Antimicrobial resistance (AMR): action plans implementation

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The Industry Declaration

Has been signed by 98 companies and 11 industry associations in 21 countries*

1. Work to reduce the development of antimicrobial resistance	2. Invest in R&D that meets global public health needs with new innovative diagnostics and treatments	3. Improve access to high-quality antibiotics and ensuring that new ones are available to all
Support appropriate use and improved stewardship	Invest in innovative antibiotics, vaccines, alternative technologies, and diagnostics	Ensure affordable access to new and existing antibiotics
Encourage infection control	Support research in academia and Small and Medium Enterprises on new and re-purposed antibiotics	Support programs to improve global access
Support the one health approach and responsible use	Support open collaboration between industry and public researchers	Launched on 21st January 2016 in Davos
	Develop new valuation mechanisms and commercial models with payers and policy makers	

Global Risks Report 2016: […] **endemic infectious diseases remain a major problem, and new or resurging infections, the spread of drug resistance** and the rise in non-communicable diseases all pose enormous challenges to often fragile health systems.

*as of April 2016

Combating Antimicrobial Resistance (AMR)

GSK public policy position

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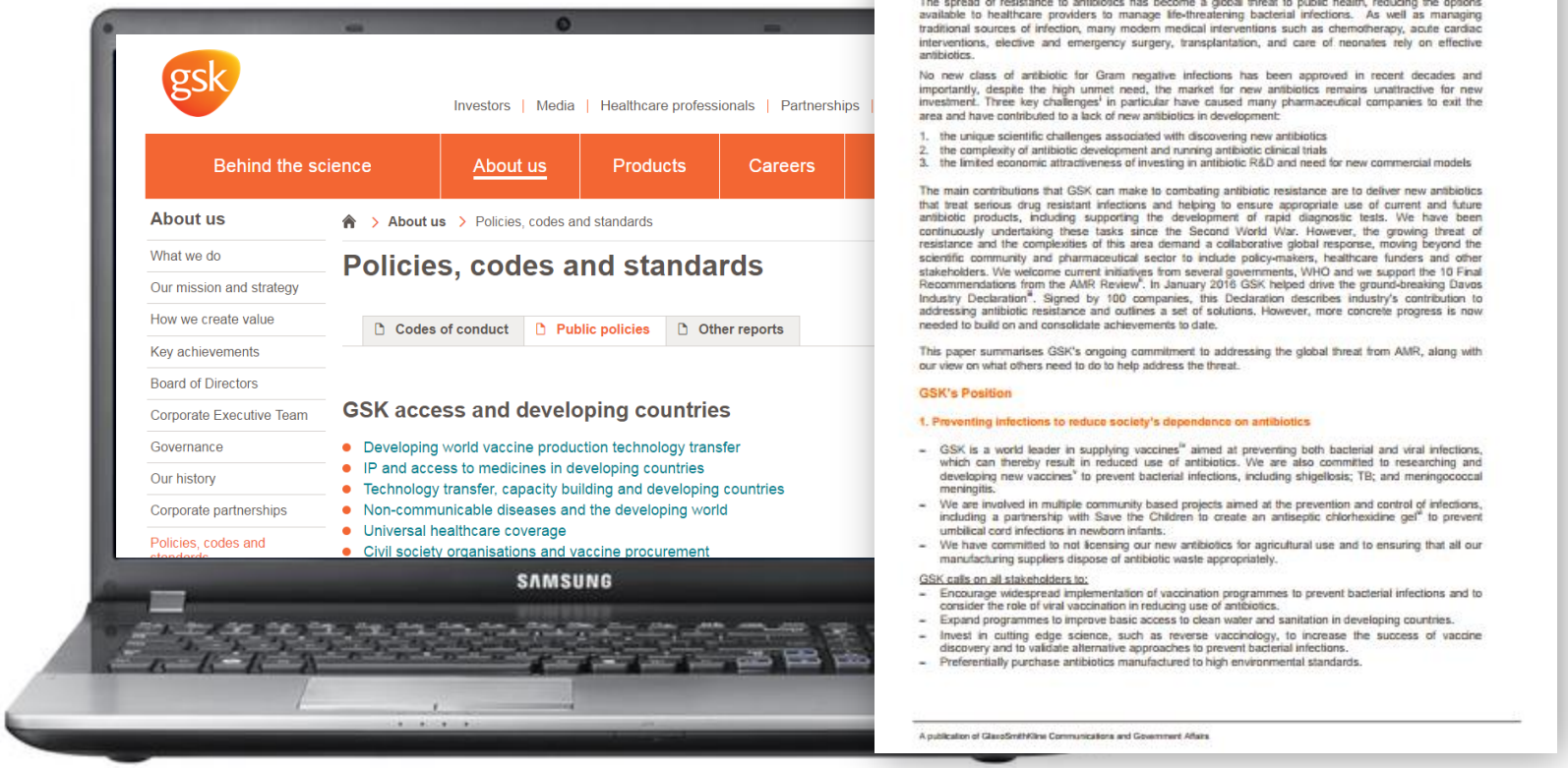

GSK public policy positions

Combating Antimicrobial Resistance (AMR)

The Issue

The spread of resistance to antibiotics has become a global threat to public health, reducing the options available to healthcare providers to manage life-threatening bacterial infections. As well as managing traditional sources of infection, many modern medical interventions such as chemotherapy, acute cardiac interventions, elective and emergency surgery, transplantation, and care of neonates rely on effective antibiotics.

No new class of antibiotic for Gram negative infections has been approved in recent decades and importantly, despite the high unmet need, the market for new antibiotics remains unattractive for new investment. Three key challenges[i] in particular have caused many pharmaceutical companies to exit the area and have contributed to a lack of new antibiotics in development:

1. the unique scientific challenges associated with discovering new antibiotics
2. the complexity of antibiotic development and running antibiotic clinical trials
3. the limited economic attractiveness of investing in antibiotic R&D and need for new commercial models

The main contributions that GSK can make to combating antibiotic resistance are to deliver new antibiotics that treat serious drug resistant infections and helping to ensure appropriate use of current and future antibiotic products, including supporting the development of rapid diagnostic tests. We have been continuously undertaking these tasks since the Second World War. However, the growing threat of resistance and the complexities of this area demand a collaborative global response, moving beyond the scientific community and pharmaceutical sector to include policy-makers, healthcare funders and other stakeholders. We welcome current initiatives from several governments, WHO and we support the 10 Final Recommendations from the AMR Review[ii]. In January 2016 GSK helped drive the ground-breaking Davos Industry Declaration[iii]. Signed by 100 companies, this Declaration describes industry's contribution to addressing antibiotic resistance and outlines a set of solutions. However, more concrete progress is now needed to build on and consolidate achievements to date.

This paper summarises GSK's ongoing commitment to addressing the global threat from AMR, along with our view on what others need to do to help address the threat.

GSK's Position

1. Preventing infections to reduce society's dependence on antibiotics

- GSK is a world leader in supplying vaccines[iv] aimed at preventing both bacterial and viral infections, which can thereby result in reduced use of antibiotics. We are also committed to researching and developing new vaccines[v] to prevent bacterial infections, including shigellosis; TB; and meningococcal meningitis.
- We are involved in multiple community based projects aimed at the prevention and control of infections, including a partnership with Save the Children to create an antiseptic chlorhexidine gel[vi] to prevent umbilical cord infections in newborn infants.
- We have committed to not licensing our new antibiotics for agricultural use and to ensuring that all our manufacturing suppliers dispose of antibiotic waste appropriately.

GSK calls on all stakeholders to:

- Encourage widespread implementation of vaccination programmes to prevent bacterial infections and to consider the role of viral vaccination in reducing use of antibiotics.
- Expand programmes to improve basic access to clean water and sanitation in developing countries.
- Invest in cutting edge science, such as reverse vaccinology, to increase the success of vaccine discovery and to validate alternative approaches to prevent bacterial infections.
- Preferentially purchase antibiotics manufactured to high environmental standards.

A publication of GlaxoSmithKline Communications and Government Affairs

1. Preventing infections to reduce society's dependence on ABs

2. Generating innovative treatments and a vibrant environment for antibiotic R&D

3. Creating a sustainable business environment that incentivizes appropriate use & investment

1. Preventing infections to reduce society's dependence on ABs

World leader in supplying vaccines aimed at preventing both bacterial and viral infections. Wide-spread use of vaccines result in fewer infections, lower demand for AB and contribute to reduced use of antibiotics. Example – GSK pneumococcal vaccine has been used to protect >70 mn children from pneumococcal infection. Non-bacterial vaccines avoid diseases that can trigger inappropriate use of ABs

Committed to researching and developing new vaccines to prevent bacterial infections incl. shigellosis, TB and meningococcal meningitis

Committed to not licensing our new AB for agricultural use and to ensuring that all our manufacturing suppliers dispose of AB waste appropriately

What needs to be done:

- Widespread implementation of vaccination programs to prevent bacterial infections, consider role of viral vaccination in reducing use of antibiotics
- Elaboration of economic models for vaccines which account for the value they deliver through reduced use of antibiotics
- Investment in new vaccine development

2. Generating innovative treatments and a vibrant environment for antibiotic R&D

GSK is fully committed to the R&D of medicines aimed at treating bacterial infections. One of the few companies in the sector to continue discovery and development of new AB treatments, having an active pipeline despite scientific and economic challenges

Three dedicated DPU

Pooling knowledge and expertise via multiple PPPs. Example: IMI initiative “ND4BB” which is now values at 700M Euro with 11 pharma partners and >100 academic and public groups.

What needs to be done:

- Ensure sustainable funding for AB R&D PPPs that would increase the success and efficiency of antibiotic R&D
- Support legislation that streamlines the development of antibiotics for high unmet need

3. Creating a sustainable business environment that incentivizes appropriate use & investment

Need for new commercial models that would separate or “de-link” revenues (reward) from the amount of antibiotic that gets used. That would incentivize investment in AB R&D while enabling access and reducing the pressure to maximize returns through increasing use of the new medicine

Providing scientific advice and seed-funding for PPPs aimed at catalyzing the development of fast (<20 min), accurate and cost-effective point-of-care diagnostics that will allow direct the use of ABs only in patients that need them, i.e. allow the appropriate use

Support strict regulations to prohibit provision of antibiotics without a prescription

GSK new commercial model that would help further ensure the focus is upon appropriate prescribing. Sales representatives incentivized based on their technical knowledge and quality of service and not based on their individual sales targets

What needs to be done:

- “Pilots” for new AB to be commercialized via de-linked type models
- Integration of new diagnostics into patient care
- Create an awareness campaign to reinforce an understanding of the lifesaving role of ABs, their value to the overall healthcare infrastructure and the critical need to use them appropriately
- Encourage the industry to modernize promotional practices that would avoid inappropriate use and promotion of antibiotics
- National Action Plans to reduce inappropriate use, including enforcement of prescription and dispensing regulations.