Ajit Singh – Chairman, ACG

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Solid dosage forms like capsules and tablets make up over 70 percent of all medicines prescribed globally. In the view of Ajit Singh, chairman of Indian solid dosage form pioneer ACG, these products continue to be the "backbone" of the pharmaceutical industry and hold particular relevance given ongoing global debates around affordability and accessibility. In conversation with PharmaBoardroom, Singh highlights how his firm – established in 1964 and today boasting 25 manufacturing sites, over 8,000 employees and operations in more than 100 countries – is innovating and adapting to the upcoming wave of biologic medicines, which generally come in injectable forms. He also rebuts some of the criticisms of Indian pharma in international media and asserts how India is helping the world obtain global quality-standard medicines in large quantities at affordable prices.

ACG has built its business around solid dosage form manufacturing for almost 60 years. Why is this still such a fundamental part of the pharma industry in 2023?

Solid dosage forms make up more than 70 percent of all dosage forms today, whether in the form of tablets, soft capsules, hard capsules, or suppositories. Additionally, solid dosage forms are relatively inexpensive, easy to take, and effective. They remain the backbone of the pharma industry.

However, it should be noted that many new molecules being developed by the global pharmaceutical industry today tend to be biological in nature, and therefore are more likely to end up being administered as injections. That is a matter of concern for the health of developing nations like India. Injections need to be given by a healthcare professional, and if injections are the only format in which new medicines are available, this creates issues in terms of accessibility in remote and rural areas. These areas may lack sufficient healthcare professionals to administer vaccines and medicines in the case of a viral outbreak, for instance.

New molecules are already priced highly so this injectables issue adds yet another barrier to access in developing countries. If, as looks likely, more medicines will come in the form of injectables in the next five to ten years, then more life-saving medicines will be beyond the reach of the public and more fraudulent healthcare operators will operate in the market.

What role do you see ACG playing in countering this looming crisis of injectable accessibility?

Certain companies, including ACG as one of the leaders, are working on ways to convert injectables into solid dosage forms. Our research teams have been busy on this for some time, and we are confident in our ability to deliver.

The next step will be to secure the right tie-up with a good biotech partner. We still need to learn more about the biotech aspect of this novel dosage form requirements, like cold chain logistics, which may get eliminated**.** It will take us a short while to perfect the product, but I feel strongly that this will be a fundamental change for both our company and the pharma industry.

How else might rural and remote communities benefit from more biologics being available in capsule form, rather than as injectables?

For starters, injectables, made up of prefilled syringes or vials, are a dosage form that comes at a higher initial cost than capsules. Then, if the injection detritus is administered in a small village with inadequate trash or recycling facilities, it may be thrown on the side of the road and ingested by an animal, leading to all kinds of problems.

With capsules, these problems do not exist. Moreover, capsules can be filled with powder, paste, liquid or even controlled released pellets meaning that any form of biologic can be dosed to a high

accuracy. The down-the-line formulation equipment is at a much lesser cost. There is less packaging, transportation is easier, *and* the administration is simpler.

What approach to patenting and IP protection do you envision taking with these biologics in capsule form?

Revolutionary technology like this needs a patent, and we have already started this process. For individual products, we may patent jointly with the biotech sponsor. They will probably end up making the product while we will supply the *novel* capsules and the specialised machinery *and* technology to fill these delicate products. We currently have around *60* patents which can be accessed by our customers. Most of these patents are there to protect the technology rather than make money.

Indian pharma has taken on a greater role in global supply chains in the last half-century. However, the growth of your industry's trading prowess has not been accompanied by a commensurate growth in trust. What is your take on how best this can be addressed?

It has been commented by Indian observers that international media, for some reason, seems keen to pick up on any negative publicity they can find about the Indian pharma industry. However, trust is present in over 200 countries that use Indian formulations, including vaccines.

It appears that the growth of trust in some sectors of the Indian economy would improve if the country or the sectors would reach out to overseas media or engage services of countervailing media.

It should be remembered that four out of every ten medicines prescribed in many leading Western countries come from this country. India therefore plays a vital role in the healthcare ecosystem of these countries.

If India had a stronger tier-one regulator akin to those in the US, Europe, Japan, or even Saudi Arabia and Brazil, might this help shift the narrative?

The Government is providing additional funding to support tier-one regulation.

Would a more robust regulatory framework help Indian companies to better meet global quality standards and internationalise even further?

India would not be the world’s largest exporter of pharma generics if the regulatory framework were not robust.

Do you have any concluding thoughts?

The ‘‘India Story’’ is very good. It needs to be communicated and used for the advantage of the entire world that depends on India for timely supplies, affordable prices, and acceptable quality of medicines.

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