Mahajan, Vinay

From: Riemenschneider, Marion on behalf of Office, Vas Narasimhan (Gen)
Sent: Wednesday, January 27, 2016 1:31 PM
Subject: Enhancing and enabling one Global Development organization
Attachments: 2015 full year results: Improving patients' lives through innovation

Dear Colleagues,

Today, we announced the next steps in our growth and innovation strategy (see David's letter, attached). For Development teams across Novartis, these changes will over time help us to pursue our mission to discover new ways to improve and extend people's lives. Working collaboratively across Divisions, I am certain we can create an even better environment where our people and teams thrive and can deliver innovations that will change the lives of millions. While some things will change, much will remain the same: our Divisions drive the strategy and execution of trials and we will always put the success of our projects first.

WHY DO WE NEED TO ADAPT?

Over the past several years, we have built a successful Development enterprise. We have led the industry in the number of approvals over the last five years and are globally recognized and respected for the quality of our work. However, the world is changing rapidly. While we are proud that we lead the industry in investing in research and development, we must relentlessly become more efficient and productive at developing new medicines. Digital technologies, genomics, real world evidence and other disruptive technologies are rapidly transforming how medicines are developed. In this ever evolving environment, we need to find new ways to manage our portfolio, drive common technology and standards, and capture synergies between our development organizations wherever possible.

WHAT WILL WE DO?

We are creating a group-wide pharmaceutical Development organization which I am humbled and privileged to lead as the newly appointed Global Head of Drug Development and Chief Medical Officer. A central leadership team will be established including central function heads and divisional Development heads who will report functionally to me. In this new Development organization, we will integrate portfolio level decisions and decisions about how Development at Novartis operates:

- **Integrated Portfolio Management**: the IMB will expand to include group-wide portfolio oversight to ensure optimal use of R&D resources
- **Disease Area Alignment:** Alcon pharmaceutical development will be integrated into Pharma Development
- **Clinical Operations Excellence**: we will create a Group Clinical Operations Unit that will bring together Data Management/Statistical Programming/Medical Writing for Development. This unit will also provide functional leadership across the group and ensure coordination/standardization across digital technologies, trial management, and trial monitoring.
- **Regulatory Excellence:** we will establish a Group-wide Global Head of Drug Regulatory Affairs supporting our divisions to have best-in-class strategies and providing integrated regulatory operations globally and in countries
- **Integrated Chief Medical Office and Safety:** consistent with our commitment to patients, safety and compliance, we will create an Integrated Chief Medical Office and group-wide Safety/Pharmacovigilance

In addition, TRD and Drug Supply Management will be centralized and serve all of our Development units across the Group.

WHAT WILL NOT CHANGE

Our success has been driven by the close alignment between our Development, Commercial and Medical teams. To ensure we maintain this partnership, the divisional development units will remain in the divisions and continue to host key functions which manage our development programs and brands. This includes:

- Strategic and key operational functions within global drug development teams, i.e. clinical, biostatistics, program level regulatory, program leadership and project management
- Trial management and monitoring
- Medical affairs
- Sandoz small molecules and Alcon device development (surgical equipment, intraocular lenses, contact lenses), except for safety/pharmacovigilance and certain country regulatory activities

WHAT ARE THE NEXT STEPS?

The new Development structure is expected to become effective on July 1. Until that time, governance, project prioritization and current organizational models and responsibilities will stay in effect. Within the next days, we will create several cross-divisional workstreams to assess options around organizational set-up and operational models.

I realize there will be a lot of questions about what this means for each of you as individuals. Please be assured that we will clarify the details of the new organization and provide answers to your questions over the coming months.

I ask all of you in this time of change to ensure we maintain our focus on our development programs to ensure we deliver for patients. We are confident that the changes announced today will make us the world's leading and most efficient Development organization, leading in the science of breakthrough medicine and in the science of operations.

Best regards,

Vas