limited clinical data, lack of national registration, high prices and a lag in implementing new treatment guidelines (see Chapter IV, section B.3).

NCDs put an enormous and continuous financial strain on household budgets, and major gaps in access to both originator and generic medicines for NCDs persist. Shortcomings in access have been highlighted, for example, for newer cancer treatments and insulin for diabetes. For all countries, the cost of inaction far outweighs the cost of taking action on NCDs (see Chapter IV, section B.4). Health systems, including in high-income countries, face rising launch prices, in particular for cancer and "orphan" medicines.

Hepatitis C has seen treatment breakthroughs, but these new treatments entered the market at very high prices, leading to treatment being unavailable, rationed or delayed in numerous countries. Thanks to the conclusion of licensing agreements for some of the treatments, generics are available at relatively low prices in most LMICs (see Chapter IV, section B.5). National immunization programmes are a highly effective public health tool for the prevention of illness and the spread of infectious diseases. Distinct market conditions and know-how requirements create a different landscape for the development and dissemination of vaccines (see Chapter III, section B.4(e) and Chapter IV, section B.7; see also Chapter III, section E).

to improving access to quality medical products in developing countries through ensuring compliance with quality standards (see Chapter IV, section A.11(a)).

Innovation in medical technologies: the evolving policy landscape

Innovation in medical technologies requires a complex mix of private- and public-sector inputs. It differs from innovation more generally due to the ethical dimension of health research, a rigorous regulatory framework, liability questions and the high cost and high risk of failure. Economic, commercial, technological and regulatory factors have precipitated rapid change in the current landscape for R&D, involving more diverse innovation models and a wider range of active players. Providing adequate incentives to absorb the high cost and associated risks and liabilities is a central policy challenge; this has been the historic role of the patent system, in particular as applied to pharmaceuticals. While estimates vary of the actual cost of medical research and product development, innovation is undoubtedly costly and time consuming. The risk and uncertainty of innovation increases R&D costs in this sector, which include the development costs of the vast majority of inventions that fail before reaching the market (see Chapter III, section B.3). Rising expenditure for medical research has not been matched by a proportionate increase in new products entering the market, sparking a qu0mmed75s and a wider raincreases R&D he ats efin

and improve access (see

has reinforced the trend towards voluntary licensing programmes that increase access to medicines by enabling new formulations and enhancing provision of cheaper generic medicines for developing countries (see Chapter IV, section C.3(b)).

Policy options and IP flexibilities also impact on public health

A wide range of policy options and flexibilities are built into the international IP regime and can be used to pursue public health objectives. Action is needed at the regional and domestic levels to determine how best to implement such flexibilities, so that the IP regime responds to each country's individual needs and policy objectives. Key options include transition periods for least-developed countries (LDCs) (see

Free trade agreements have increasing relevance to access

The international policy and legal framework has been made more complex by the growth of free trade agreements (FTAs) and international investment agreements, outside the established multilateral fora (see Chapter II, section B.5 and Chapter IV, section C.5). Policy debate in this context has focused on IP, such as patent term extensions, regulatory exclusivities and other measures, such as patent linkage, as well as pharmaceutical regulation provisions in these agreements, and their impact on access to medicines. The later generation of FTAs often includes side letters or provisions confirming the Doha Declaration and, in particular, the right of WTO members to take measures to protect public health. These agreements also set standards in other policy areas with implications for access, notably, standards established on government procurement and competition policy, as well as preferential tariffs on pharmaceuticals, inputs and other health products. FTAs usually require implementation in domestic laws, which, in turn, can directly affect access to, and innovation in, medicines and medical technologies.