Novartis Position on Value-Based Healthcare

Healthcare systems around the world face growing demands and limited budgets and will undergo profound changes in the coming years. By 2030, the global population will increase by one billion people, and with improvements in life expectancy, populations will age. The impact of these demographic shifts will be increasing health needs, especially for chronic diseases. Total healthcare costs are growing at roughly twice the rate of growth in gross domestic product (GDP), putting severe pressure on budgets. If unaddressed, the share of GDP spent on health and long-term care could double by 2060.

Most healthcare systems base their payment models on volume of procedures such as numbers of visits to the doctor, days spent at the hospital or number of medicines delivered – which often results in suboptimal allocation of resources. In addition, procurement processes often set volume incentives, which can indirectly limit the number of available treatment options and reduce competition.

There is also widespread variation in medical practice, costs, and outcomes across providers, regions, and countries, which is further amplified by the lack of assessment of the quality of services provided. Growing evidence indicates that 50% of clinical interventions are of unknown effectiveness and that 20-40% of health expenditure is wasted on unproven or unnecessary treatments. As such, there is a huge potential to increase effectiveness and efficiency.

Novartis Position

A value-based approach to healthcare can meet the goal of access to effective and affordable care by addressing inefficiencies and quality issues. It can be achieved by focusing and incentivizing all stakeholders on delivering the best possible outcomes for patients, healthcare systems and society.

- **A value-based approach improves quality of care by being patient-centered.** By systematically measuring patient outcomes and costs, value-based systems can identify best practices and reduce both ineffective health interventions and avoidable complications. Transparent health outcomes and healthcare cost data enable patients and healthcare professionals to make informed choices, give providers an incentive to improve the quality of their services, and can spur competition to deliver better outcomes.

- **A value-based healthcare system is more efficient and sustainable.** By setting and rewarding a common and measurable goal, all stakeholders are encouraged to work together across the healthcare system to coordinate care and optimize results, rather than focusing only on their individual input. Outcomes and cost data allow providers to benchmark their performance and learn from peers that consistently achieve the best results. By identifying interventions that work, the healthcare system can stop wasting resources on those that do not, and shift funding across budget lines to where outcomes are achieved at the lowest possible cost. For example, where medicines can reduce hospital spending, funds
can be allocated accordingly. Therapies targeted at a well-defined patient population can reduce waste given their high probability of response. Following loss of exclusivity, biosimilar and generic medicines may allow health systems to maintain the same level of outcomes at lower cost. These savings can be used to expand access to existing and innovative therapies.

- **A focus on value drives research agendas and investment in the areas of highest value for patients.**
  Drug developers can deliver value in the form of innovative medicines, new value-adding features of existing medicines, biosimilars, and generics. Rewarding interventions that deliver the best possible value for patients, health systems and society set the right incentives to develop and deliver effective and efficient care.

Novartis is committed to moving towards value-based healthcare, and has already begun to lead this change through a number of initiatives around the world.

- **We are focusing our Research & Development ("R&D") on outcomes that matter to patients.**
  We systematically engage with stakeholders throughout the R&D lifecycle to optimize the impact of our medicines on patient, healthcare system and societal outcomes. We also use real-world evidence to identify population segments and to support the development of customized interventions aimed at improving value for each population segment.

- **We offer innovative, generic and biosimilar medicines to expand the availability of treatments to patients and reduce overall public spending.**
  In addition to innovative medicines developed by our Pharma and Oncology divisions, our Sandoz portfolio consists of high-quality biosimilars and generics. Following loss of exclusivity, these products deliver the comparable outcomes as their reference medicines at affordable prices, thus contributing to increased value.

- **We aim to complement our medicines with value-adding features.**
  Health intervention success often depends on the right mix of services provided to patients and providers, and we now offer a wide range of value-adding features to complement our medicines. This includes improved formulations and delivery devices as well as digital solutions, all of which contribute to optimizing patient outcomes.

- **We are tying payments to the value of our medicines.**
  Novartis is committed to a value-based pricing framework, where payments depend on the patient, healthcare system and societal value of our medicines. Where possible, we are entering into contracts where the payer pays according to how well our medicine works in clinical practice. We are committed and are working with payers to expanding this on a broader scale, including through system-level mechanisms, in order to align payments with outcomes and enable reduction of ineffective spending.

To make value-based healthcare a reality, a number of investments, collaborative initiatives and policy changes are required:

- **Alignment around a value-based framework and standardized outcome metrics**
  Systematic measurement of outcomes and costs is the foundation of any value-based healthcare system. Hence, a crucial first step is the identification of key outcomes that matter to each population segment – including patient, healthcare system and societal elements. They should be agreed upon by all stakeholders involved in the provision of care. Policy makers should facilitate and eventually mandate the measurement of outcomes and costs over the lifetime of patients in a standardized way.

- **Investment in robust data and information systems and into the capability to analyze and learn from data**
  Routine collection, analysis and sharing of outcomes and cost data require a strong information infrastructure. Current systems do not systematically track
outcomes and costs. The quality of the data that exists varies significantly, so that trust in the insights generated from the data may be low. Policy makers should invest in an integrated data infrastructure that facilitates sharing of information and coordination of care as well as in efforts to build analytical capabilities to enable best possible use of the data.

• **Balanced trade-offs between patient privacy and data sharing**
  Data privacy concerns can hinder data collection and use. Governments need to establish guidelines for data integrity and security, processes for shared governance, rules for access, and methodologies to ensure data can be shared without violating an individual patient’s privacy. We believe that removing all personal identifiers from a data set (a process called pseudonymization or de-identification) can provide adequate protection of privacy in the context of biomedical R&D while enabling generation of important insights about interventions and outcomes for patients, healthcare systems and society.

• **New legal and regulatory frameworks, including removal of disincentives that create distortion**
  Existing legal and regulatory requirements do not always allow for the adoption of a value-based approach, and often act as disincentives to effective and efficient healthcare delivery. For example, in many jurisdictions there is either no legal framework or very little experience with payment models beyond fee-for-service. Governments and payers should encourage innovative bundled payments, as this can lead to a better understanding of which payment mechanisms are most appropriate for improving value in a given disease area or for a specific population segment.

• **Breaking down of budget silos at the healthcare system level, along with willingness to establish longitudinal payment models**
  Current healthcare budgets are often rigidly separated into cost categories, making it difficult to realize savings across budget lines and over the lifetime of the patient. For example, the use of medicines may result in avoided hospitalizations, but has to be financed from the medicines budget alone. Similarly, better outcomes and savings may be generated over a longer time horizon and off-set future costs. This implies a need to move beyond annual budgets, and to focus on longer-term results.

• **Procurement criteria that focus on value, not solely on price**
  In many procurement processes, the lowest price is the only or major deciding factor. Focusing only on the lowest price fails to take into account value components which may be beneficial for patients and the wider healthcare system. Procurement decisions should consider other factors such as quality, organization, qualification and expertise, after-sales service and technical assistance, or delivery conditions – in order to maximize value delivered.

• **Partnerships between stakeholders involved in the provision of care, focusing competition on value for patients**
  A transition towards value-based healthcare also relies on changing the provision of care into a multi-stakeholder collective action. Partnerships should be encouraged and rewarded, while transparency around outcomes and costs can focus competition towards collectively providing the best value to patients. As such, a value-based healthcare system can combine aspects of both cooperation and competition.

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