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LETTERS

HIGH COST OF NEW DRUGS

Regulatory agencies should engage in drug pricing

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Mazzucato argues that drug pricing policies "must be completely transparent, so that governments can negotiate for better value on behalf of their populations."[1] She also observes that the US government never exercised its right to cap prices of drugs developed through publicly funded research.[2] In Europe, the European Medicines Agency (EMA) does not decide on drug prices, since these pertain to member states.[3]

Today many companies tend to set the highest prices the market can bear rather than a "just price."[4] Some EMA approved drugs have grown so disproportionately expensive that they cannot be reimbursed under national assurance schemes or are subject to strict eligibility criteria.

We previously suggested that, when discussing the development plan of a potentially lifesaving drug, the regulatory agencies granting initial marketing authorisation should require an "ethical clause" binding the marketing authorisation holders to register the drug in all middle income countries involved in its clinical development and to make it available at tiered prices.[5] The case of hepatitis C now shows that high prices are becoming a global barrier to access to essential treatments.[6]

Considering that a regulatory seal of approval is an important factor in allowing high prices,[7] we now further advocate that leading regulatory authorities should consider engaging in evaluation of pricing policies for new medicines. They could require innovator companies to complement the marketing authorisation application with comprehensive information on research and development costs, with an overall justification for the proposed pricing policies.

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Full response at: www.bmj.com/content/354/bmj.i4136/rr-1.

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