figure 1). A VMP that would also ordinarily stop at Phase I may also progress through a provision commonly referred to as the “however clause”, where there are known environmental risks associated with the VMP.⁸

Phase II is designed to quantify the degree of persistence and bioaccumulation in the environment, and toxicity to the ecosystem including the micro- and macro-organisms within it. Harmonisation of this complex process has been assured by guidelines detailed in VICH GL 38.⁹ Phase II

is itself divided into three increasingly complex tiers (Figure 1): Tier A (acute effects), Tier B (chronic effects & reproductive effects), and Tier C (refined analysis).

At each tier, a predicted no effect value (PNEC) and the PEC are calculated using toxicological endpoints. A risk quotient (RQ) is calculated by dividing exposure by toxicity (PEC/PNEC) for each affected ecological compartment.⁶ A value < 1 is considered low risk sufficient to terminate the ERA (Figure 1). A value > 1 results in progression to the next tier. If, after tier C, the RQ is persistently elevated, an overall benefit/risk judgement is taken by the Committee for Medicinal Products for Veterinary Use (CVMP). A positive opinion leads to a MA for the VMP, often with product-specific risk-mitigating measures (RMM). RMMs are most commonly handling and administration measures for the VMP detailed in the summary of product characteristics (SPCs).¹ A negative opinion results in the refusal of the MA. This is a provision that sets Directive 2001/82/EC apart from the equivalent directive for humans is 2001/83/EC, where a negative outcome of the ERA cannot be used as a basis to refuse a MA.¹ Phase II analysis also determines if the candidate VMP meets persistent,

bioaccumulative or toxic (PBT) or very persistent, very bioaccumulative (vPvB) criteria. Under the current regulations, this usually results in the requirement for RMM and pharmacovigilance measures.¹⁰

Limitations of the current veterinary ERA (under Directive 2001/82/EC)

Do the current regulations satisfy the three requirements for environmental regulation of VMPs, as proposed by Casa-Resino et al.²⁶ They have argued not. ERAs of VMPs have been harmonised since they were first introduced in 1998, when there was an unacceptable variation in quality and scope. As a result, there is a discrepancy between the ERAs of older VMPs and those with more recent MAs. VMPs authorised before 1998 have no ERA at all. Therefore, the environmental risk of all VMPs is unknown, and all existing ERAs are not consistent and reliable. Furthermore, the ERAs prescribed by Directive 2001/82/EC are product-based rather than active substance-based. That is to say that for every VMP undergoing an MA application, an ERA is mandated. Even if the active ingredient is a generic and the reference drug has already undergone a full ERA. This is a source of friction

and inefficiency in the regulatory framework and, it is argued, places an unnecessary regulatory burden on applicants wishing to bring a VMP to market.¹

The “referral procedure” (Article 35 of Directive 2001/82/EC) gives provision for a VMP that already has an MA to be “referred” for post authorisation review. This is a mechanism by which older VMPs can be updated by review of the risk-benefit balance. However, the legislation lacks a systematic mechanism to identify these products, relying instead on member states to take the initiative to trigger a referral.⁶ In reality, this is a seldom-used legislative route, with only 20 referral procedures triggered to date.¹

The inferior quality of older ERAs and the lack of a systematic “catch up” mechanism for updating them is a recognized weakness of the current legislation.⁶ Another perceived weakness includes the absence of legally binding pharmacovigilance of the environment, although this is partially achieved indirectly through the Water Framework Directive [2008/105/EC].¹ Furthermore, the directive governing ERAs does not take into account emissions that result from the manufacturing of VMPs, which many would consider a significant omission.

Regulation (EU) 2019/06: What's new?

One of the overriding objectives of the EC regulations for VMPs (EU) 2019/06 is better alignment with the European Green Deal.^{6,11} An additional aim is to reduce the legislative burden that encumbers the MA of a new VMP to increase the market availability of VMPs, while “guaranteeing the highest level of public and animal health and environmental protection” (Recital 5). With these stated policy drivers, what changes come into effect on January 28, 2022? And will they usher in the improvements needed?

The technical aspect of undertaking an ERA for a candidate VMP changes very little with the new legislation. The 2-phase framework of the ERA is preserved, along with the criteria which determine its progression through the phases.⁶ The ERA process also remains product-based rather than pivoting to an active-substance-based framework. However, the legislation has required that the EU publish a feasibility study (Article 156) of a “monograph system” (or alternative) to establish an ERA database of active ingredients that could pave the way for such an active substance-based assessment.

Article 72 gives member states the power to request additional environmental hazard information, the “catch-up procedure” lacking in the

prior legislation. More explicitly stated than in the preceding legislature, it determines the right for the EMA or other competent authority to request an ERA for the VMP of a generic, where the reference VMP was granted before October 1, 2005. Once again, however, it relies on the initiative of the competent authority, and critics fear the essential mechanism to systematically pick up these older VMPs is lacking.

Elsewhere, Article 37.2, for the first time, gives regulatory guidance on the management of VMPs categorised as PBT/vPvB. It gives provision for the refusal of a MA because the candidate VMP is a PBT/vPvB. There are, however, a couple of caveats. The first is that this applies only for VMPs intended for use in food-producing animals, implying PBT/vPvB VMPs will be authorised in pets as before. The second is that PBT/vPvB VMPs can be authorised for production animals if it is “essential to prevent or control a serious risk to animal health”. A definition of “serious risk” has not been provided.

These are the headline changes in the legally binding aspects of ERA legislation. Additionally, Regulation EU 2019/06 contains some notable recitals, which, although not legally binding, can be interpreted as a statement of intent from the EU and may signpost the direction of travel for future legislation. The recommendation that any VMP posing a severe environmental risk be subjected to monitoring (Recital 32) could feasibly be delivered through the Water Framework Directive (2008/105/EC) by inclusion on the surface water watch list. Or the list of priority substances, which facilitates the setting of environmental standards and addresses emissions from manufacturing (Directive 2010/75/EU). Adverse event reporting is also encouraged, where elevated concentrations of the VMP in soil or water are identified (Recital 56).

Fipronil: a case study and a cautionary tale

In their review of the ERAs of centrally authorised VMPs undertaken between 2005 and October 2019 (n=109, with 200 authorised before 2005), Fabrega and Carapeto¹ found that 95% were considered sufficiently low risk to have terminated the ERA at the end of Phase I. This included the 65 that were intended for companion animal use only. Of the five VPMs that underwent Phase I and Phase II processes, two were identified potentially PBT. One

product, eprinomectin, an antiparasitic treatment in cattle, was refused MA in 2018 due to environmental concerns. A further two have had their MA withdrawn for the same reason: zinc oxide in pigs and tylosin in calves, pigs, turkeys, and chickens, after being subjects of a referral procedure. If this data from centrally authorised procedures can be extrapolated to VMPs that have received MA through other routes, then it could be surmised that the number of VMPs subjected to the higher tier environmental risk assessment is low. This may be justified, but the systematic audit of the ERA process itself is lacking, so it is difficult to tell.

Fipronil is an insecticide widely used in agriculture as a crop pesticide and VMP to treat external parasites in companion animals. Fipronil has been identified as toxic to honey bees, having been implicated as a causative agent in a mass mortality event in France in the mid-nineties.¹² As a result, it has not been used in the agricultural sector in the UK since 2015,¹³ and the EU regulatory body revoked its authorisation for use as a plant protector in 2017 (Commission Regulation [EU] 2019/ 1792). Nevertheless, fipronil is still extensively used in cats and dogs to treat fleas and ticks. Furthermore, in the UK and elsewhere, it is available without a prescription. In 2020, there were 66

authorised products containing fipronil in the UK.¹³

Perkins et al.,¹³ using data obtained from 20 English freshwater rivers between 2016 and 2018, found fipronil residues at all 20 sites, and that 16 of these had mean concentrations exceeding the chronic toxicity limit, with a further six sites having mean concentrations that exceeded the acute toxicity limit. The calculated risk quotients indicated a high risk to aquatic ecosystems. Given that agricultural use had all but ceased, the authors claimed this was evidence of companion animal VMPs entering the waterways via household drains and called for a change in the regulations that govern the ERA of companion animal parasiticide products.

This evidence gives rise to several questions about the effectiveness of ERAs. Is the assumption embedded in VICH GL 6 that VMPs used to treat companion animals are at low risk of environmental exposure erroneous? With this derogation, pets' VMPs never undergo higher-level environmental testing and are never screened for PBT/vPvB status. The rationale for this assumption states that high-risk emission of

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non-food animal VMPs is less likely because there is less of the “total amount of product used”.⁷ However, there are estimated to be 85.2 million dogs and 103.8 million cats in Europe, compared with 87 million bovines and 98 million small ruminants.¹⁴ The logic of this assumption is open to challenge, particularly when the VMP is accessible without a prescription, which probably increases its use substantially. Incidentally, there is a provision in Regulation (EU) 2019/06 to restrict the prescribing practice of off-licence VMPs in aquaculture (Article 114.3) for environmental reasons.

The EMA has acknowledged the emerging evidence regarding the use of parasitocides in companion animals and is in the process of preparing a reflection paper on the issue.¹⁴ Nonetheless, this demonstrates how, as knowledge gaps are closed, insufficiencies in the current veterinary ERA framework are unveiled.

Veterinary ERAs and medical writing

There is no doubt that environmental issues are front and centre in the public discourse. Ecotoxicity caused by human and animal pharmaceutical products is a subject of public interest, as evidenced by the fact that the paper by Perkins et al. has been reported in the mainstream media.¹⁵ This has resulted in a debate on social media platforms amongst both lay and professional groups. Robust communications criticising the current VMP ERA framework have been published in the veterinary press¹⁶ and documents produced in their defence.¹⁷ This ongoing controversy belies an unmet need for stakeholders to sit down and determine what protection society wants from ERAs, not just for pet flea products but all pharmaceuticals. There is also criticism of the tension between commercial confidentiality and accessibility of the information contained in ERAs, with confidentiality currently taking precedence.¹⁸ Veterinary ERAs are no longer a niche concern and will require biomedical communication services beyond the regulatory writing domain. For medical writers and communicators wishing to learn about human and veterinary ERAs, this article is the first of a series in *The Crofter* that will take an in-depth look at ERAs. A webinar on ERAs for EMWA members is also coming soon.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by EMWA.

Conflicts of interest

The author declares no conflicts of interest.

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Distributed manufacturing and other factors in building a sustainable vaccine industry

Introduction

At the Research Quality Association (RQA), 14 attendees came together to discuss distributed manufacturing on May 4, 2021. A *Trends in Biotechnology* article called “Build a Sustainable Vaccines Industry with Synthetic Biology” provided the basis of discussion. Centralised manufacturing commonly practiced by the pharmaceutical industry is challenging as it uses extensive supply chains. These supply chains are risk laden during transport of sensitive medicines in remote locations. Participants were industry quality management professionals. To raise more awareness of distributed manufacturing a similar meeting was held by the European Medical Writers Association (EMWA) Veterinary Special Interest Group (vetSIG) on July 30, 2021. The participants were medical writers and communicators. An observer report was written after the meeting. A link to the observer report is available at the EMWA vetSIG homepage @

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<https://www.emwa.org/media/3936/vetsig-q3-meeting-july-30th-observer-report-with-slides-.pdf>.

The aim of this article is to further build awareness in the EMWA community of the role of distributed manufacturing and other considerations in building a sustainable vaccines industry, and opportunities for medical writers and communicators. The article integrates key points from two previously published articles, “Distributed Manufacturing of Accessible Treatments” and “Build a Sustainable Vaccines Industry with Synthetic Biology – a Summary.”^{1,2,3}

Roughly 75% of the 1.8 billion vaccine doses administered worldwide have gone to just 10 countries.

In the news

The Telegraph published an article on June 1, 2021 saying:⁴

- “Roughly 75% of the 1.8 billion vaccine doses administered worldwide have gone to just 10 countries.”
- “Nations including Madagascar, South Sudan, and Papua New Guinea have vaccinated less than 0.01% of their population.”
- “WHO chief Dr Tedros Adhanom Ghebreyesus alongside the heads of three other UN bodies, said a “two-track pan-

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demic” was developing “with richer countries having access and poorer ones being left behind”.

On August 18, 2021, the WHO Director-General Dr Tedros Adhanom Ghebreyesus, explained that he asked for a “temporary moratorium on boosters to help shift supply to those countries that have not even been able to vaccinate their health workers.” In his opening statement he highlighted:⁵

- “Just 10 countries have administered 75% of all vaccine supply and low-income countries have vaccinated barely 2% of their people. I called for a temporary moratorium on boosters to help shift supply to those countries that have not even been able to vaccinate their health workers and at-risk communities and are now experiencing major spikes.”
- “Vaccine injustice is a shame on all humanity and if we don’t tackle it together, we will prolong the acute stage of this pandemic for years when it could be over in a matter of months. When G20 health ministers meet on

the 5th and 6th of September in Rome, I will call on them to consider the fragility of this historic moment and make a clear defining commitment to solidarity.”

There is pressure for a COVID-19 vaccine to be available for everyone on the planet.

The vaccine production model needs to change

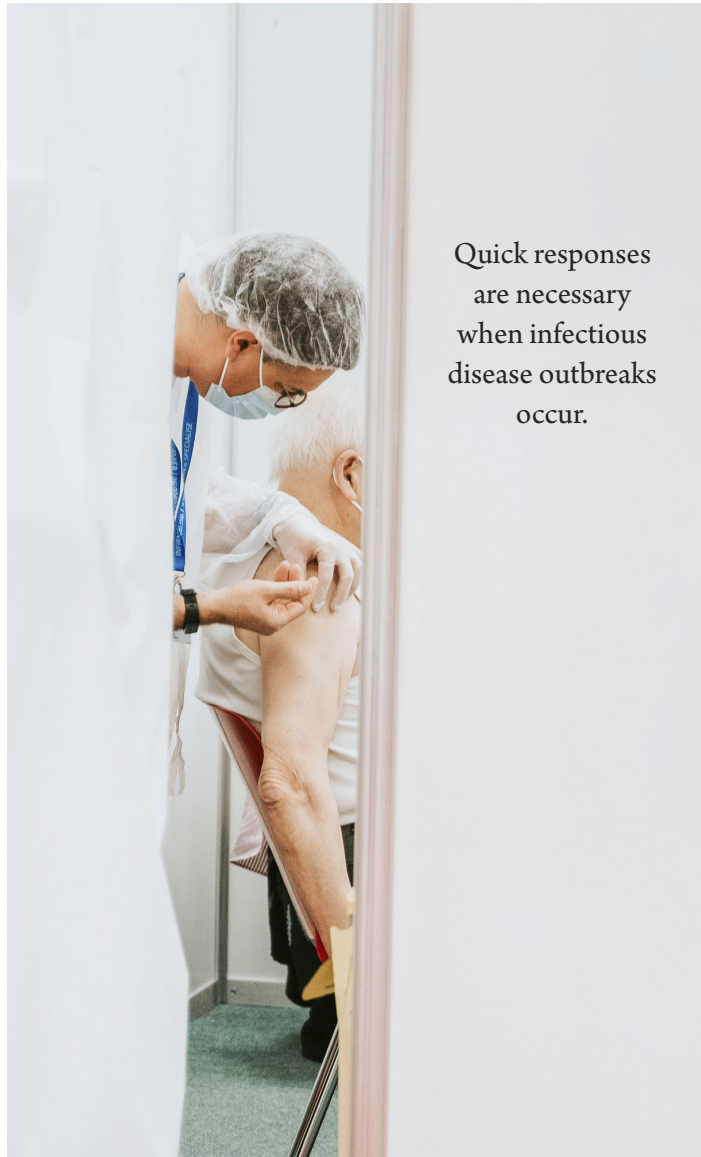
The vaccine industry has been in a difficult situation for a long time. Spending on vaccines is insignificant compared to other interventions. Five multinationals produce 80% of vaccines. There are poor financial returns to the vaccine industry and high production and R&D costs. Manufacturing facilities are capital intensive. Lower-income countries buy vaccines when they are more affordable. Before that, manufacturing costs are covered by vaccine sales in high-income countries.

Distributed manufacturing, a more sustainable vaccine model

Traditional centralised vaccine production supply chains do not have complete geographical coverage. In 2015 distributed manufacturing was in the World Economic Forum top 10 emerging technologies. Distributed manufacturing complements centralised vaccine production and would ensure vaccine production is close to the final customer. Much of the material supply chain is replaced by information.

The distributed manufacturing idea overcomes supply chain issues. All required information is electronically transmitted directly to local manufacturing sites. In theory, distributed manufacturing could enable regions to access treatments for themselves. Underserved communities are often thought of as existing in low- and middle-income countries, but they exist in high-income countries too.

The pharmaceutical industry has a wealth of knowledge and experience. It started immense efforts to manufacture and distribute medicine to over 8 billion people. This distributed manufacturing idea complements pharmaceutical



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industry efforts. It is an idea that requires thought and collaboration from lots of people. Constructive, transferrable, and innovative ideas are needed as the model has its own challenges.

Pharmaceutical and medical device areas which should be considered include various operations, GxPs, and regulations. (GxP is a collective acronym for industry standards like Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice and more.) Some other considerations include angel investors, accreditation, AI, biofoundries, business ecosystems, chemicals, clinics, communication, computing, consumables, crowd funding, culture, digital biology, documents, economics, engineering biology, environment, epidemiology, equipment, ethics, franchises, information technology, law, logistics, machine learning, medicine, mobile labs, mobile manufacturing,

monitoring, policy, politics, prediction, records, reagents, regulation, revitalisation, robotics, small scale manufacturing, society, standardisation, supplies, sustainability, synthetic biology, university hospitals, and writing.

In time, community manufacturing sites could result in business ecosystems. This would bring more opportunities to those locations. A broader range of biotechnology products could be manufactured. For example, medicines for a variety of conditions or enhancement of crops for growth under difficult environmental conditions.⁶

Other considerations

Downstream of synthetic biology

Small volumes of mRNA vaccines can produce a large number of vaccine doses. A smaller facility footprint would benefit from single-use disposable culture systems. These systems reduce fixed costs dramatically and can be established more quickly than hard-pipe facilities. Many chemical engineering tools for bioprocess intensification are already available.

Robustness, standardisation, and quality

Process standardisation and robustness are essential to guarantee the safety, efficacy, quality,

and consistency of product. Environment, equipment, reagent, and operator skill variations influence robustness. Standardising and measuring influences show compliance with manufacturing limits documented in regulatory dossiers. Automation will make processes at each manufacturing site more comparable.

Safe-by-Design synthetic biology will incorporate robustness into the automated engineering cycle. Safe-by-Design is consistent with pharmaceutical industry Quality-by-Design outlined by the US FDA.

Data format standards include Synthetic Biology Open Language (SBOL)⁷ and Digital Imaging and Communications in Medicine-Synthetic Biology (DICOM-SB).^{8,9}

Responsive regulation

National regulatory authorities need to be

flexible. They need to follow the evolving science to develop regulatory requirements.

Distributed manufacturing of vaccines needs greater regulatory harmonisation between countries. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a global standard harmonisation resource.

The “WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products” helps guide countries on what to do to register medicines to treat their population.^{10,11} The global benchmarking tool points out that there are established guidelines that national regulatory authorities need to follow to approve medicines for use. They include:

- “Critical requirements need to be reviewed ... For example, label indication, mode of usage or application, storage conditions, and Good Manufacturing Practice certificates and reports.
- “Information ... should be documented and monitored. For example, location of deployment, quantities to be deployed, and identity of persons to receive and manage deployment.”

In 2017, only 30% of WHO member country national regulatory authorities could regulate their own medical products.¹² WHO has 194 member states.

Sustainability

A large number of countries could conduct final manufacturing in small facilities. This would give global coverage and bring manufacturing closer to the point of need. The United Nations Sustainable Development Goals make explicit reference to the need for affordable vaccines. There is evidence that the pharmaceutical industry is more emissions intensive than the automotive industry. Information transfer, instead of material transport, saves money and emissions, lowers risk due to cold chain failures, and speeds innovation.¹³

Vigilance

Since 2000 several human viral disease outbreaks have occurred. We have been unprepared for all of them. For each outbreak, money became available. Then money disappeared when the immediate danger subsided. Quick responses are necessary when infectious disease outbreaks occur. Electronic real-time tracking and predictive tools help public health decision making.

Challenges

Distributed manufacturing raises questions about challenges. For example:

- What is economic viability like? What happens during periods of low demand?
 - There are opportunities in biomolecules and biosystems innovation – perhaps \$500 billion to \$1.2 trillion worth of opportunities.
 - Biofoundries support in vitro and in silico toxicology testing.
- How are cyber-attacks prevented?
 - Blockchain technology is the obvious solution to enhance cyberbiosecurity.
- How can talent and education systems be developed?
 - Biologists need greater knowledge of computer science and IT systems and vice versa.

Outstanding questions

- What technical barriers exist to getting mRNA vaccines to the marketplace?
- How feasible is vaccine production in very small production plants?
- What biofoundry key attributes are needed for this model?
- Realistically, is this model economically viable?

See the answers to these questions in “Build a Sustainable Vaccines Industry with Synthetic Biology”: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>

Immediately apparent public policy issues

Distributed manufacturing of vaccines has an immature infrastructure that needs focused development. Several key technologies need to be integrated:

- Predictive epidemiology tools
- Real-time tracking of the evolution and spread of a virus in an open access platform
- Rapid detection of mutants
- Technologies like RNA printing
- Responsive regulation
- Cyberbiosecurity like Blockchain solutions
- Talent and education to create a workforce.

The University of Cambridge estimates an “optimistic loss” to the global economy due to COVID-19 of \$3.3 trillion and, in the worst case, a loss of \$ 82 trillion over 5 years.¹⁴ The World Economic Forum predicted \$1 trillion of damage

to global tourism in 2020 alone. The World Bank predicted that 150 million more people would enter extreme poverty by 2021 as a result of COVID-19.¹⁵

Spending on a solution to enable the world to respond quickly in the future will not seem expensive in comparison.

Please take this idea, make it your own and share it

Distributed manufacturing provides lots of writing opportunities. There are opportunities to share the distributed manufacturing idea with communities who might be interested in getting involved. As well as that, there are opportunities to turn documents already developed within the medical writing and communication spectrum towards distributed manufacturing, i.e., making document templates that already exist fit-for-purpose for distributed manufacturing.

“Build a Sustainable Vaccines Industry with Synthetic Biology” was published online in January 2021. Please read the paper: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834237/>

The Global Biofoundries Alliance (GBA)¹⁶ is based at Imperial College London.¹⁷ It is a network of institutions that share knowledge, infrastructure and expertise. The GBA objectives are to:

- “Develop, promote, and support non-commercial biofoundries established around the world.”
- “Intensify collaboration and communication among biofoundries.”
- “Collectively develop responses to technological, operational, and other types of common challenges.”
- “Enhance visibility, impact and sustainability of non-commercial biofoundries.”
- “Explore globally relevant and societally impactful grand challenge collaborative projects.”

If you are interested in getting involved with biofoundries, message the GBA directly. Here is a link to their contact page:

<https://biofoundries.org/contact>

RNA technology experts are in university molecular biology departments. Look at the GBA members list and consider expanding the alliance to include your chosen university: <https://biofoundries.org/members>

The University of Cambridge estimates an “optimistic loss” to the global economy of \$ 3.3 trillion due to COVID-19, and in the worst case, a loss of \$82 trillion over 5 years.

The Research Quality Association (RQA) is dedicated to informing and advancing its members.¹⁸ They provide status and visibility for individuals concerned with the quality of research and development concerning pharmaceuticals, agrochemicals, chemicals and medical devices. Since its inception in 1977, the RQA has grown and developed to reflect regulatory changes, the impact of regulatory inspection and the changing structure and needs of industry. The RQA has set up a special interest group to work through the aforementioned challenges. There is a great depth of skills and knowledge that can take this idea forward. If you are interested in joining and participating in this group, please contact: info@therqa.com

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Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employers or EMWA.

Disclosures and conflicts of interest

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