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PANASONIC B&I SUPPLY CHAIN WHITE PAPER

Supply Chain Shortages in Bio Pharma – The Role of Technology

START

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Introduction

Worldwide supply chains continue to be affected by challenges relating to fallout from the pandemic including shortages, delays, and disruption. Today, business leaders identify supply chain turmoil as one of the greatest threats to their organisation's growth. Therefore, organisations need to reimagine and manage their supply chain differently to ensure business continuity and support expansion.

This is especially true in Bio Pharma, where companies are embracing the challenge of sustainability and responsible business, with a heavy focus on how the industry can better engage, monitor, and improve its relationship with suppliers and manufacturers. It is understood across the industry that environment, safety, and social outcomes are critical. Ultimately, we are all patients when it comes to the production of pharmaceutical drugs.

Here at Panasonic Connect Europe, we have combined our longstanding reputation for manufacturing technology with a focus on supply chain solutions such as SMT machines, cold chain, IoT sensors, software, and robotics. Keen to get under the skin of issues impacting the supply chain in Bio Pharma, and to understand more clearly the role that technology plays, we recently sponsored a Digital Think Tank roundtable discussion with some of the leading lights from the industry.

During the discussion we talked about how technology can be leveraged to address supply chain challenges more effectively; how supply chain shortages in pharmaceutical production impact supply chain issues related to clinical trials, including the R&D phase of products, and how risks can be mitigated. We also discussed the importance of sustainability and whether that influences decision-making processes, as well as looking at the measures organisations have implemented and their sustainability objectives.

Here we have collated the top ten takeaways from what was a highly illuminating discussion.

1. Improving collaboration is long overdue in Bio Pharma

In today's increasingly digitised world, there are new technologies being deployed across the life sciences industry all the time. These include AI, digital twinning, data analytics, and more. One of the big challenges is understanding how these technologies can be used within the Bio Pharma supply chain. But the challenge here is not the adoption of those technologies, it is bringing the people within organisations and beyond organisational walls together to implement and use them.

There certainly needs to be more cross-industry pollination of ideas around utilising technology. According to one participant we keep reinventing the wheel, when the wheel is already out there.

So how do we better leverage tech across the industry? The new hybrid environment has not only enabled flexibility, it is also encouraging more collaboration. In the past organisations were guilty of cocooning themselves within the walls of their company, but today more knowledge sharing is a positive step for the industry.

However, creating better skills velocity and digital training to adapt to new technology is a challenge, as well as determining how the industry should adapt and reshape processes based on new technology.

The safety and security of the supply chain is critical in Bio Pharma, as mass-produced drugs are used by society. While patients need medicine in a timely fashion, quality is the watchword, and drugs must have the right raw materials and ingredients.

One recent example of a lack of materials is the COVID-19 booster vaccines and the shortage of syringes which presented a challenge for drug distribution. So how should Bio Pharma companies contend with supply shortages? Here, all agreed that suppliers must be treated as key partners. A Bio Pharma company can make a vaccine in six months, but there must be enough available raw materials both up and down the supply chain for it to be effectively distributed.

“We keep reinventing the wheel, when the wheel is already out there.”

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2. Transparency and flexibility across the supply chain are essential

To better understand raw material requirements data analytics and predictive analytics play a vital role, alongside technologies such as agnostic self-planning supply chain tools where AI comes into the equation.

COVID-19 highlighted how fragile the supply chain was and how the focus for relationships with suppliers in the past was all about cost reduction and lowering inventory models. However, when clinical products are being trialled, the Bio Pharma industry must wait on the results from these studies before moving into mass production. These trials could be inconclusive, which may mean more clinical studies need to be done. This makes managing inventories and forecasting incredibly challenging.

During that process, technology can help manage overall stock and inventory levels, providing the required flexibility. IT solutions like the Blue Yonder Luminate Control Tower, for example, enable organisations to aggregate all this information to manage what they can't see and plan for what they don't know, providing dynamic, real-time visibility, with an AI/ML backbone to power end-to-end visibility of the supply chain.

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3. Understand the risks associated with distribution

All agreed that COVID-19 taught the industry that focusing on cost reduction and lowering inventory levels is risky for large-scale health challenges like the pandemic. Going forward, Bio Pharma companies must make decisions around inventory by determining the level of distribution risk associated with key products. This will, of course, be dependent on the product and influence all decisions, such as the location of its production, for example. Not all of those decisions will be made on the sole economic basis of profitability. It may be the case that Bio Pharma companies need to accept slightly higher costs for certain products, knowing that they have lowered the risk of non-delivery of a particular drug to market.

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4. The platform for improvement requires change management with a tech-positive mindset

Ensuring an understanding of responsibilities across the supply chain ecosystem is imperative. Until recently, Bio Pharma companies have struggled to effectively communicate and be transparent with partners. Post pandemic, organisations must ensure the supply chain is involved in the end-to-end process, right up until the drug reaches the patient, all understanding their respective roles and responsibilities.

Implementing user friendly technologies is key; technologies that everyone across the supply chain can easily access. Making sure partners are aligned, with the same mindset and roadmap to take ideas forward, is also crucial. If the Bio Pharma sector is only looking to achieve maximum benefit at the lowest costs, ultimately margins will be too stretched. Small steps, such as focusing on a certain segment of the supply chain, to make inroads into a process that generates value, may well provide the company with the ability to move an idea forward.

Above all, the industry needs to manage any resistance to change, ensure senior management support and buy-in, and where possible they should share examples of where supply partners have had success.

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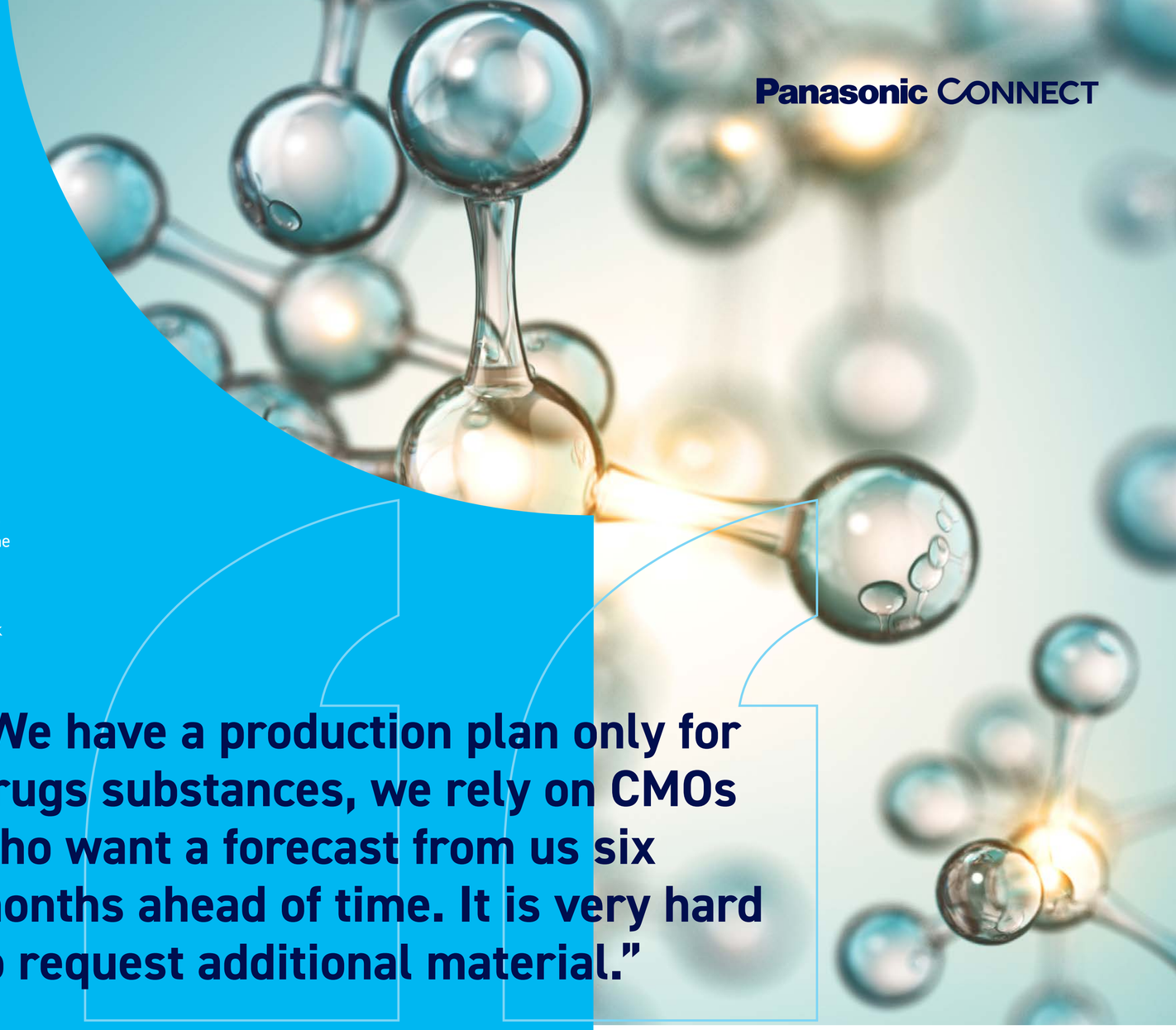
5. Coping with shorter timescales for clinical trials

When asked whether supply chain shortages in pharma production could impact supply chain issues in relation to clinical trials and, if so, how such impacts can be mitigated, all agreed that with clinical supply it is often hard to know what raw materials are needed to supply the study. In fact, the time frame for the whole process has shrunk from years to months.

Additionally, where tests were once only extended to local populations, now they must scale to global populations. This makes it hard to predict requirements. However, those in charge of production should implement and adapt their raw material strategy to acquire similar materials as back up. By doing so, they will always have raw materials to hand and an ability to react quickly and mitigate risk. It was noted that if there is a contract manufacturing organisation (CMO) undertaking drug development through to drug manufacturing on behalf of the Bio Pharma company, this can be more challenging to achieve.

One participant said, "we have a production plan only for drugs substances, we rely on CMOs who want a forecast from us six months ahead of time. It is very hard to request additional material." This is why it is important to build a partnership with the CMO with umbrella contracts that are not product specific, but focus on capacity reservation. As long as products are similar; this provides a fallback. Ultimately, if you want to mitigate the risk of a lack of inventory you must have a strong relationship with the CMO.



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6. Agree alternate supply sources

Likewise, it has become more important to have alternate partners in the pipeline in case there is an issue, so the Bio Pharma company can avoid any potential risk in the supply chain. Often the company is susceptible to the partners' supply chain issues and, in some instances, it will manage the partner's supply chain for them to de-risk any supply shortages or other challenges in their chain. To actively address this issue, Bio Pharma companies should explore alternative supply sources over a period of time.

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7. The number of clinical trials has reduced to pre-pandemic levels

According to the World Health Organisation the number of clinical trials in progress has started to decrease, and is now more in line with pre-COVID-19 levels. However, this could very easily switch course again and it is therefore important for organisations to always undertake cost-to-benefit trial calculations.

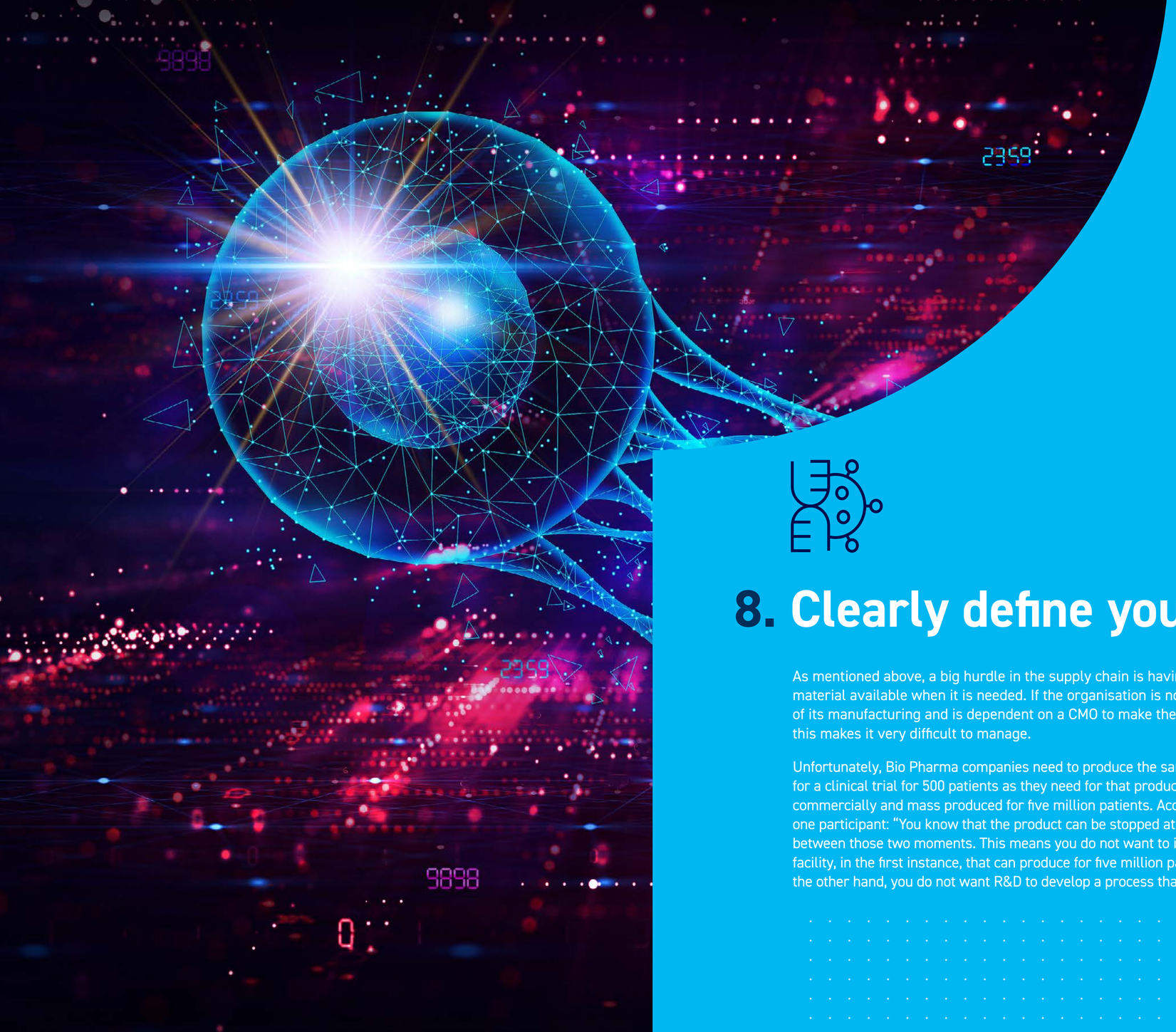
For those trials where there are high expectations, the advice is to consider having internal teams working on these initiatives so that knowledge is retained within the business, and outcomes can be closely managed.

The different phases of clinical trials vary enormously, now even more than before COVID-19 , and organisations can wait a long time for data and results from all their patients. Once back, results are analysed to understand if there is potential for a drug to work. To test the efficacy of a drug, the Bio Pharma company needs a certain amount of raw material and they must also adapt material based on any feedback.

Clinical trials tend to be increasingly global and different genetics and nationalities can play a role and affect the results. Costs are huge and Bio Pharma companies must plan for a certain percentage of failures. This was always the case, to some degree, but the pressure on the process has increased, according to the participants in the roundtable.

What is hard to calculate is that if they don't reserve space with CMOs they might not obtain the material they require. Some CMOs demand that manufacturing slots are booked one year ahead of time and, if this is not reserved, then the organisation won't make its drug trial. This is where a good relationship with the CMO to respond quickly is imperative.

“While the number of trials has reduced to pre-COVID-19 levels, this could change again in the future.”



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8. Clearly define your manufacturing strategy

As mentioned above, a big hurdle in the supply chain is having the material available when it is needed. If the organisation is not in charge of its manufacturing and is dependent on a CMO to make their material this makes it very difficult to manage.

Unfortunately, Bio Pharma companies need to produce the same product for a clinical trial for 500 patients as they need for that product to be sold commercially and mass produced for five million patients. According to one participant: "You know that the product can be stopped at any time in between those two moments. This means you do not want to invest in a facility, in the first instance, that can produce for five million patients. On the other hand, you do not want R&D to develop a process that you cannot scale." Here, it is important to work with a small-scale manufacturing line. If possible, using a service provider that is focused on clinical trials but can produce for a larger scale further down the line is advised.

Building out the manufacturing strategy and network with alternate sites as back-up is important. It is important to understand what R&D is doing. 80% of the manufacturing network design is defined by R&D and decisions they make will very much limit options in the high-scale phase. In particular, the advice here is to map out the hidden elements of the supply chain. During the R&D phase use technology to map everything out so that there is a playbook for the commercial phase and the organisation knows what to do.

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9. Sustainability is not an option – it is mandatory

When asked how sustainability influences the decision-making process and what are participants' long-term sustainability initiatives, everyone agreed that sustainability must be mandatory.

In the future, all agreed that it is important to utilise digital solutions that help map out a proactive and reactive sustainable supply chain strategy. For example, why isn't every vial reused – rather than thrown away in hospital? Could it be manufactured for reuse? Here, the circular economy and technology that enables sustainability become very important.

Circular management is important, and the industry needs to judge and balance when it makes sense. To achieve this, data is absolutely critical so that service providers, and production suppliers can all remain informed. This will become an absolute requirement in the future and by natural selection the ones who are not acting sustainably will be left out of tenders.

"If you are not sustainable you can't be part of the market."

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10. Cold storage remains a challenge

Cooling remains a big challenge for the industry in terms of how to make it sustainable.

Panasonic reinforced how one of its core philosophies focuses on society and it is focused on reaching its net zero goal by 2050. As a global manufacturer, via its factories, it is addressing renewable energy and creating innovative products and solutions, for example, cooling boxes for the rollout of vaccines. Now, Panasonic has developed a reusable box with innovative insulation. The box is not only recyclable, but features ice packs to reduce the use of dry ice, a hazardous material that requires special safety measures. Instead of simply selling cooled boxes, Panasonic has introduced an international deposit system that incentivizes pharmaceutical manufacturers to ensure boxes are returned for subsequent use.

It is difficult and expensive to change processes in the Bio Pharma industry for many of the reasons highlighted during the discussion. The cost of change, particularly for the smaller players in the current economic climate, can make certain practices prohibitive. However, where sustainability is concerned, there are smaller steps that can be taken that will reduce the environmental impact, such as utilising trucks better, planning routes, thinking about recycling and reuse, and observing some of the principles of a circular economy.

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