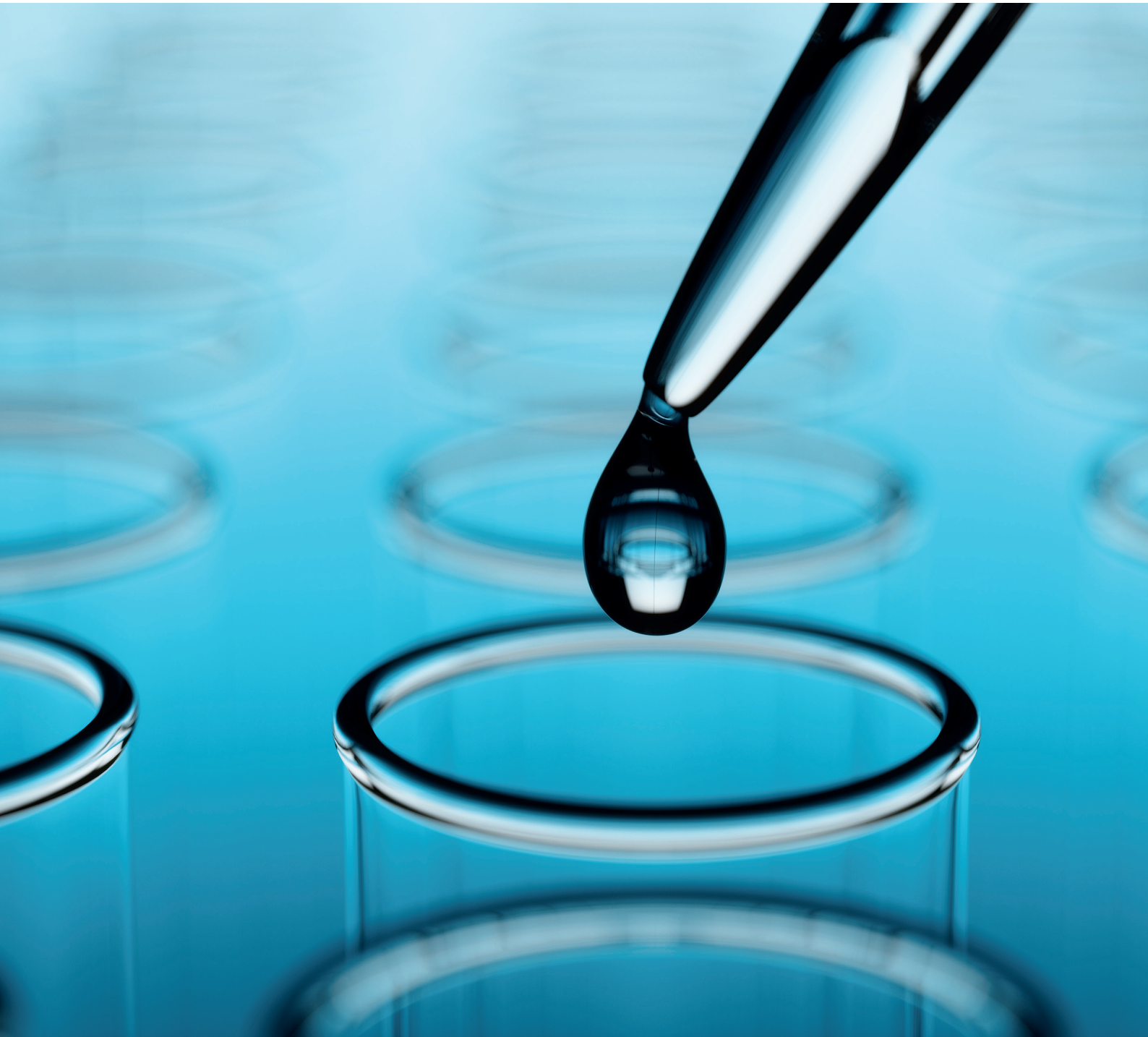
DIAGNOSING CURRENT AND FUTURE WATER RISKS FACING THE PHARMACEUTICAL SECTOR



ABOUT THE STUDY

The original concept for this case study emerged out of the water stewardship partnership between WWF and AstraZeneca. As with many sectors, there are certain shared water challenges that are more strategically relevant across multiple businesses within a sector. Common reasons for these shared water interests emerge from businesses having similar business models, operating within similar geographies, or sharing similar suppliers deeper within supply chains. This study aims to identify what aspects of water the pharmaceutical sector are currently most focused on, what potential shared water challenges may be strategically relevant for the sector in key geographies and then use these to present the sector with a set of recommended next steps.

Both WWF and AstraZeneca are extremely grateful for the participants of the Pharmaceutical Environment Group (PEG) who actively participated in helping shape this case study. The PEG consists of leading pharmaceutical companies that collaborate in order to demonstrate and promote environmental leadership in the pharmaceutical industry.

EXECUTIVE SUMMARY

THE PHARMACEUTICAL SECTOR EXISTS TO IMPROVE THE WELLBEING AND HEALTH OF BILLIONS OF PEOPLE GLOBALLY. THE PRODUCTION AND USE OF ITS PRODUCTS ALSO HAVE THE POTENTIAL TO NEGATIVELY IMPACT HUMAN AND ECOSYSTEM HEALTH - IF APPROPRIATE ACTION TO MANAGE THESE POTENTIAL IMPACTS ON WATER IS NOT TAKEN.

The sector is generally very aware of the dependencies it has on water and the potential it has for impacting water. This report focuses on how the sector is currently addressing water across its value chains and what shared water challenges it faces in the places it operates.

The report begins with an overview of the pharmaceutical sector's impacts on water and the current water focus areas across its value chain. The report then draws on the insights from a basin water risk assessment, using WWF's Water Risk Filter, of 5,272 pharmaceutical manufacturing sites around the world involved in the manufacturing of human-related pharmaceuticals. The basin risk assessment also considered future water-related basin risks by applying TCFD-aligned scenarios to the results. These insights help to illustrate how water quality risks represent a significant current and future water-related risk for the sector. It also identifies 27 large basins that host more than 60% of all pharmaceutical sites assessed. These basins present an opportunity for the sector to act collectively on shared water challenges. The last part of the report draws together all the earlier insights to present a series of 6 recommendations for the pharmaceutical sector to consider adopting both as individual companies but also as a sector.

The purpose of this report is to analyse the sector's positioning of water within the current and future water contexts in which it operates and provide recommendations for a strategic sectoral repositioning on water to meet these future challenges. The implementation of many of the recommendations within this report will represent logistical, operational, and potentially legal challenges for pharmaceutical companies. However, many of the future trends identified in this report are likely to impact how the sector operates in the future.

The report concludes that ***there is an opportunity for pharmaceutical companies to anticipate future impacts of both water quality and quantity. They could take a lead beyond regulation and work together to develop new approaches to protect these essential resources.***

PART 1
PHARMACEUTICALS & WATER

Globally it is estimated that the pharmaceutical sector contributes US$ 1,838 billion to the global GDP and the sector directly employs approximately 5.5 million people[1]. Beyond this direct contribution to the global GDP, COVID-19 has further highlighted the sectors enormous indirect contribution to the global economy. However, as with other sectors it unsurprisingly relies on human and natural resources to manufacture its products and there is a growing recognition that these collective impacts pose a potential threat to ecosystems and, human health globally.

One natural resource that the sector is both highly dependent on, and has both a direct and indirect impact on, is water. Water is a critical input into the manufacturing of medications with 85% of respondents to CDP saying that good quality water is vital for their operations[2]. The bulk of water used in manufacturing is used for cooling and maintaining temperatures of critical manufacturing steps while a smaller proportion is used for cleaning equipment and as a solvent within the manufacturing process[3]. Within the manufacturing process, the quality of the withdrawn water that is used for cooling during manufacturing is largely unchanged[4]. The water used for cleaning and as a solvent is typically subjected to treatment prior to being discharged[4]. These discharges are a potential source of residual Active Pharmaceutical Ingredients (APIs). As such, Environmental Risk Assessments (ERAs) that study the impact of APIs on the environment are included as part of the regulatory approval process for pharmaceuticals[5].

Global attention around the presence and impact of APIs in the environment is growing. An Organisational for Economic Cooperation and Development (OECD) report published in 2019 noted that there are about 2,000 APIs being produced and administered globally[6].

The excretion of APIs from patient use of medications is the primary source of how APIs enter the environment with the disposal of unwanted medication being a secondary, but also substantially lower contribution compared to patient use[7]. Pharmaceuticals are designed to have a biological effect on humans, and as such excreted APIs, when left untreated, have potential for effects on non-target animals and organisms in freshwater systems at low doses[3]. For human health, the untreated excretion of residual antibiotics in freshwater systems can exacerbate the issue of antimicrobial resistance which the WHO has noted as being a growing threat to global public health[3].

Currently, the pharmaceutical sector is generally very aware of how critical water is to its operations and as a raw material, but also as a risk to operational resiliency. Over 80% of the top 30 global pharmaceutical companies list water as one of their top sustainability focus areas (Figure 1) and 83% of pharmaceutical companies who responded to CDP in 2020 say that regularly undertake water risk assessments[2].

The current sectoral focus on water, and its associated risks, appears to be concentrated within the *Formulation/ Production* stage of the value chain (93% of companies – Figure 2). Water within *API manufacturing* is another area of publicly mentioned focus for the sector with 50% of the global top 30 pharmaceutical companies highlighting water-related activities associated with this part of the value chain. This observation is consistent with the responses to CDP in 2020 where 85% of pharmaceutical respondents said that they engaged their suppliers on shared water challenges[2]. However, despite this only 18% of these same respondents said they required more than 50% of the value chain to report against water use and provide water risk information[2].

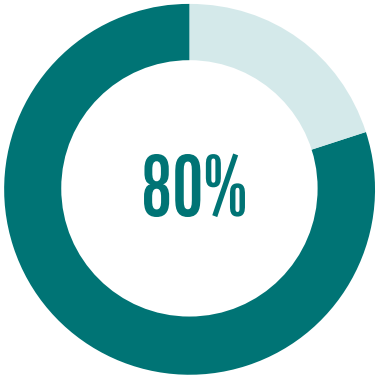
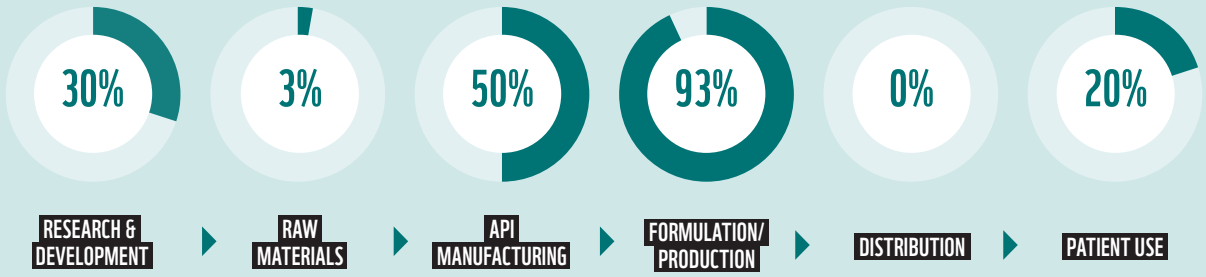


FIGURE 1:
Percentage of the top 30 global pharmaceutical companies that list water as one of their top sustainability focus areas

FIGURE 2: Simplified pharmaceutical value chain indicating where the top 30 global pharmaceutical companies (percentage) have publicly indicated where they are taking water-related actions[8]



Only 30% of the top 30 global pharmaceutical companies publicly mention undertaking water activities within the Research and Development stage of the value chain - either to reduce impacts of manufacturing or product use by patients. Another observation was that only 3% of the top 30 global pharmaceutical companies publicly mention engaging in water-related activities, or risk assessments, linked to the raw materials (most notably bulking agents that are linked to both mining and agriculture) that are used (Figure 2). A lower focus on water within raw materials is often observed across other sectors. Often this is a result of a limited visibility into suppliers who make up this part of the value chain, a lack of a direct contractual relationship with these suppliers (making it harder to "control" these impacts) or because of the structure of the market for a particular raw material (e.g., use of aggregators who buy from many small suppliers). Despite these, it often remains a potentially big water risk blind spot for companies. Lastly, only 20% of the companies publicly mention water-related activities linked to patient use, most of these are limited to general activities tied to the education of APIs in the environment or an acknowledgement of the potential impacts of APIs in the environment.

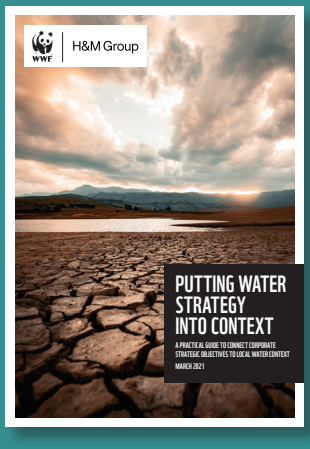
The COVID-19 pandemic has shown recently that the world is highly connected, meaning that the probability of similar global medical events, that will require a rapid deployment of the collective pharmaceutical sectors resources and knowledge, is extremely high. Rapid advancements in technology and data availability will likely need to be leveraged to respond to these events as will flexible, agile and resilient supply chains.

At the same time, there is more generally a growing public and investor expectation that the business community must focus on, and reduce, the big environmental impacts on nature and people across the full value chain. Traditionally corporate sustainability programs have focused only on managing and reporting on the reduction of environmental impacts from direct operations - in many cases this is not where the biggest significant environmental impacts on nature and people reside. Addressing these significant environmental impacts will require the business community to contextualise their water strategies – ensuring strategic action addresses big impacts across the value chain rather than just those impacts that are "easy" to reduce (See WWF's *Putting Water Strategy Into Context* for more practical guidance).

PUTTING WATER STRATEDGY INTO CONTEXT

Water is fundamentally a local resource meaning it has a unique context – therefore transformational water strategies must account for this context at their core. The way a business operates, and its contextual footprint is unique, so while there may similarities within sectoral business models it is important that every business works to evaluate its unique water context and uses this to develop an appropriate contextual water strategy. Without embedding water context into the core of a strategy, it is far harder to contextualise or adopt a "science-based" approach to target setting. WWF's guidance "Putting Water Strategy Into Context" provides a framework to embed context into strategy.

Globally there has been a general deterioration in water quality status in many local basins[2] and the growing ease of access to near-real time water data, all business that may be perceived to be contributing to the deterioration of local water quality may become targets of greater public and regulatory scrutiny. For the pharmaceutical sector this could mean greater scrutiny related to APIs in the environment – not only from manufacturing operations but also from patient use.



PART 2

WATER RISKS FACING PHARMACEUTICALS

The extent to which an individual company is exposed to water risks is unique to that company and the location(s) where it operates. This is because water risk is a function of the existing state of water surrounding it (or basin risk) and how the individual company uses water within its operations (or operational risk).

However, aspects of the local status of water (or basin risk) may result in greater potential for the exposure to water risk for companies within the same sector – primarily because these companies have similar business models. Identifying these common basin risks, within areas that have a high concentration of companies from that sector, can be a useful platform to begin to coordinate sectoral responses and actions aimed at mitigating these common sectoral basin water risks.

To identify the possible sectoral basin risks facing the pharmaceutical sector and to recommend basins in which the sector should prioritise for taking collective action, WWF ran more 5,273 pharmaceutical sites through the WWF Water Risk Filter. Global sites linked to the manufacturing of human-related APIs were identified, extracted and combined using 2 publicly available industry sources, namely: European Medicines Agency's [9] EuraGMDP database (sites from Europe and rest of the world) and the U.S. Food & Drug Administration's (FDA) Drug Establishments Current Registration Site[10].

WWFS' WATER RISK FILTER

The WWF Water Risk Filter (WRF) is The WWF Water Risk Filter (WRF) is a free online water risk assessment tool that screen for a wide range of water risks. It is the only water risk tool that can assess both basin and operational risk (which are needed to inform a complete picture of a business' water risk) and combine these to inform mitigation responses using peered reviewed global water indicators. The WRF's risk assessment framework uses a common approach to categorising water risks into three risk types, namely physical, regulatory and reputational. These risk types are broken down further into 12 risk categories. The data that informs these categories come from risk indicators, which are updated annually and sourced from trusted peer reviewed global data. Behind the scenes all this data is classified into risk score values ranging from 1-to-5 (i.e., equivalent of a scale from very low (1) to very high (5)) and adjusted to common geographical scales to allow for comparability. The aggregation of the above is presented and referred to as overall water risk.

The WRF (and other similar tools) are an important starting point in the process of understanding the potential exposure of operations to water challenges. While most of the WRF source data comes from global datasets, the tool does also have a select number of high-resolution datasets (i.e., more granular local data). Despite this, it is always recommended that the outputs of any water risk assessment from the WRF (or other similar tools) are validated by local operations.

Water Risk Filter

DISTRIBUTION OF PHARMACEUTICAL SITES GLOBALLY

The analysis of the clustering of pharmaceutical sites globally (at a basin level) showed a diverse spread across the world with most of the larger clusters being found in the Europe, India, the United States of America, and China (Figure 3). Most of the larger clusters appear to be exposed to either medium or high levels of overall water risks (Figure 3).

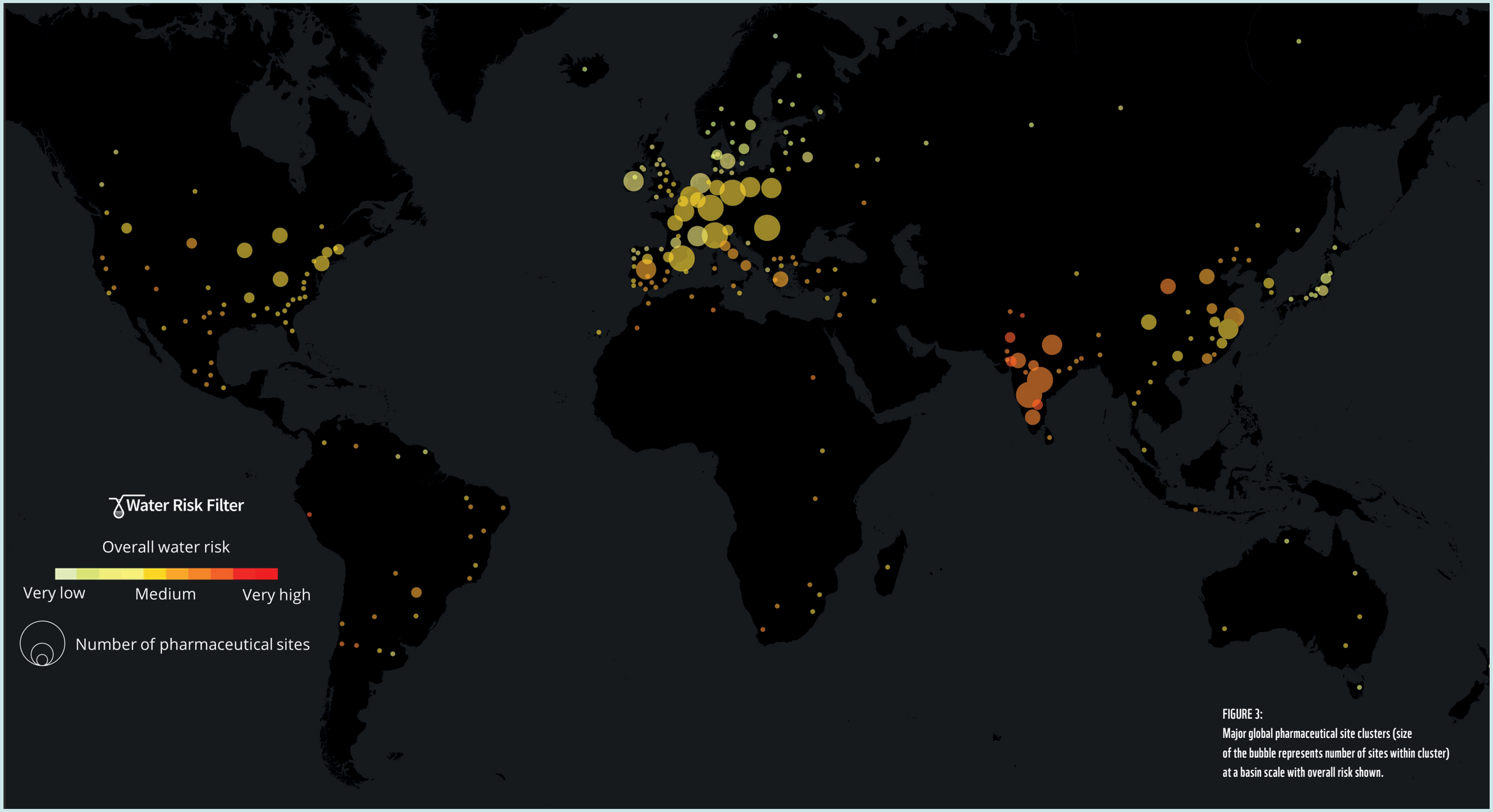


FIGURE 3:
Major global pharmaceutical site clusters (size of the bubble represents number of sites within cluster) at a basin scale with overall risk shown.

CURRENT SECTORAL WATER RISK PROFILE

The summary of the major water risk types (Figure 4) highlights that the main basin-related water risks facing the pharmaceutical sector are Quality and Flooding. Water quality is of particular concern for the sector, with more than 78% of sites operating in basin facing either very high or high water-related quality risks (Figure 4). This does not mean that the sector is necessarily responsible for the degraded state of water quality in these basins, however, is does mean that there is potential for those companies, who may be perceived to be contributing to local water quality issues, to potentially face greater stakeholder and/or media scrutiny. Water quality impacts are highly localised but as an example, degraded water quality in an area may affect the ability of local municipalities to provide safe access to treated water due to the background contaminant loading. Flooding risks are another category that should be of interest to the sector with more than 89% of sites being exposed to either very high, high or medium flooding risks. The specific exposure to flooding risks are very site-specific (i.e., operational and locationally dependent); however, these risks have the potential to disrupt supply chain resiliency and logistics, which will be critical to maintain if the sector is to respond effectively to rapidly changing global health needs. Lastly, nearly 25% of the sites were exposed to high or very high water scarcity, which could be significant at the individual company level and also has the potential to begin to impact the surrounding quality status o ver time (Figure 4).

Through WWF's analysis of the top 30 global pharmaceutical companies, 80% of companies publicly discussed or reported against quantity related performance targets compared to only 30% who discussed or reported against quality related performance targets (CDP reported only 17% of pharmaceutical respondents in 2020 reported having set formal quality-related targets[2]). This observation appears misaligned to the basin-related risks (Figure 4) that the sector potentially faces, with only 21% of sites facing very high- or high-water scarcity basin risks but 88% of sites facing very high or high water quality basin risks. Comparatively, very few discuss regulatory or reputational risks associated with water and operations or how their programs are working to mitigate these potential risks.

While the clustering of the sites is distributed across the world, there are 27 basins that have more than 50 pharmaceutical sites located within them – collectively representing 60% of all sites assessed (Figure 5). Notable basins that the pharmaceutical sector may want to prioritise for sectoral collective action activities includes the Danube (335 sites), Krishna (302 sites), Po (245 sites), Elbe (207 sites) and Rhine (200 sites) basins. While the basin-related risks for each of these potential priority basins are unique, there remain some water risk types that are consistently high across many of these basins – water quality being one of these risk types. This observation indicates potential opportunities for cross sector and basin collaborations that are focused on specific water-related challenges.

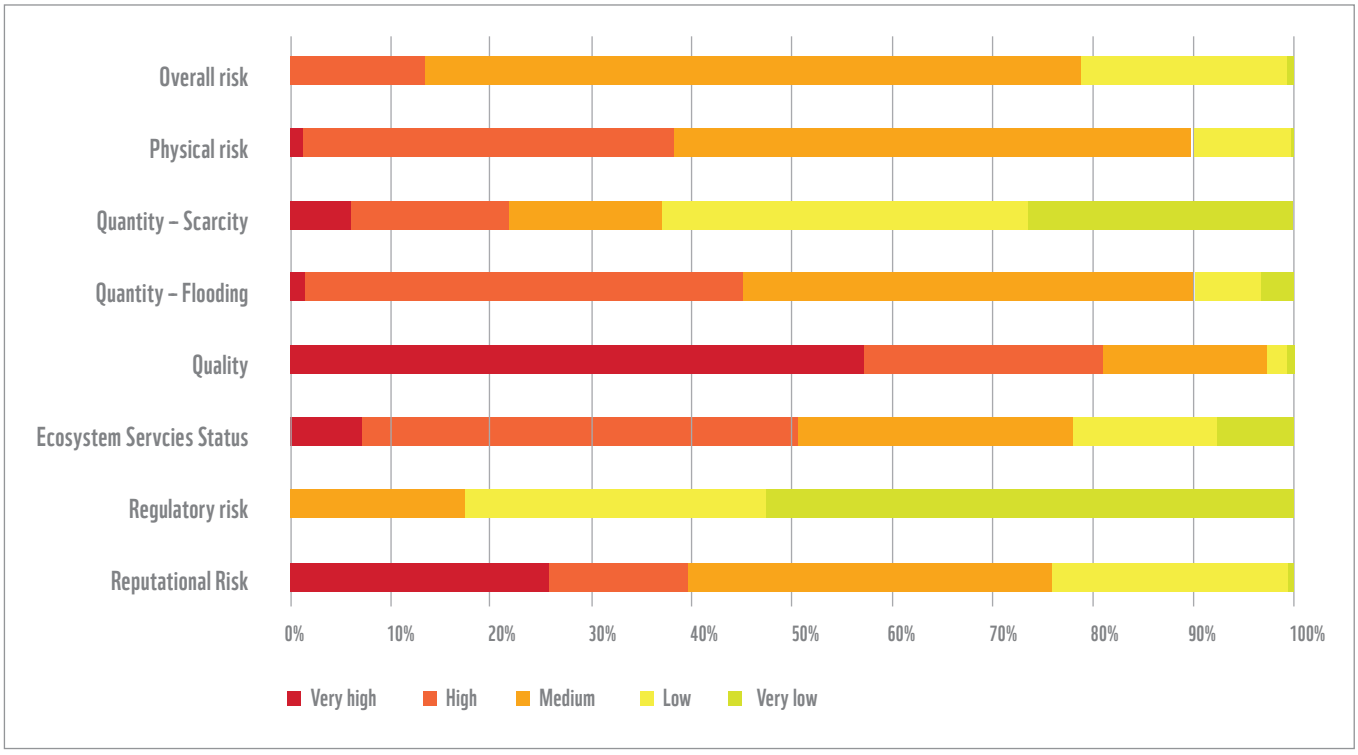


FIGURE 4:
Summary of the current Physical, Regulatory and Reputational basin water risks faced by 5,272 pharmaceutical sites globally

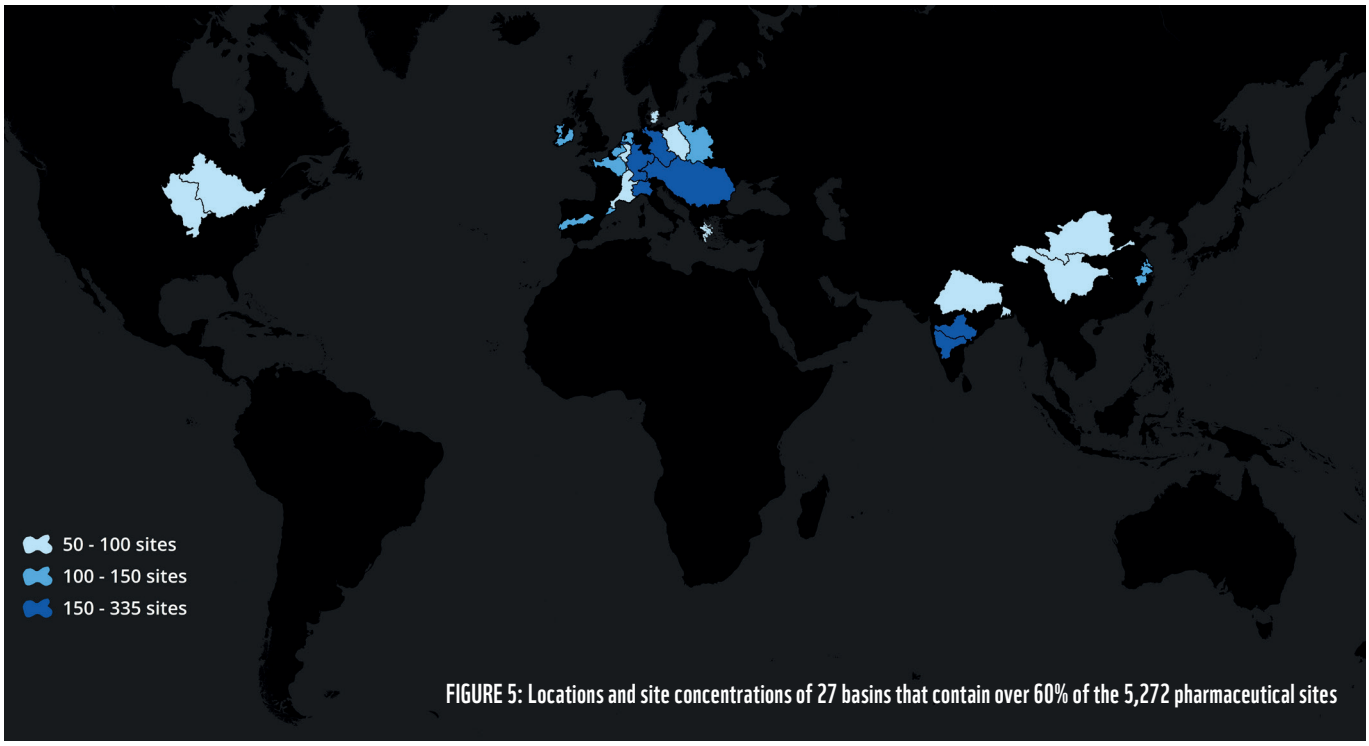


FIGURE 5: Locations and site concentrations of 27 basins that contain over 60% of the 5,272 pharmaceutical sites

2050 SECTORAL WATER RISK PROFILE SCENARIO

With a changing global climate it is inevitable that these basin water risks will change over time. More and more companies are being asked by stakeholders (e.g., investors) to identify and disclose future climate-related risks and discuss what actions are being taken to mitigate these risks. To understand what potential future water risks the pharmaceutical sector may be exposed to, WWF used the WRF's new TCFD-aligned Scenario tool. The analysis used a 2050 pessimistic scenario to understand the changes to the sectors basin water risk profile. This scenario represents unequal and unstable socio-economic development (SSP3) and high GHG emission levels (RCP 6.0 / RCP 8.5), leading to increases in the global mean temperature of about 3.5°C by the end of the 21st Century[11]. The comparison between the sectors current (left) and future (right) basin water risk profiles is shown in Figure 6.

As expected, there is a general increase in potential basin water risk exposure across all risk types for the sector in the scenario assessment. Water quality is again a risk type that is worth focusing on. The 2050 scenario indicates a dramatic increase in the number of sites exposed to extreme (new 2050 pessimistic scenario rating)

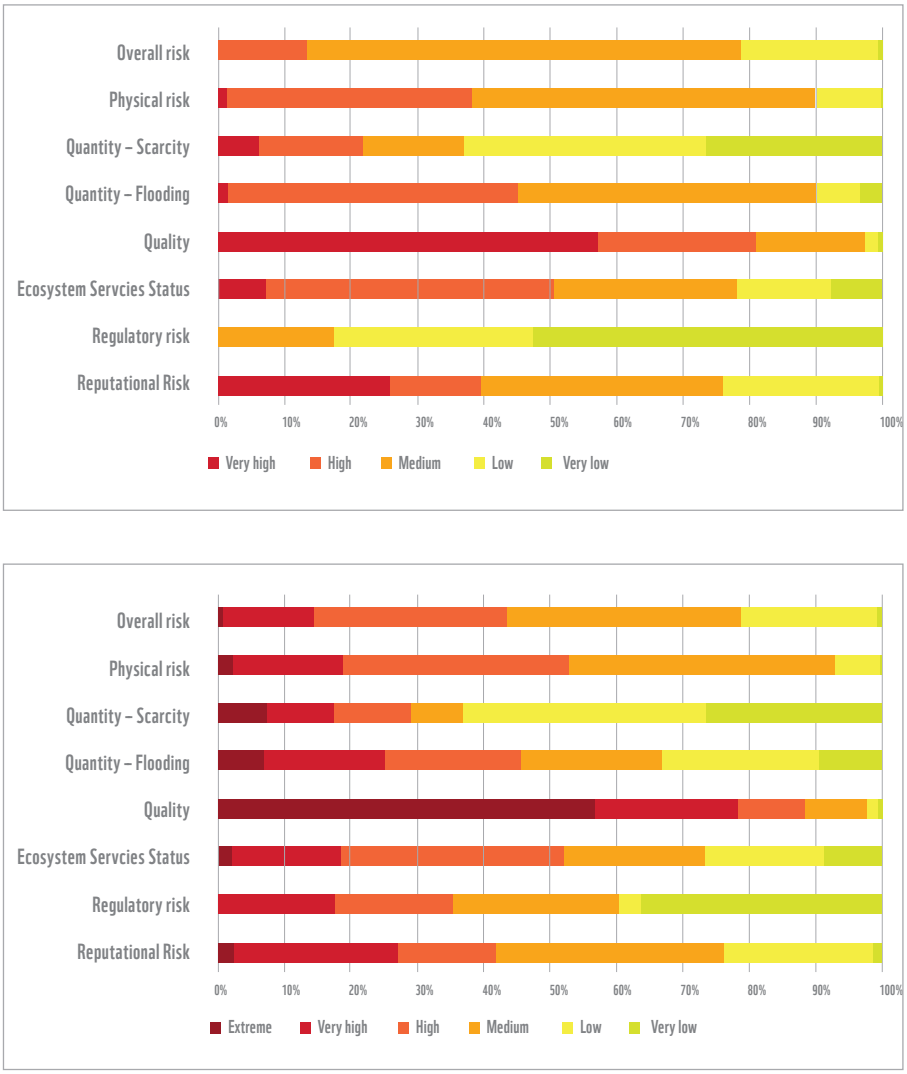
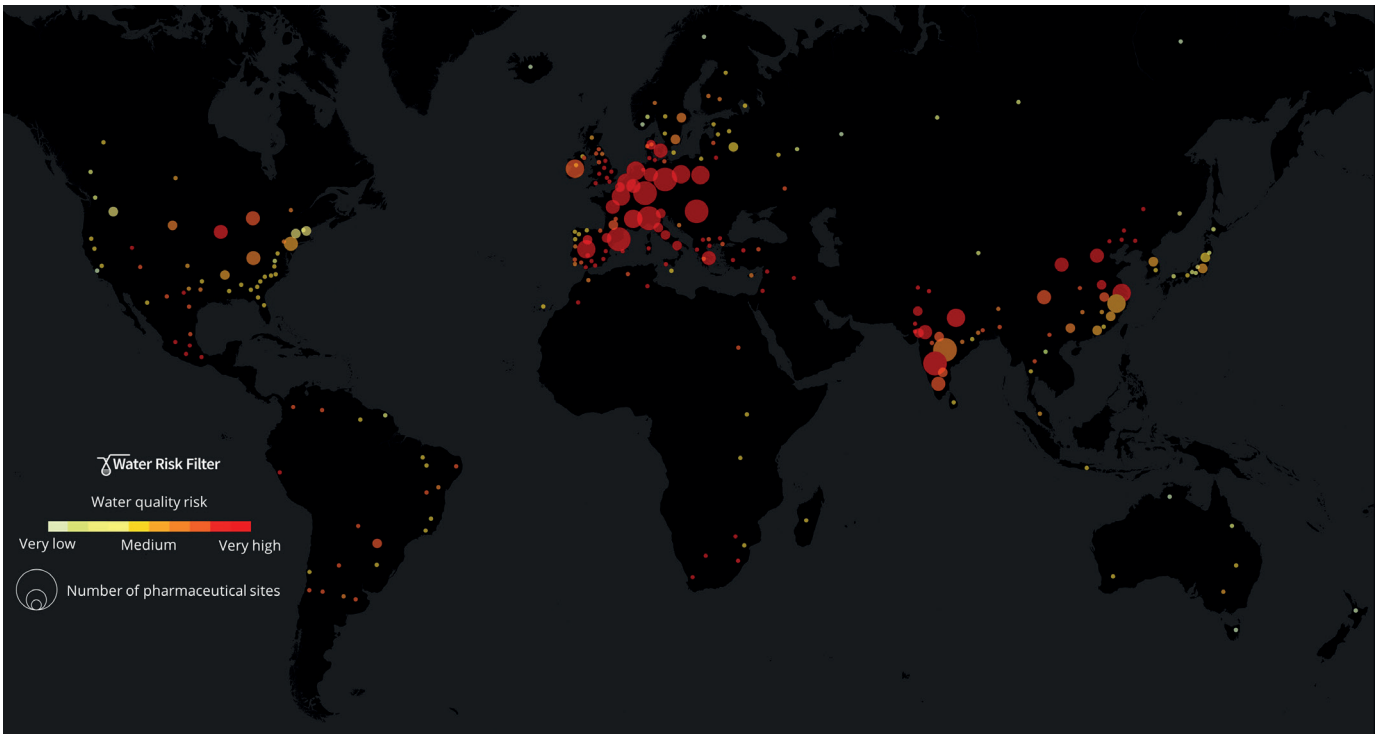


FIGURE 6: Summary of the current (top) and simulated future (2050 pessimistic TCFD-aligned scenario) (below) Physical, Regulatory and Reputational basin risks facing 5,272 pharmaceutical sites globally

and very high water quality risks – rising from 55% of all sites (current) to 75% of all sites in the 2050 scenario (Figure 6). The change in the exposure to basin water quality for basin clustering of all sites globally can be seen in Figure 7 below. The manifestation of these risks at a site level are contextual and very site-specific, however tangible examples of how sites may be impacted could include increased pre-treatment costs for incoming water, accelerated degradation of plant & equipment or increased regulatory and stakeholder scrutiny of operational practices and performance.

The 2050 pessimistic scenario is characterised by an increase in water use through a more unequal world that is exposed to greater regulatory exceptions because of the higher instances of the failure of governments to enforce legislation, and broadly a likely rise in the concerns around public health and safety of water quality[8]. The characteristic of the scenario can be visualised by the shift in the Regulatory risk profile (Figure 6), meaning that sites may face failing regulatory systems and/or weaker enforcement. Interestingly, while the water scarcity risk profile also increases over time (especially for some sites), the overall increase is not that pronounced compared to other risk types. In combination, these observations reinforce earlier observations that the pharmaceutical sector's primary basin water-related risks are (currently and in the future) more tied to water quality and regulatory enforcement rather than water scarcity.



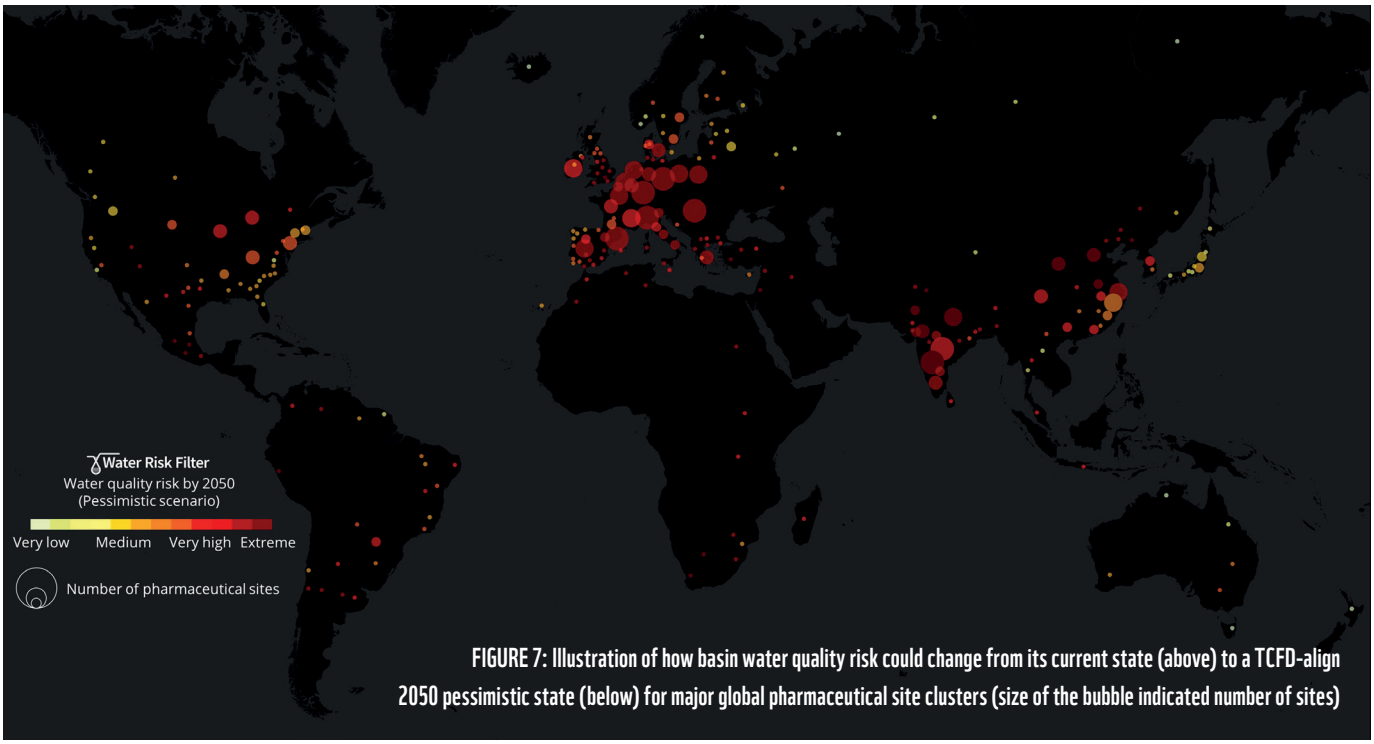


FIGURE 7: Illustration of how basin water quality risk could change from its current state (above) to a TCFD-align 2050 pessimistic state (below) for major global pharmaceutical site clusters (size of the bubble indicated number of sites)

PART 3

ADOPTING WATER STEWARDSHIP

The pharmaceutical sector plays a critical role in our global economy. It is a sector that is already aware of the importance water plays within its value chain is already actively taking action to mitigate its impacts on water globally. However, looking at both the current strategic focus areas of the top 30 biggest pharmaceutical companies globally and the results of the sectors basin water risk, there are 6 opportunities that the sector may want to consider adopting moving forward.

PHARMACEUTICAL SECTOR WATER STEWARDSHIP OPPORTUNITIES

1 LEAD WITH STEWARDSHIP RATHER THAN MANAGEMENT

The pharmaceutical sector is already a highly regulated sector, meaning it has advanced internal water management practices within its operations. However, it is highly likely that the water-related risks facing the sector in the future won't be mitigated through internal management actions alone. Adopting water stewardship as the default framing for water better positions companies to engage with others to find solutions to these external water-related risks.

2 ENHANCE SECTOR'S STRATEGIC WATER FOCUS ON QUALITY

Many external stakeholders and disclosure platforms place an emphasis on reporting withdrawals as a function of scarcity. However, these requests should not be construed by individual companies that scarcity should be the most materiality issue for its programs. Considering the pharmaceutical value chain and its geographic hotspots located, water quality (in both current and future scenarios) appears to be the dominant contextual and strategically relevant water issue for the sector rather than water scarcity (which may be relevant for select actors, but less so for the sector as a whole).

3 STRATEGICALLY ADDRESS WATER QUALITY MORE COMPREHENSIVELY ACROSS THE VALUE CHAIN

The pharmaceutical sector has made good progress in understanding issues relating to APIs in the environment and, in many cases, it has robust controls to monitor and manage water quality from manufacturing activities. This approach limits the focus on water quality and APIs to a narrow part of the pharmaceutical value chain where potential impacts from APIs in the environment is already well managed. The general trend towards deteriorating global water quality status may result in greater public attention, and thus the expectation for action, on APIs in the environment, regardless of their source.

4 UNDERSTAND RAW MATERIAL WATER-RELATED RISKS

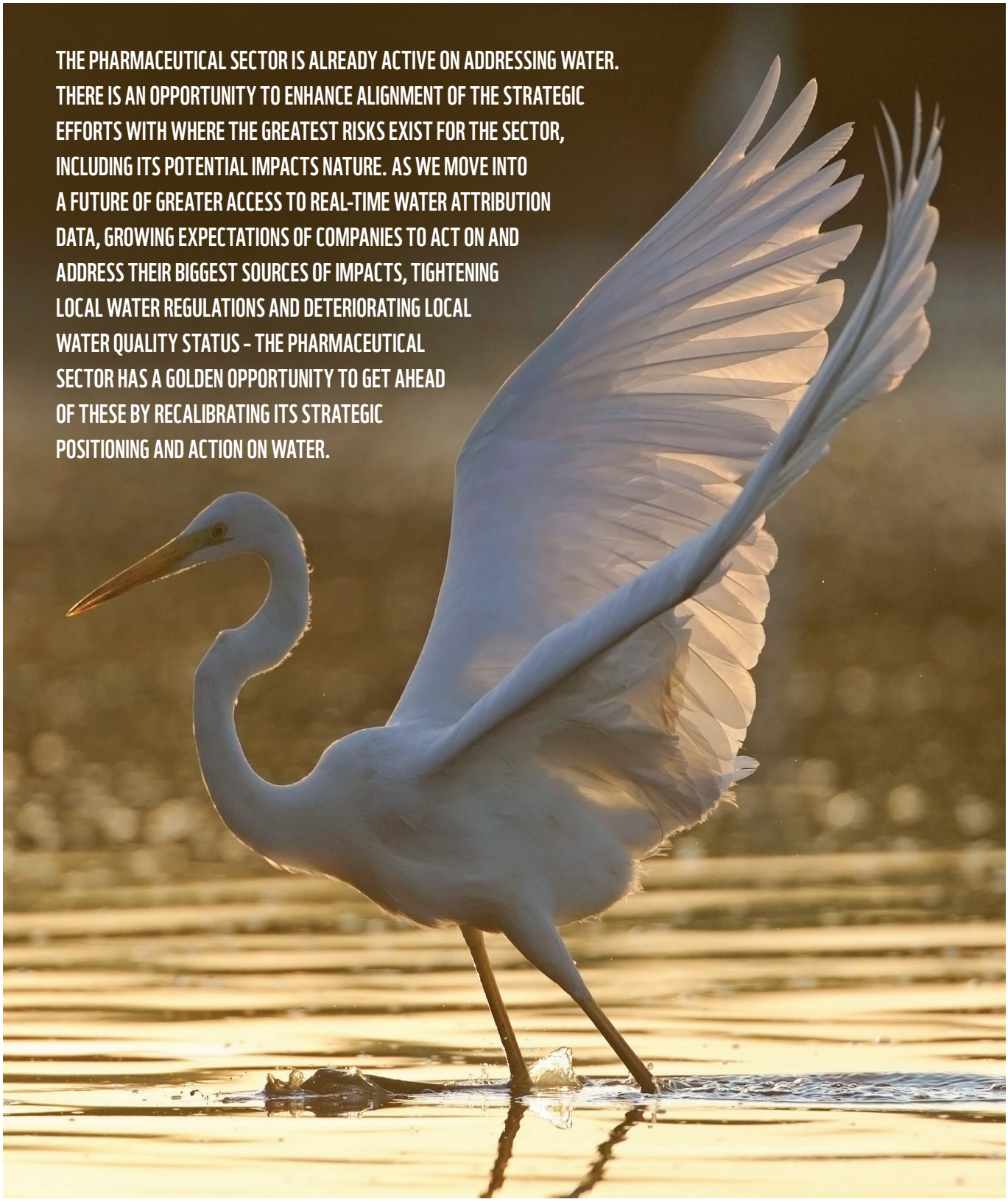
Of WWF's analysis of the focus areas of the top 30 global pharmaceutical companies, none specifically mentioned public activities related to understanding or mitigating water-related risks within the raw materials part of the value chain. Bulking agents used within the pharmaceutical sector often have ties back to mining and agriculture and these sectors are known to not only be water intensive, but also often face notable water-related challenges. While the quantities of raw materials may be perceived to be small it may be incorrect to assume that the water-related risks are equally small.

5 COLLECTIVELY RESPOND TO SHARED WATER CHALLENGES IN PRIORITY BASINS

There are 27 basins globally that appear to host more than 60% of the sites linked to human-related pharmaceutical product manufacturing. While each of these basins have their own unique basin risks, there are common shared water challenges across many of these basins. These common basin-scale shared water challenges represent a potential risk and opportunity for the sector to take a leadership in finding solutions for these issues and thus creating benefits for both the sector and the surrounding communities. This is particularly relevant for the rising flood risks which are projected under the 2050 climate scenarios, and the need to respond through the restoration of nature-based solutions.

6 SUPPORT THE ENHANCEMENT OF LOCAL WATER QUALITY REGULATIONS

The pharmaceutical sector is already a highly regulated sector and is has devoted enormous resources towards understanding the science of its products - not only within the human body but also within the environment. While it may seem counter-intuitive, there is an opportunity for the sector to collaborate and share its knowledge with local regulatory bodies to help strengthen and improve their general awareness and science of APIs in the environment rather than just focusing on internal management of point source discharges. Generally strengthening water governance structures as we move towards 2050 can help to mitigate the possible impacts of deteriorating basin water quality risks and the potential for growing regulatory risks, especially in Europe and India.



THE PHARMACEUTICAL SECTOR IS ALREADY ACTIVE ON ADDRESSING WATER. THERE IS AN OPPORTUNITY TO ENHANCE ALIGNMENT OF THE STRATEGIC EFFORTS WITH WHERE THE GREATEST RISKS EXIST FOR THE SECTOR, INCLUDING ITS POTENTIAL IMPACTS NATURE. AS WE MOVE INTO A FUTURE OF GREATER ACCESS TO REAL-TIME WATER ATTRIBUTION DATA, GROWING EXPECTATIONS OF COMPANIES TO ACT ON AND ADDRESS THEIR BIGGEST SOURCES OF IMPACTS, TIGHTENING LOCAL WATER REGULATIONS AND DETERIORATING LOCAL WATER QUALITY STATUS - THE PHARMACEUTICAL SECTOR HAS A GOLDEN OPPORTUNITY TO GET AHEAD OF THESE BY RECALIBRATING ITS STRATEGIC POSITIONING AND ACTION ON WATER.

ENDNOTES

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Publisher
WWF-Germany & WWF-Sweden

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Acknowledgements
Alexis Morgan (WWF-DE)
Sarah Argoud (AstraZeneca)
John Atkinson (AstraZeneca)
Harsh Sheth (WWF-SE)
Pharmaceutical Environment Group (PEG)

Design
Lou Clements

Cover image
© istockphotoLP / deliormanli

November 2021

Please cite this report as:
Dobson, R (2021).
Diagnosing current and future water risks facing the Pharmaceutical sector. WWF

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